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<td><strong>SUMMARY</strong></td>
<td>This policy and procedure detail the approved requirements for the identification, notification, investigation, action planning/ implementation, monitoring, closure and communication of Serious Incidents (SIs) within NHS North Central London Cluster.</td>
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<td><strong>RESPONSIBLE PERSON:</strong></td>
<td>Assistant Director of Quality</td>
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<td><strong>ACCOUNTABLE DIRECTOR:</strong></td>
<td>Director of Quality and Safety</td>
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<td><strong>APPLIES TO:</strong></td>
<td>All staff employed within NHS North Central London Cluster (encompasses five boroughs: Barnet, Camden, Enfield, Haringey and Islington) and Independent Contractors (General Practitioners, Dentists, Pharmacists and Optometrists).</td>
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<td>5</td>
<td><strong>GROUPS/ INDIVIDUALS WHO HAVE OVERSEEN THE DEVELOPMENT OF THIS POLICY:</strong></td>
<td>Alison Pointu Director of Quality and Safety, Diane Curbishley Deputy Director of Quality, Jenny Goodridge Interim Assistant Director of Quality</td>
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<td><strong>GROUPS WHICH WERE CONSULTED AND HAVE GIVEN APPROVAL:</strong></td>
<td>Safeguarding Children Leads: Jane Chapman NHS London Patient Safety Manager: Joanne Hillier</td>
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<td>November 2013, or sooner if there are changes to legislation etc. that impact on this policy and procedure</td>
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POLICY

Policy Statement

NHS North Central London is committed to ensuring incidents and serious incidents are reported in a timely fashion and investigated to the appropriate level to maximise learning for the future, and reduce the likelihood of recurrence. The policy is supported by the procedure for reporting, investigating and managing incidents and serious incidents, and the National Patient Safety Agency’s (NPSA) Being Open process.

Incidents are managed and investigated according to their severity. The ultimate aim is to learn and make improvements as a result of incidents in order to enhance safety for patients, visitors, staff and contractors. Qualitative and quantitative data analysis is used to highlight any trends which may be occurring and uncover any need for further intervention.

Incidents that are graded 15 and above using NHS North Central London’s risk matrix are reported as necessary to NHS London by the Patient Safety Team. There may be certain cases that warrant the Health and Safety Executive (HSE) or Police involvement. The procedure includes recommendations made by the publication, The Memorandum of Understanding (MOU) which stipulates how organisations should work together when managing an incident investigation.

A table of definitions of terms can be found in Appendix 1.

Rationale

NHS North Central London is committed to implementing systems, processes and interventions that actively and continuously reduce risks to patients, staff and visitors. Healthcare relies on a range of complex interactions between people, skills, technologies and drugs. The Department of Health estimated that one in ten patients admitted to hospitals will be unintentionally the victim of an error. In primary care, however, the evidence is much more sparse. Studies have widely varying estimates of harm, from less than 1% to 24%. The reporting of incidents and learning from experience is fundamental in promoting patient safety.

Scope

This policy and procedure details how to report all incidents and near-misses. Whether clinical or non-clinical, including Serious Incidents and Never Events. It applies whether incidents involve patients, carers, visitors, staff, Independent Contractors, premises, property, other assets, information, or any other aspect of the organisation.

This policy is aimed at all staff and contractors within North Central London who witness, or are involved in, an incident or incident investigation, and those staff responsible for the management and monitoring of incidents. The policy also applies to anyone involved in research activity approved by NHS North Central London. It is the responsibility of all researchers to ensure that at each of NHS North Central London’s sites, where research is carried out, clear instructions for all participants regarding how to report an incident is available. This must be reported as specified in guidance from the Research and Development Team at the North Central London Research Consortium which is also reiterated in research approval letters.

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1 Memorandum of Understanding 2006, Department of Health
2 Memorandum of Understanding, 2006 Department of Health
3 Safety First 2006, Department of Health
4 Safety First 2006, Department of Health
5 Levels of Harm in Primary Care, 2011, The Health Foundation
6 Seven Steps to Patient Safety 2004, NPSA
Principles

Learning from experience is critical to NHS organisations and staff in delivering a safe and effective service to patients and clients. NHS North Central London is committed to finding ways to understand the underlying causes of patient safety incidents; communicate and share such information and formulate plans for improving safety.

Incidents with a risk assessment score of 15-25, graded red when utilising NHS North Central London’s Risk assessment tool (see Appendix 2a), are considered a Serious Incident (SI) and an investigation is completed within 45 working days. Incidents that score 8-12, graded amber, are completed within 20 working days.

These timescales relate to both clinical and non-clinical incidents.

All Serious Incidents are graded according to the level of investigation required based on the NPSA’s criteria, so timescales and level of investigation reflect the level of scale, scope and complexity of each incident and are consistent with the triggers and levels of RCA investigation.

Monitoring and Assurance of this Policy and Procedure for the Reporting, Investigating and Management of Incidents and Serious Incidents

NHS North Central London is committed to providing and Commissioning healthcare within acceptable standards of medical/professional care, as well as ensuring and monitoring the safe delivery of this care to its patients.

The following tools are used to review performance:

- Incidents are reported and entered onto Datix, the local reporting management system. An increase in number of incidents being reported is likely to indicate a positive reporting culture.
- A continued process of quality control checks is carried out on all data entered onto Datix prior to data being uploaded to the National Reporting and Learning System (NRLS).
- All Serious Incidents are recorded onto the STStrategic Executive Information System (STEIS), and these are cross-referenced with the information held on Datix.
- Quarterly reports that illustrate incident reporting trends are presented to the NHS North Central London Quality and Safety Committee (Joint Board sub-committee) for review. This committee monitors and reviews the risk, control and governance processes which have been established within NHS North Central London, and the associated assurance processes.
- The National Patient Safety Agency (NPSA) provides feedback to the organisation in the format of a bi-annual report that compares the organisation’s reported data with organisations of similar status.
- Risk issues arising from incidents are recorded on the appropriate local risk registers, and on the organisational risk register when assessed as being a high risk.

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7 National Framework for Reporting and Learning from Serious Incidents Requiring Investigation, 2009, NPSA
FLOWCHART FOR INCIDENT IDENTIFICATION AND MANAGEMENT

Near Miss/Incident Occurs

Does it result in an unexpected death or major permanent harm?

Yes

Take immediate action as appropriate (make people safe etc) Inform line manager immediately (after Hours Phone: 07623 908008) and the patient safety team on: 0207 685 6697/6530.

No

Incident Report Form completed by staff member before end of shift and forwarded to person in charge of department/area

Person in charge of dept/area to grade incident and sign off Incident Report Form within 24 hours of receipt

Grading

Green Incident (score=1-3)

Local management action as appropriate

Yellow Incident (score=4-6)

Copy of incident report form forwarded to Patient Safety Team at ncl.incidents@nhs.net Patient Safety Team alerts Director of Quality & Safety

Amber Incident (score=8-12) Potential Serious Incident

Red Incident (score=15-25) Potential Serious Incident (SI)

Initiate the Serious Incident Procedure

Investigation to be undertaken by local senior Manager or appropriate person. Patient Safety Team to provide advice on the process. Director of Quality & Safety to approve orange incident report within 20 working days of incident. Copy of report attached to Datix. Investigator responsible for providing copy of completed investigation to staff member who completed original incident form, and other staff as appropriate.

Reviewed at Serious Incident Monitoring Group

Reviewed at Quality & Safety Committee

Action plans implemented locally, and monitored through the Patient Safety Team, Primary Care Commissioning Group and the Serious Incident Monitoring Group

Trend analysis by Patient Safety Team.

FOLLOW UP for INCIDENT IDENTIFICATION AND MANAGEMENT
Process for the Management of Potential Serious Incidents in the First 48 hours

Potential Serious incident (SI) Take immediate action as appropriate (make people safe etc)

Most senior person present immediately phones Manager responsible for incident management of that area – they inform the Patient Safety Team (or on-call manager 07623 908008). Patient Safety Manager informs Director of Quality & Safety (within 24 hours)

The Manager responsible for incident management (or on-call Manager) ensures:
1. A member of staff is identified to co-ordinate the immediate management of the incident (see the box to the right)
2. The patient(s) and/or relatives have been informed as appropriate (Being Open Process)
3. The Patient Safety Team have been informed
4. An incident form has been completed and sent to the Patient Safety Team (within 24 hours)

The Patient Safety Manager:
1. Ensures that the incident has been reported on Datix, and STEIS (if required)
2. Provides advice and support

The Director of Quality & Safety:
1. in discussion with relevant experts/stakeholders will agree an incident status – i.e. whether to formally declare a SI (within 48 hours).
2. Identifies a Lead Investigator
3. Selects an Executive Panel to oversee the investigation.
4. ensures, and informs, relevant stakeholders that an incident has occurred

Is it an SI?

Follow procedure for Orange incidents

Follow process for RCA investigation
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1.0 RESPONSIBILITIES AND ACCOUNTIBILITY

1.1 All Staff

It is the responsibility of all staff to ensure they are aware of, and comply with, all NHS North Central London’s policies, procedures and guidance surrounding incident reporting and management.

1.1.1 All staff have a duty to:

- Assist in the immediate management of incidents (where appropriate). This includes making the environment, staff and patients safe, and providing any necessary treatment required
- Identify and secure any equipment involved in the incident
- Report the incident to their line manager at the earliest opportunity (in the case of suspected Serious Incidents see section 16.0 of this document)
- Report all incidents using the online Datix reporting system or, if access is unavailable, using the electronic form and sending via email, or via safe haven fax (0207 813 8739) or secured post (addresses for all types of notification can be found in Appendix 3) to the Patient Safety Team
- Complete a statement (if a witness or involved in the incident) as soon as possible after the incident (guidance on how to write a statement can be found in appendix 4)

NB. If sending an incident form via secured post, the Patient Safety Team must be informed about the incident by telephone to ensure that relevant individuals are notified of the incident, and any immediate actions required are undertaken in a timely manner

1.2 Independent Contractors

Independent Contractors, as providers of NHS funded care, are required to report all incidents and near misses. It is the responsibility of Independent Contractors to ensure that the Practice culture is encouraging with regard to incident reporting, and that staff and patients are supported in the aftermath of an incident. Other responsibilities include:

- Adopting this policy for use in local practices
  Reporting all incidents using the online Datix reporting system or, if access is unavailable, using the electronic form and sending via email, or via safe haven fax or secured post (addresses for all types of notification can be found in Appendix 3)
- Ensuring that all staff are trained in incident reporting, and relevant staff are trained in Root Cause Analysis techniques for investigations
- Managing incidents relevant to the grading as in sections 6.0, 7.0, 8.0 and 9.0
- Implementing any action plans that are developed as a result of an incident investigation
NB. If sending an incident form via secured post, the Patient Safety Team must be informed about the incident by telephone to ensure that relevant individuals are notified of the incident, and any immediate actions required are undertaken in a timely manner.

1.3 All NHS North Central London Managers
It is the responsibility of all managers to ensure that:

- All staff (including bank, agency and contractors) within their areas of responsibility follow this policy and procedure
- All relevant stakeholders and notifiable agencies (such as the Health & Safety Executive) have been informed that an incident has occurred
- Any relevant treatment required is provided to the patient involved in the incident, and that the patient/s, staff, visitors and the environment is made safe
- Any evidence, including faulty equipment, has been secured
- An incident form has been completed satisfactorily and sent to the Patient Safety Team within 72 hours, or 24 hours for all actual or potential Serious Incidents
- All incidents graded below 8 have been appropriately managed
- The incident form has been completed
- Risk assessments are reviewed or performed as appropriate following an incident, and that risks are added to the relevant risk register
- Staff are fully supported and, where appropriate, referred to Occupational Health
- Report thefts, assaults and other criminal activities towards, or by, staff and patients to the Police
- Feedback is provided to staff involved in an incident, and the Being Open process\(^8\) is adopted for communication with patients involved in an incident. (Weblink to Being open process: [http://www.nrls.npsa.nhs.uk/resources/?entryid45=59792](http://www.nrls.npsa.nhs.uk/resources/?entryid45=59792))
- Action plans that are developed following incident investigations are fully implemented

1.4 On-call Managers
It is the responsibility of on-call Managers to ensure that, if they are alerted to a Serious Incident, they assist with the immediate management if required. They are also responsible for deciding who needs to be notified of the Serious Incident if it has occurred out of hours. The on-call Manager will also ensure that the Patient Safety Team, and other relevant individuals, have been made aware of the Serious Incident as soon as possible following the incident, and ensure that an incident report form has been completed.

1.5 Patient Safety Team
It is the responsibility of the Patient Safety Team to:

- Manage and promote this policy and procedure

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\(^8\) Being Open when Patients are Harmed, 2006, NPSA
Monitor the quality of incident reporting forms to ensure that there is sufficient information contained within them for reporting to the National Patient Safety Agency and NHS London where appropriate

Review the quality of the grading of all incidents

Offer support to staff and Independent Contractors on how to complete an incident form on Datix.

Ensure that all relevant stakeholders (including the Director of Primary Care for Independent Contractor incidents) and notifiable agencies (including NHS London) have been informed where appropriate and within the required timescales

Ensure that all Serious Incidents are recorded on the STrategic Executive Information System (STEIS)

Provide advice and support to staff and Independent Contractors undertaking investigations using Root Cause Analysis (RCA) techniques. This includes ensuring investigators are using the appropriate RCA tools and templates

Review the quality of investigation reports and action plans, ensuring that actions are SMART (Specific, Measurable, Accurate, Realistic and Timely)

Produce quarterly reports which identify trends through analysis of incidents and Serious Incidents, and present these to the NHS North Central London Quality and Safety Committee

Provide Datix and RCA training, or direct staff and Independent Contractors to appropriate sources of education and training in this area

Ensure that action planning and implementation is undertaken, and that lessons have been learned and shared

Develop and maintain systems and processes promoting the reporting of all incidents and a culture of learning from mistakes

Cross-check any incidents with the complaints module on Datix to establish if an incident is already being progressed through the complaints process

1.6 Director of Public Health Camden (Lead for Screening)

It is the responsibility of the Director of Public Health Camden to:

Ensure that all NHS North Central London screening incidents that are reported to staff within the Public Health directorate is communicated to the Patient Safety Team. An incident form will be completed by the relevant Lead within Public Health and forwarded to the Patient Safety Manager. This will be followed up with a telephone call from the Lead to the Patient Safety Manager.

Liaise with the Director of Quality and Safety to decide on the grading of potential screening Serious Incidents

Establish a Serious Incident panel in liaison with the Director of Quality and Safety

Provide advice to the Director of Quality and Safety in relation to public health incidents, including screening incidents.

1.7 Director of Quality and Safety

On a day to day basis the Chief Executive Officer will normally delegate the responsibility for managing incidents to the Director of Quality and Safety who will usually take a lead role in ensuring integration between the organisation’s incident
management function and internal and external governance and assurance processes. The Director of Quality and Safety is also responsible for:

- Ultimately deciding the grading of incidents scored 12 and above (amber and red), and declaring which are to be classified as Serious Incidents. This is achieved through consultation with relevant experts and stakeholders within the organisation.
- Providing Board Assurance that effective systems, processes, policies and procedures for incident management are in place within the organisation.
- Ultimately deciding when a Serious Incident investigation report is ready for submission to NHS London, and also when Amber incidents have been investigated and managed to an appropriate conclusion for closure – this will usually be done through the Serious Incident Monitoring Group, but may also be done on an ad hoc basis if the timing of the group means that submission of investigation reports to NHS London will fall outside the required timescales.
- Informing the Chief Executive Officer, Chair and Non-Executive Director (leading on patient safety) when a Serious Incident or Never Event has been reported by NHS North Central London staff and Independent Contractors.

1.8 Chief Executive Officer
As accountable Officer, the Chief Executive has overall responsibility for ensuring a risk management system is in place and is managing incidents safely.

The Chief Executive is ultimately accountable for the quality of care within the organisation. As part of good governance arrangements, the Chief Executive is responsible for ensuring the implementation of this policy and maintaining an overview of incidents.

1.9 Corporate Governance Team
The Corporate Governance Team is responsible for providing advice and overseeing all non-clinical incidents including:

- Information Governance incidents
- Health and Safety incidents and Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDORS). See section 14.0.

2.0 TRAINING AND EDUCATION
2.1 All NHS North Central London staff will receive essential training on incident reporting as part of their mandatory induction programme.

2.2 The Patient Safety Department will ensure that Root Cause Analysis training is provided for staff who will be undertaking incident investigations, and Being Open guidance will also be made available.

2.3 The Patient Safety Department will provide specific training to staff as identified through a training needs analysis by themselves and their line managers.

2.4 The Patient Safety Team will provide training on DATIX (NHS North Central London’s incident management database) where required.
3.0 INCIDENT REPORTING

3.1 What is an Incident?

3.1.1 An incident can be described as ‘An unintended or unexpected event which could have, or did lead to loss or harm. In relation to both clinical (i.e. patient safety) and non-clinical settings e.g. health and safety related incidents.’

3.1.2 The term incident includes:
- clinical and non-clinical incidents and accidents
- accidental injuries
- near misses
- incidents that might happen
- Serious Incidents
- Never Events
- unusual and dangerous occurrences
- damage to NHS North Central London or Independent Contractors’ property or equipment including fire and flood
- medication incidents
- Children and adult safeguarding incidents
- security incidents
- medical devices and other equipment incidents

Further examples of incidents and Serious Incidents can be found in Appendix 5.

3.2 Identifying an incident

3.2.1 Incident Report forms are to be completed, either using Datix online: http://camproapp001v.cit.forest1.local/Datix/Live/index.php - from Stephenson House or http://nww.datix.camdenpct.nhs.uk/Datix/live/index.php - from all other areas) or using the form in appendix 6, by the relevant staff member before the end of the shift and forwarded to the person in charge of incident management for their area.

3.2.2 The manager in charge of incident management is to complete the manager’s section of the incident report form, including grading the incident (using NHS North Central London’s Risk Matrix, Appendix 2a).

3.3 Managing an incident

3.3.1 The flowchart for Incident Management, Reporting and Investigation (Appendix 7) outlines the process for when an incident or near miss occurs.

3.3.2 For unexpected deaths or major permanent harm immediate action is to be taken as per section 16.0 onwards.

3.4 Timescales for reporting incidents

Timescales for reporting incidents depend on the severity of the incident. These timescales are:

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9 Seven Steps to Patient Safety, 2004, NPSA
- Incidents graded green and yellow are reported to the Patient Safety Team within 72 hours.
- Potential Serious Incidents (red and amber) are reported to the Patient Safety Team within 24 hours of the incident.

If the investigator thinks that they may have problems achieving the deadlines they will speak to the Patient Safety manager in the first instance.

**4.0 NEVER EVENTS**

4.1 Never Events are serious, largely preventable, patient safety incidents that should not occur if the available preventative measures have been implemented.\(^{10}\)

4.2 Never Events are recorded as ‘Never Events’ on Datix, and are treated and investigated as serious Incidents. As such, they are also recorded on STEIS. An up to date list can be found at: [http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_124552](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_124552)

**5.0 RAISING A MATTER OF CONCERN (WHISTLEBLOWING)**

5.1 NHS North Central London promotes a safe culture in which staff should feel comfortable raising concerns about their colleagues, superiors and any staff who are not acting within their professional code of conduct or who put the safety of patients at risk.

5.2 Staff will be supported if they raise a matter of concern, and further guidance can be found in NHS North Central London’s Whistleblowing policy.

**6.0 MANAGEMENT OF INCIDENTS OF ALL GRADES**

There are certain steps that are taken in the management of ALL incidents, and these are:

- Take immediate action to ensure that patients, staff, visitors and the environment are safe
- Remove any faulty equipment or medication and place in a safe area for examination as part of any investigation that may follow
- Ensure relevant agencies have been informed e.g. police
- Inform patients, relatives, staff, visitors and any other relevant people that an incident has occurred
- Complete an incident report form and ensure that the manager responsible for incident management sees this within 24 hours
- Ensure the Patient Safety Team (or on-call manager) are aware of the incident within 48 hours of the incident occurring

**7.0 MANAGEMENT OF INCIDENTS GRADED GREEN AND YELLOW (Score of 1-6)**

7.1 For Green and yellow incidents local management action is taken as appropriate.

7.2 The investigation and action fields in the manager’s section of the incident form (both Datix online and paper version) are completed by the manager responsible for incident management within the area the incident occurred.

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\(^{10}\) Never Events List, 2011, Department of Health
7.3 The Quality and Safety Committee is responsible for monitoring incident trends on a four-monthly basis.

7.4 The Patient Safety department will be informed of all actions taken/implemented.

8.0 MANAGEMENT OF INCIDENTS GRADED AMBER (Score of 8-12)

8.1 Where an incident is risk assessed and graded Amber the Manager responsible for incident management within that area will inform the Patient Safety Team immediately. If this is outside core working hours (09.00 to 17.00 hours Monday to Friday) the on-call Manager is to be informed.

8.2 The Manager responsible for incident management within the area the incident occurred will fax a copy of the incident form to the Patient Safety Team within twenty four hours of the incident occurring, and follow this up with a telephone call to ensure receipt of the fax.

8.3 The responsible Manager will undertake the investigation with advice and support available from the Patient Safety Team on the investigation process.

8.4 The Director of Quality and Safety will approve the amber incident report (investigation template can be found in appendix 9) within 20 working days of the incident occurring.

8.5 Once approved, the incident file will be closed and the completed investigation report will be attached to DATIX, NHS North Central London’s incident reporting database.

8.6 The person undertaking the investigation is responsible for providing feedback on the investigation and actions taken to the staff member who completed the original incident reporting form, and also to other staff as appropriate.

8.7 The local Primary Care Commissioning Group performance manages the implementation of amber incident action plans.

8.8 The Serious Incident Monitoring Group oversees the implementation of all Amber investigation action plans.

8.9 Analysis of amber investigations is included in the quarterly incident trend report that is seen by the Quality and Safety Committee.

9.0 MANAGEMENT OF INCIDENTS GRADED RED (Score of 15-25)

9.1 The management and investigation procedure for incidents graded Red is detailed in section 16.0 onwards.

9.2 When reporting a serious incident on STEIS there are three grading options available:
10.0 MANAGEMENT OF SAFEGUARDING ADULTS INCIDENTS

10.1 Serious Incidents involving adults at risk should be investigated in accordance with NHS North Central London’s Safeguarding Adults Policy (2011).

10.2 Advice and support can be sought from a member of the relevant Borough’s Safeguarding Adults Team.

11.0 MANAGEMENT OF SAFEGUARDING CHILDREN INCIDENTS

11.1 All staff must understand their responsibilities in safeguarding children and reporting incidents/serious incidents to the appropriate authority. (Please refer to Safeguarding Children Policy June 2011 - 

11.2 Incidents that potentially meet the criteria for Serious Case Review (as described in “Working Together to safeguard children 2010”) are managed in accordance with this guidance and with the “London Child protection procedures 2010”. The multi-agency response to such incidents will be overseen by the Local Safeguarding Children Board of the relevant borough. This will include the decision as to whether or not a serious case review is to be undertaken.

11.3 Please note that incidents, where there are no suspicions of child abuse or neglect in the history, will not trigger a SCR. These incidents will be managed as serious

<table>
<thead>
<tr>
<th>Grade</th>
<th>Severity</th>
<th>Timescale</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Notification only - it is unclear if a serious incident has occurred. The organisation must update the SHA with further information within three working days of a grade 0 incident being notified. If within three working days it is found not to be a serious incident, it can be closed with the agreement of the SHA. If a serious incident has occurred it will be re-graded as a grade 1 or 2.</td>
<td>45 days</td>
</tr>
</tbody>
</table>
| 1     | PCT will monitor the case and report to the SHA, findings and recommendations and associated action plans. SHA will monitor progress on a quarterly basis with PCT unless earlier discussion is required or the serious incident is re-graded. **Examples:**  
- Drug errors leading to severe harm or Death  
- Unavoidable/unexplained death  
- Mental health – attempted suicides as inpatients  
- Data loss and information security (DH Criteria level 2) | 45 days |
| 2     | Case will be monitored by the SHA in conjunction with the reporting organisation. The SHA will review findings, recommendations and associated action plans. For ‘Never events’, the commissioning PCT will be obliged to monitor overall numbers and report these in its annual reporting arrangements. **Examples:**  
- Homicides  
- Serious or intentional harm to patients  
- Maternal deaths  
- Child protection  
- Data loss and information security (DH Criteria level 3-5)  
- Never Events | 60 days |
incidents and investigated as such, but the relevant Borough-based designated professional will be kept informed of the progress of the investigation to ensure that any emerging safeguarding issues are considered and addressed.

11.4 The process for responding to a Safeguarding Children serious, or potentially serious, incident is as follows:

- When the Patient Safety Team receive notification of an incident, which may meet the criteria for an SCR, then the Patient Safety Manager will inform the relevant Borough designated nurse/doctor and the Executive Lead for Safeguarding Children at NHS North Central London.
  
  If a Borough designated nurse/doctor receives notification from a source outside of the patient safety team they will notify the Patient Safety Manager.

- All incidents that trigger a Serious Case Review are automatically graded as Serious Incidents.

- Where a Serious Case Review is not triggered and/or during the period whilst a Serious Case Review decision is being made, the relevant Borough designated nurse/doctor will discuss with the Director of Quality & Safety as to whether the incident should be reported on STEIS as a serious incident and inform the relevant Borough Director.

- When a decision to undertake a SCR the designated nurse/doctor should inform:-
  a) Borough director
  b) Executive lead for safeguarding
  c) The Patient safety team

- The Patient Safety team will
  - complete the STEIS notification
  - inform NHS London
  - notify the Care Quality Commission
  - Inform the Head of Communications if it is felt there may be media interest

- The designated nurse/doctor will provide regular updates on progress with reviews as requested by the Child protection /safeguarding lead at NHSL until the SCR is completed and the action plan is fully implemented.

- The designated nurse/doctor will provide the Patient safety team with updates at key points in all reviews for entry onto STEIS

- The Patient Safety Team will record all Safeguarding Children Serious Incidents on STEIS and Datix, and all lower graded safeguarding children incidents onto Datix alone.

- The Borough Director and Vice Chair (Non Executive)- of the PCT Board for respective Boroughs should in partnership with the Executive Lead for Safeguarding Children (NHS North Central London) oversee and sign off Health Overview Reports for SCRs written by designated nurses and doctors in NHS North Central London (as described in the safeguarding policy).

- The Borough based designated nurses will provide the Patient Safety Manager with a copy of the Health Overview report for attachment to the relevant record on Datix.

11.5 Please refer to Safeguarding Children Policy June 2011 for further guidance. If required, advice and support should be sought from a member of the relevant Borough’s Child Protection Team.
12.0 MANAGEMENT OF SCREENING PROGRAMME INCIDENTS

12.1 Existing national guidance recommends that where a serious incident involves a national screening programme, the Director of Public Health, or delegated officer (North Central London Cancer or non-Cancer Screening Lead), of the responsible Commissioning body is responsible for taking oversight of the incident with the Provider organisation or Independent Contractor where the incident has occurred.

12.2 The Director of Quality and Safety will involve the Director of Public Health, or delegated officer (North Central London Cancer or non-Cancer Screening Lead), in decision-making around identification, grading management, action, dissemination and learning from the all NHS North Central London and Independent Contractor serious screening incidents.

12.3 All screening incidents should be reported to the Patient Safety Team via ncl.incidents@nhs.net using the Datix Web or proforma. Serious screening incidents should be reported within 24 hours.

12.4 If the Patient Safety Team become aware of any potential screening Serious Incidents, they will notify the North Central London Public Health Cancer Screening Lead and/or non-Cancer Screening Lead of serious screening incidents.

12.5 Serious Incidents in non-Cancer Screening Programmes will be managed in line with this policy.

12.6 The Patient Safety Team, in consultation with the North Central London Public Health Cancer Screening Lead and/or non-Cancer Screening Lead, ensures that all Serious Incidents are reported on STEIS.

12.8 All screening incidents will be investigated in accordance with the policy ‘Managing Incidents and Serious Incidents in the NHS North Central London Screening Programmes’.

13.0 MANAGEMENT OF INFORMATION GOVERNANCE INCIDENTS

13.1 In the event of a potential Information Governance incident, the Patient Safety Team will notify the Information Governance Manager for possible onward circulation to the:

- Caldicott Guardian
- Senior Information Risk Officer (SIRO)
- Information Security & Privacy Officer
- Information Commissioners Office

13.2 The immediate response to the incident, and the escalation process for reporting and investigating, will vary according to the severity of the incident (see appendices 11 and 12 for more information on grading and reporting of Information Governance incidents).

13.3 Further information on all types of information governance incident management can be found in the Information Security Event Reporting Procedures document.
14.0 REPORTABLE INJURIES, DISEASES OR DANGEROUS OCCURRENCES (RIDDOR) (1995)\textsuperscript{11}

14.1 These are defined in Schedules 1, 2 and 3 of The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR) and are detailed in Appendix 13).

14.2 Any incidents which potentially fall into this category will be reported immediately onto Datix. In addition, Managers and Independent Contractors report potential RIDDORs directly to the Health and Safety Executive (http://www.hse.gov.uk/riddor/)

14.3 Unexpected deaths and/or incidents resulting in serious harm to patients will be reported by NHS North Central London to the Health and Safety Executive under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR). If something happens that did not result in a reportable injury, but could have done (near miss), then it may be a dangerous occurrence which will also be reported immediately to the HSE.

14.4 It is a legal requirement to report the following work-related incidents:

- Death
- Major injuries
- Over-three day injuries – where an employee or self-employed person has an accident and the person is away from work or unable to work normally for more than three days.

14.5 At the point of referral an appropriately qualified individual will take responsibility for preserving any relevant evidence and, if appropriate, safeguard the scene.

14.6 The number of RIDDOR incidents reported by the organisation/business is included in the four-monthly incident reports that are presented to the Quality and Safety Committee.

14.7 RIDDOR incidents are also monitored through NHS North Central London’s Health and Safety Committee.

15.0 SUSPENSION AND DISCIPLINARY PROCEEDINGS

In line with NHS North Central London’s promotion of a fair blame culture, disciplinary proceedings will only be initiated where the incident investigation reveals:

- An intentionally unsafe act
- Reckless taking of an unjustifiable risk where the risk was known or the person’s mind was deliberately closed to its existence
- Gross negligence - a consequence was brought about which a reasonably competent person would have foreseen and avoided
- A criminal act has been committed.

These situations are covered by NHS North Central London’s Disciplinary Policy, and Independent Practitioners’ local policies.

16.0 INFORMING INDIVIDUALS WITHIN NHS NORTH CENTRAL LONDON

16.1 An incident with a risk assessment score of 15 and above (Red) is classified as a Serious Incident.

16.2 Once an incident has been identified as a potential Serious Incident using the NHS North Central London’s risk matrix (Appendix 2a) the most senior person present at the time of the incident will immediately inform the person responsible for incident management in that area, who in turn will inform the Patient Safety Team (see Appendix 8 for flowchart of the process for the first 48 hours following a potential Serious Incident).

16.3 If a potential Serious Incident occurs between 17.00 and 09.00 hours and at weekends (outside working hours) the on-call Manager (07623 908008 – see appendix for instructions on how to contact the on-call Manager) is to be contacted. They will brief the Director of Quality and Safety within 24 hours of the incident occurring, or at the earliest opportunity. An Incident Reporting form will be faxed to the Patient Safety Team.

16.4 The Director of Quality and Safety, in discussion with relevant key individuals e.g. Director of Public Health, will agree the status of the incident – i.e. whether to formally declare the incident a Serious Incident.

16.5 Within 36 – 48 hours of the Serious Incident occurring, the Director of Quality and Safety will brief NHS North Central London’s Chief Executive and agree a plan for briefing other internal and external agencies, including the communications team.

16.6 The Director of Quality and Safety will form a Serious Incident investigation team, and identify an appropriate investigator. Independent Practitioners will usually identify an investigator from within their area who is appropriately trained to undertake root cause analysis investigations, but who was not involved in the incident.

17.0 EXECUTIVE PANEL

17.1 An Executive Panel will be selected by the Director of Quality and Safety who will ensure there is appropriate panel membership according to the serious incident

17.2 Executive Panel membership will comprise of:

- Director of Quality and Safety or Deputy Director of Quality and Safety
- Medical and/or nursing representative as required
- Lead investigator
- Other technical advisor as appropriate e.g. governance lead, primary care lead
- Senior Administrator.

17.3 The Executive Panel will review the initial investigation report and risk assessment to determine the severity of the incident and whether it is a serious incident. In addition the Executive Panel will:

- Draw up terms of reference for an investigation (see appendix 14).
• Review and approve the investigation report, including recommendations.
• Develop an action plan specifying an appropriate lead for each action point and timescales to reflect urgency of the required action.
• Agree how the action plan will be shared with identified leads (if they are not present at the panel meeting);
• The Serious Incident Monitoring Group receives the approved report and action plan for final executive ‘sign off’.

17.4 An investigating team with terms of reference will be appointed by the Executive panel to support the investigation using Root Cause Analysis.

17.5 The Executive panel will decide if an incident co-ordination group (see section 20.1.2) needs to be established for an incident that may span third party organisations.

18.0 INFORMING RELEVANT EXTERNAL AGENCIES

18.1 Making a referral to the police and/or Health and Safety Executive (HSE).

18.1.1 NHS North Central and Independent Practitioners may be faced with an incident that will require investigation by the police and/or Health & Safety Executive (HSE).\textsuperscript{12} This will be in cases of gross negligence or manslaughter. This offence is committed when a person who owes a duty of care to another, breaches that duty of care which leads to the death of the other person. The conduct of the person who owes duty of care is considered to be so bad as to be criminal.

18.1.2 The types of patient safety incident that may prompt involvement of the police are those that display one or more of the following characteristics:

• Evidence or suspicion that the actions leading to harm were intended
• Evidence or suspicion that adverse consequences were intended
• Evidence or suspicion of gross negligence and/or recklessness in a serious safety incident, including as a result of failure to follow safety practice or procedure or protocols.

18.1.3 When the Police and HSE are involved, specific guidance in line with the Memorandum of Understanding\textsuperscript{13} is given on how organisations should work together. The Patient Safety Team can provide specific guidance on the process and procedures required when following a joint investigation with external agencies.

18.4 Other External Agencies

18.4.1 Other external agencies that have an advisory or analytical function will need to be informed of the event depending on the type of Serious Incident. The investigative function of these bodies includes medical

\textsuperscript{12} DH, Feb 2006, Memorandum of Understanding Investigating patient safety incidents involving unexpected death and serious untoward Harm: a protocol for liaison and effective communications between the National Health Service, Association of Chief Police Officers and Health & Safety Executive.

\textsuperscript{13} Memorandum of Understanding, DH November 2006
devices/equipment, individuals, organisations and systems. Guidance will be given by the Patient Safety Team. These agencies include:

- NHS London
- Other Trusts/Commissioners/Providers that the Serious Incident has impacted upon
- The Home Office
- National Health Service Litigation Authority (NHSLA)
- Coroner
- Social Services
- Medicines and Healthcare Products Regulatory Agency (MHRA)
- Health and Safety Executive (HSE)
- Public Health Bodies (e.g. Health Protection Agency)
- NHS North Central London’s legal advisers
- Local supervising authorities for a maternal death.
- Monitor
- The Care Quality Commission (CQC)
- National Confidential Enquiry into Patient Outcome and Death (NCEPOD)
- National Patient Safety Agency (NPSA)
- NHS Counter Fraud & Security Management Services (CFSMS)
- Professional regulatory bodies e.g. General Medical Council, Nursing & Midwifery Council

18.4.2 Independent Practitioners e.g. General Practitioners may need to be informed before patients, as they may be an essential part of the support mechanism. They may be needed to provide re-screening facilities and give follow up care.

19.0 MANAGEMENT OF THE INCIDENT (first forty eight hours)

19.1 An investigator and Executive Panel are identified by the Director of Quality and Safety. A Root Cause Analysis (RCA) is undertaken within 45 working days and a report (Appendix 10 for report template) is submitted to the Patient Safety Team. The investigation team will be multidisciplinary and one of the members will have been trained in RCA investigation methods.

19.2 The Director of Quality and Safety has overall responsibility for management of incidents which occur within core working hours (09.00 – 1700 hours Monday to Friday), and ensures that immediate management of the incident occurs and designates a member of staff to be responsible for securing evidence, for example:

- Label and secure any material evidence
- Record readings, settings, position of switches, valves and dials
- Take photographs
- Label and prevent further use of equipment or products
- Secure patient X-ray, test results, and photocopy the medical records.

19.3 The on-call Manager has overall responsibility for the management of a Serious Incident that occurs outside core working hours between 17.00 and 08.00 hours and at weekends and Bank Holidays).

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14 Guidance Document for managing an RCA
20.0 CONDUCTING THE INVESTIGATION USING ROOT CAUSE ANALYSIS

20.1 Root Cause Analysis (RCA)

20.1.1 RCA is a systems based approach to undertaking an investigation. It is led by a person who can demonstrate a degree of independence from the incident and who has had training and experience in RCA techniques\(^{15}\). For near misses or incidents with less harmful outcomes (green and yellow graded incidents) where a full investigation/RCA is not considered appropriate, much learning can be derived by carrying out a less intensive investigation approach. The Lead has overall responsibility for ensuring results are disseminated to those involved in the incident investigation.

20.1.2 If third parties are involved, an incident coordination group will be set up (the Patient Safety Team will advise on the tools and process for this). Evidence should be collected as stipulated in the guide below.

20.2 Preserving evidence and safeguarding the scene

20.2.1 In the immediate aftermath of a patient safety incident, steps need to be taken to secure and preserve evidence.

20.2.2 Physical, scientific and documentary evidence may be critical to understanding what has happened and to the conduct of a satisfactory investigation by any agency.

20.2.3 It is especially important where a criminal offence is suspected that evidence is retained, since failure to do so may mean that legal proceedings are undermined.

20.2.4 Some healthcare incidents only come to light some time after the event(s). In this case, the evidence may be difficult to identity and locate.

20.2.5 Practical steps are to be taken by staff to preserve and safeguard evidence – particularly the following:

- Records
- Equipment e.g. instruments, syringes and devices
- Clothing, including that of patients and staff
- Packaging e.g. from drugs and equipment
- The scene more generally e.g. treatment room
- Personal possessions
- Photographs of the scene, with time and date

20.2.6 The use of a numbering or referencing system will assist in referring to and tracking information easily as detailed in Table 1.

Table 1 to show: a referencing and tracking system

<table>
<thead>
<tr>
<th>Ref. Number</th>
<th>Information / Data Source (what, who)</th>
<th>Date requested</th>
<th>Date Received</th>
</tr>
</thead>
</table>

\(^{15}\) NPSA guidance is available at http://www.saferhealthcare.org.uk/IHI/Products/E-learning/rcatoolkit.htm
20.3 Protecting evidence

Once evidence has been identified, all efforts need to be taken to protect it. Such steps may include putting a clinical area temporarily “out of bounds” to staff and patients but for no longer than necessary. Support staff e.g. cleaners and engineers need to be notified too. An identified person needs to take responsibility for holding such evidence and for safeguarding it. Receipts should be obtained and a record kept of any evidence including equipment that is handed to another agency.

20.4 Statements and Interviews

20.4.1 Statements (Appendix 4 for guidance on how to write a statement) will be taken from people directly involved in the incident and, where appropriate, consideration will be given to gathering information from people who were on the periphery at the time. This process should be supportive and non-judgemental. Interviews will be arranged to gather more information (see NPSA website for guidance on how to conduct an interview: www.npsa.nhs.uk/nrls).

20.4.2 A site visit may assist the investigation team and photographs, measurements, sketches or building plans can help analysis. Assessment of the culture and working methods of the team may provide important context to the information collected.

20.5 The Serious Incident Report

The report (see Appendix 10 for report template) will be written and submitted to the Patient Safety Team, following which it will be submitted to the Director of Quality and Safety (through the Serious Incident Monitoring Group) and then onto NHS London. A post investigation meeting will be held by the Serious Incident panel team who will feedback findings and share lessons. When the report is written, individuals mentioned will also be acknowledged by their job status so their names can be later removed when using the incident report for learning and discussing solutions.

20.6 Tabular Timeline

A tabular timeline is a tool for collecting detailed information and gives an opportunity to record what happened in a time sequence, with supplementary information. It notes good practice, and detail of care delivery, problems that arise with the process of care, usually actions or omissions by staff (something that should have happened or was omitted) or service delivery issues that are
associated with decisions procedures and systems that are part of the process of service delivery. It is essential to note good practice so that changes implemented may build upon and compliment existing good practice.

20.7 Chronology

This forms part of the report and gives an outline of what happened. A chronology can be easily written from the Tabular timeline and assists in ensuring that vital detail is not omitted.

20.8 Review Meeting

It is important to invite the relevant stakeholders to the meeting and outline the purpose of the meeting. Information that has been gathered is shared with those at the meeting. At this stage it would have been identified if there was a disciplinary issue and the Incident Decision Tree (IDT)\(^ {16} \) should have been used to determine any course of action towards staff involved in the Incident. This tool can be used as a record of decision making in such circumstances. A systems approach recognises that there are failures which apply at all levels of the business/organisation. There is a balance between individual human factors and business/organisational factors in each incident which should be explored through root cause analysis.\(^ {17} \)

20.9 Contributory Factors

Contributory factors represent active and latent factors that contributed to the identified problem issue. Active factors, or failure, are those actions or omissions by staff in the process of care. Latent factors, or conditions, are those decisions taken some time before the incident or event which lie dormant. These are usually associated with management decisions concerning service delivery. It is only when various active and latent factors combine that they are shown to have the potential to cause harm. Contributory Factors\(^ {18} \) can be identified using the Fish Diagram and are listed as follows:

- Patient factors
- Individual factors
- Task factors
- Communication factors
- Team and social factors
- Education and training
- Equipment and resource factors
- Working conditions and environmental factors

20.10 Root Causes

A root cause is the cause(s) that, if addressed, will prevent or minimise the chances of an incident recurring. Although the term can imply that there is a single root cause, typically there are often a number of aspects to the incident which if they were rectified may have prevented the incident from occurring.

\(^ {16} \) Incident Policy, Section - Suspension and Disciplinary Proceedings
\(^ {17} \) Seven Steps to Patient Safety, NPSA 2004 Step 1, Patient safety, accountability and open and fair culture, p32
\(^ {18} \) Seven Steps to Patient Safety, NPSA 2004, Step 6, NPSA contributory factors
20.11 Action Plans

Action plans will incorporate **SMART** objectives that are **S**pecific, **M**easurable, **A**ccurate **R**ealistic and **T**imely. Solutions may require risk assessment and consideration should be given to the effect certain solutions will have on patient pathways, especially where there may be services operating across boundaries.

20.12 Sharing Lessons Learned

20.12.1 NHS North Central London recognises that it is essential to learn from Serious Incidents to prevent recurrence, and this is supported the Department of Health’s ‘An Organisation with a Memory’.19

20.12.2 A post investigation meeting is held by the investigation team who will feedback findings and share lessons.

20.12.3 The lead investigator is responsible for providing feedback on the investigation and actions taken to the staff member who completed the original incident report form, and also to other staff as appropriate.

20.12.4 The Patient Safety Team monitors incident reporting feedback, and shares lessons learned across NHS North Central London where there are significant trends or high risks to patient safety identified through a Serious Incident investigation.

20.12.5 The Health and Safety Committee will ensure that Health and Safety incident trends are communicated to staff.

20.12.6 A brief synopsis of the incident and actions taken is included in the quarterly incident reports.

20.12.7 The Director of Quality and Safety provides the Quality and Safety Committee with information on incidents, including green graded incident trends, to achieve organisational learning.

20.12.7 The Patient Safety Team is responsible for providing the NPSA with anonymised information of all Serious Incidents so learning can take place nationally.

21.0 INFORMING THE PATIENT(S) AND/OR RELATIVE(S)

21.1 In the first 48 hours, the most appropriate person will be responsible for ensuring the patient(s) and/or relatives are given information about the incident. This person may be the professional responsible for the patient’s care (General Practitioner, Dentist, Optometrist etc.) or it may be a Manager with an interest in the area being investigated (Primary Care, Medical Director etc.) Direction can be obtained from the Being Open principles and guidance document [http://www.nrls.npsa.nhs.uk/resources/?entryid45=59792](http://www.nrls.npsa.nhs.uk/resources/?entryid45=59792).

21.2 The patient(s) and/or relative/s will be informed in advance of the media wherever possible. On occasion, particularly where many patients have been involved, or the

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19 An organisation with a memory: Report of an expert group on learning from adverse events in the NHS chaired by the Chief Medical Officer, 2000, Department of Health
incident has come to light some months later, it may not be possible to inform the patient prior to the media becoming aware, although every effort will be made to do so. In this instance the Director of Quality and Safety, the Primary Care Medical Director and the Director of Communications will advise on this matter.

22.0 SUPPORTING PATIENTS AND RELATIVES

22.1 In the case of Serious Incidents leading to the death of a patient, the bereaved should have access to the information and support they need, including specialist support or counselling services where appropriate. 20 Details of other supporting agencies are listed in the Being Open guidance document: http://www.nrls.npsa.nhs.uk/resources/?entryid45=59792

22.2 There is likely to be additional anxiety and distress for relatives when deaths result from patient safety incidents. Liaison with other agencies, such as police family liaison officers – when such have been appointed to the investigation by the senior investigation officer and coroners’ officers,’ will be particularly important, so that relatives are given accurate and consistent information about what is happening (for example, the process involved where a coroner’s post-mortem and/or inquest is necessary).

23.0 SUPPORTING STAFF

23.1 Patient safety incidents, and the ensuing investigations, have a considerable effect on the staff involved. Appropriate and timely support should be made available to them. This may include professional counselling, which can be accessed through the Occupational Health department. Details of other supporting agencies are listed in the Being Open guidance document: http://www.nrls.npsa.nhs.uk/resources/?entryid45=59792

23.2 Those involved in an incident should be encouraged to contact their professional association and/or union representative. Legal advice for those involved, including witnesses, should usually be provided through the professional association and/or unions rather than by the NHS North Central London’s solicitors.

23.3 Decisions about the suspension of staff should be informed by the use of the National Patient Safety Agency Incident Decisions Tree21 and the NHS North Central London Disciplinary Policy or local disciplinary policy if it relates to staff employed by Independent Contractors.

24.0 RECORD KEEPING

All staff involved in the immediate management of the incident during the first 48 hours are required to keep a contemporaneous record of:

- Key decisions made
- Who made the decision/s
- Why the decision was made

20 Being Open policy and Guidance document
21 Http://www.npsa.nhs.uk
These records are to be provided to the Lead Investigator and added to the Serious Incident file/Datix record.

25.0 LEGAL ADVICE

25.1 Access to legal advice/solicitors for NHS North Central London is managed by the Corporate Governance Team. Solicitors will only accept instructions from those members of staff on the 'Authorised User' list.

25.2 Please contact Nadine Hammett, Risk Manager, for further advice via nadine.hammett@nclondon.nhs.uk.

26.0 HANDLING COMMUNICATIONS

Communication with the Media will be managed by the Primary Care Medical Director, Director of Quality and Safety and the Communications Director. The Media Policy provides guidelines for staff.

See Appendix 15 for guidance on Serious Incidents which may be of media interest.

27.0 SHARING INFORMATION

27.1 For NHS North Central London and Independent Contractors, any decision to share or withhold information should be in line with the Department of Health’s confidentiality: NHS code of Practice (November 2003) Confidentiality Code of practice.\(^{22}\)

27.2 When considering disclosing any information, advice should be sought from NHS North Central London’s Caldicott Guardian, or the Information Governance Manager (Telephone: 0207 685 6441).

27.3 Whoever authorised disclosure must make a record of any such circumstances, so that there is clear evidence of the reasoning used and circumstances prevailing. Disclosures in the public interest should also be proportionate and be limited to relevant details. It may be necessary to justify such disclosures to the courts or to regulatory bodies. A clear record of the decision-making process and the advice sought is in the interest of both staff and the organisation they work within.

28.0 MANAGEMENT OF MULTIPLE ENQUIRIES

20.1 Where an incident affects multiple patients it may be necessary to set up a helpline function. The decision to establish a helpline will be taken by the Director of Quality and Safety, Primary Care Medical Director and Director of Communications; they will identify a manager to lead on establishing and overseeing the running of the hotline. The management of multiple enquires will be based on the same process as that of the Major Incident Plan.

20.2 The hotline has two main functions:

- To take calls from switchboard in relation to the incident

• In conjunction with the telephone switchboard supervisor, to set up a dedicated telephone number to receive calls direct from members of the public who may be relatives seeking information about the incident.
<table>
<thead>
<tr>
<th>TERM</th>
<th>DEFINITION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Being Open</td>
<td>Open communication of patient safety incidents that result in harm or the death of a patient while receiving care.</td>
</tr>
<tr>
<td>Commissioner</td>
<td>A person with responsibility for buying services from service providers in either the public, private or voluntary sectors.</td>
</tr>
<tr>
<td>Incident</td>
<td>An event or circumstance which could have, or did, result in unnecessary damage, loss or harm such as physical or mental injury to a patient, staff, visitors or members of the public which does not meet the threshold of a 'serious incident'.</td>
</tr>
<tr>
<td>Investigation</td>
<td>A systematic process of inquiry</td>
</tr>
<tr>
<td>Medical Device</td>
<td>Any instrument, apparatus, appliance, software, material or other article (whether used alone or in combination) intended by the manufacturer to be used for the purpose of:  - diagnosis, prevention, monitoring, treatment or alleviation of disease  - diagnosis, monitoring, alleviation of or compensation for an injury or disability  - investigation, replacement or modification of the anatomy of a physiological process and/or  - control of conception  and which does not achieve its physical intended action on the human body by pharmacological, immunological or metabolic means, but may be assisted in its function by such means.</td>
</tr>
<tr>
<td>Near miss</td>
<td>Potential to cause harm was prevented, resulting in no serious harm or damage, or harm to patients receiving NHS-funded healthcare.</td>
</tr>
<tr>
<td>Never Events</td>
<td>Never Events are serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented by healthcare provider.</td>
</tr>
<tr>
<td>Notification</td>
<td>The act of notifying to one or more organisations/bodies. There may be different defined ways of notifying these organisations. If in doubt, discuss with the Patient Safety Team.</td>
</tr>
<tr>
<td>Patient Safety</td>
<td>The process by which an organisation makes patient care safe. This should involve risk assessment, the identification and management of patient related risks, the reporting and analysis of incidents and the capacity to learn from and follow up on incidents and implement solutions to minimise the risk of them recurring.</td>
</tr>
<tr>
<td>Patient Safety Incident</td>
<td>Any unintended or unexpected incident that could have or did lead to harm for one or more patients receiving NHS funded healthcare.</td>
</tr>
<tr>
<td>Permanent Harm</td>
<td>Directly related to the incident and not related to the natural course of a patient's illness or underlying condition is defined as permanent lessening of bodily functions; including sensory, motor, physiological or intellectual</td>
</tr>
</tbody>
</table>

---

23 Seven Steps to Patient safety, Step 4, NPSA’s preferred terms for patient safety reporting
<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Professional Body</td>
<td>An organisation that exists to further a profession and to protect both the public interest by maintaining and enforcing standards of training and ethics in their profession and the interest of its professional members.</td>
</tr>
<tr>
<td>Risk</td>
<td>The chance of something happening that will have an impact on individuals and/or organisation. It is measured in terms of likelihood and consequences.</td>
</tr>
<tr>
<td>Risk Management</td>
<td>Identifying, assessing, analysing, understanding and acting on risk issues in order to reach an optimal balance or risk, benefit and cost.</td>
</tr>
<tr>
<td>Root Cause Analysis</td>
<td>A systematic process whereby the factors that contributed to an incident are identified. As an investigation technique for patient safety incidents, it looks beyond the individuals concerned and seeks to understand the underlying causes and environmental context in which an incident happened.</td>
</tr>
<tr>
<td>Safeguarding</td>
<td>Ensuring that people live free from harm, abuse and neglect and, in doing so, protecting their health, well being and human rights. Children, and adults in vulnerable situations, need to be safeguarded. For children, safeguarding work focuses more on care and development; for adults, on empowerment, independence and choice.</td>
</tr>
<tr>
<td>Safety</td>
<td>A state in which risk has been reduced to an acceptable level.</td>
</tr>
<tr>
<td>Serious Incident</td>
<td>An incident that occurs in relation to NHS funded services and care result in: Unexpected or avoidable death of one or more patients, staff, visitors or members of the public Serious harm to one or more patients, staff, visitors or members of the public or where the outcome requires life-saving intervention, major surgical/medical intervention, permanent harm or will shorten life expectancy or result in prolong pain or psychological harm A scenario that prevents or threatens to prevent a provide organisation's ability to continue to deliver healthcare services, for example, actual or potential loss of personal/organisational information, damage to property, reputation or the environment or IT failure Allegations of abuse Adverse media coverage or public concern about the organisation or the wider NHS One of the ‘Never Events’</td>
</tr>
<tr>
<td>Severe Harm</td>
<td>Permanent harm to one or more persons</td>
</tr>
<tr>
<td>Unexpected death</td>
<td>Where natural causes are not suspected. Local organisations should investigate these to determine if the incident contributed to the unexpected death.</td>
</tr>
</tbody>
</table>
Appendix 2a: NHS North Central London’s Risk Assessment Tool

<table>
<thead>
<tr>
<th>LIKELIHOOD</th>
<th>CONSEQUENCE severity / impact of hazard being realised</th>
</tr>
</thead>
<tbody>
<tr>
<td>of hazard being realised</td>
<td>Negligible (1)</td>
</tr>
<tr>
<td>Rare (1)</td>
<td>1</td>
</tr>
<tr>
<td>Unlikely (2)</td>
<td>2</td>
</tr>
<tr>
<td>Possible (3)</td>
<td>3</td>
</tr>
<tr>
<td>Likely (4)</td>
<td>4</td>
</tr>
<tr>
<td>Almost Certain (5)</td>
<td>5</td>
</tr>
</tbody>
</table>

The consequence and likelihood scores must be multiplied and plotted on the above table to establish the overall level of risk.

The risk grading will help identify the level of investigation required. Details can be found in the NHS North Central London’s Policy and Procedure for the reporting, investigation and management of incidents and Serious Incidents.

Appendix 2b: The NPSA’s definitions of levels of harm

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>☐ Near Miss</td>
<td>This was a prevented safety incident</td>
</tr>
<tr>
<td>☐ No Harm</td>
<td>The incident occurred but no-one has been harmed as a result</td>
</tr>
<tr>
<td>☐ Low Harm</td>
<td>The incident has caused short term injury. Full recovery in &lt;3 days.</td>
</tr>
<tr>
<td>☐ Moderate Harm*</td>
<td>The incident has caused semi-permanent injury</td>
</tr>
<tr>
<td>☐ Severe Harm*</td>
<td>The incident has caused permanent injury</td>
</tr>
<tr>
<td>☐ Catastrophic*</td>
<td>An incident that leads to the death of one or more persons</td>
</tr>
</tbody>
</table>
### Appendix 3: Useful Contact details (including the Patient Safety Team contacts for all types of incident notification)

<table>
<thead>
<tr>
<th>Department/Job Title</th>
<th>Postal Address/email</th>
<th>Telephone Number/Fax Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Director of Quality and Safety</td>
<td><a href="mailto:Alison.Pointu@nclondon.nhs.uk">Alison.Pointu@nclondon.nhs.uk</a></td>
<td>020 7685 6167 (PA)</td>
</tr>
<tr>
<td>Deputy Director of Quality</td>
<td><a href="mailto:Diane.Curbishley@nclondon.nhs.uk">Diane.Curbishley@nclondon.nhs.uk</a></td>
<td>020 7685 6699</td>
</tr>
<tr>
<td>Assistant Director of Quality and Safety</td>
<td><a href="mailto:Jenny.Goodridge@nclondon.nhs.uk">Jenny.Goodridge@nclondon.nhs.uk</a></td>
<td>020 7685 6715</td>
</tr>
<tr>
<td>Assistant Director of Quality and Safety (Experience)</td>
<td><a href="mailto:Louise.Lingwood@nclondon.nhs.uk">Louise.Lingwood@nclondon.nhs.uk</a></td>
<td>020 7685 6230</td>
</tr>
<tr>
<td>Patient Safety Manager (Patient Safety Team)</td>
<td><a href="mailto:Shindi.Dhillon@nclondon.nhs.uk">Shindi.Dhillon@nclondon.nhs.uk</a></td>
<td>020 7685 6674</td>
</tr>
<tr>
<td>Patient Safety Coordinator</td>
<td><a href="mailto:Roisin.Mulvaney@nclondon.nhs.uk">Roisin.Mulvaney@nclondon.nhs.uk</a></td>
<td>020 7685 6754</td>
</tr>
<tr>
<td>Patient Safety Senior Officer</td>
<td><a href="mailto:Dawn.Campbell@nclondon.nhs.uk">Dawn.Campbell@nclondon.nhs.uk</a></td>
<td>020 7685 6676</td>
</tr>
<tr>
<td>Senior Administrator</td>
<td><a href="mailto:Jennifer.robbins@nclondon.nhs.uk">Jennifer.robbins@nclondon.nhs.uk</a></td>
<td>020 7685 6697</td>
</tr>
<tr>
<td>Senior Administrator</td>
<td><a href="mailto:Izabella.Kowalski@nclondon.nhs.uk">Izabella.Kowalski@nclondon.nhs.uk</a></td>
<td>020 7685 6530</td>
</tr>
<tr>
<td>Senior Audit/Support Administrator</td>
<td><a href="mailto:Sally.ibrahim@nclondon.nhs.uk">Sally.ibrahim@nclondon.nhs.uk</a></td>
<td>020 7685 6200</td>
</tr>
<tr>
<td>Senior Audit/Support Administrator</td>
<td><a href="mailto:Femi.bakare@nclondon.nhs.uk">Femi.bakare@nclondon.nhs.uk</a></td>
<td>020 7685 6717</td>
</tr>
<tr>
<td>On-call Manager</td>
<td><strong>Step 1</strong>&lt;br&gt;Contact the 1st On-Call Director, NHS North Central London Cluster via Page One</td>
<td></td>
</tr>
</tbody>
</table>
Wait for the operator service– Leave a short message including your name and contact number and the 1st on call director will contact you.

If there is no response, please repeat this process.

**Step 2**

If there is no response after 30 minutes, please contact the 2nd On Director via Page One

07623 549841

Wait for the operator service– Leave a short message including your name and contact number and the 2nd on call director will contact you.

If there is no response, please repeat this process.

Alternatively, you can contact Page One Bureau 0844 822 2888 and ask for NCL1 for the 1st on call NCL Director, or NCL2 for the 2nd on call Director

**Step 3**

If you cannot contact the 1st or 2nd on-call NCL Director via Pager please call the NCL Switchboard (staffed 24/7) on:

020 3317 3500

Ask for the 1st on-call NCL Manager. Switchboard staff will telephone the on-call Manager on their mobile / home number and transfer you through.

*Insert Local Reporting Manager here*
Requests for statements to assist an incident investigation may be made to any member of staff. All staff have a duty to submit a statement in a timely manner, although staff are able to seek advice. Guidance is provided below. Note that this is general guidance for completing a statement following an incident only and the Legal Services Department should be contacted for further information about how to prepare statements for the Coroner.

Statements should be addressed to the requesting individual or office. They may be headed ‘Confidential’ but staff are advised that the statements may be disclosed to various bodies or individuals in respect of internal and external procedures (e.g. a legal claim or Coroner’s investigation).

Statements **SHOULD:**

- Be typed but, if statements have to be handwritten, they must always be legible and in black ink.
- Use chronological order giving dates, times (24-hour clock), locations etc
- Be clear and concise, stating facts only
- Be a factual narrative of your own role, making clear which parts are from memory, the records or from your recollection of standard practice at the time (e.g. ‘According to the patient records I gave Mrs Smith 500mgs Paracetamol, to be taken four times daily, on 21st August 2011’, or ‘as I recall it was standard practice at the time to…’)
- Comment on any criticisms concerning your involvement, explaining why you made the decisions you made or why you took a particular course of action.
- Use the first person singular (‘I removed Mrs Smith’s tooth, ‘I gave the baby an injection of…’)
- Include any relevant conversations using direct speech and inverted commas (e.g. Dr Adam Brown said ’I will examine the patient in ten minutes’)
- List the full names of any other staff involved or present
- Have any alterations or errors signed and dated by the person providing the statement
- Have each page of the statement signed and dated by the person providing the statement

Statements **SHOULD NOT:**

- Just repeat what is written in the records; you must expand, as appropriate, what is documented
- Include irrelevant, subjective comments about the patient or colleagues
- Include abbreviations or jargon
- Include statements that cannot be proven (e.g. ‘I think he was drunk’) without qualification (e.g. ‘because he smelt strongly of alcohol’)
- Be written entirely from memory. You should always refer to the records (e.g. patient’s notes etc.) written at the time of the event and if you cannot remember something, say so.

All staff should keep copies of any statements that they provide. Statements should not be filed in the patient’s medical records.
Appendix 5: Examples of Incidents and Serious Incidents

INCIDENTS:

- Equipment failure or misuse which causes minor or no harm to an individual (patient, staff, student or visitor) on NHS/Independent Contractor premises
- Medication error. This includes any incident involving blood, blood products or transfusions
- Patient consent irregularity or error which causes minor or no harm to the patient
- A minor breach of confidentiality
- Security incident including the theft of property or personal belongings, minor damage or Threat to NHS North Central London’s or Independent Contractors property and trespass or unauthorised access
- A minor error by a member of staff or contractor
- Clinical event, occurrence or complication associated with the diagnosis and treatment of patients which are either unexpected or unintended
- Minor verbal abuse directed at staff, visitors, patients or contractors
- Moving and handling irregularity or error which leads to minor or no harm to staff or patient
- Slips, trips and falls
- Communication failure
- Minor sharps injury
- Property loss or damage
- Health records irregularity or error. This includes records not available when needed, any electronic health record irregularity or error and documentation and recording errors.
- Test result delays or irregularities which cause minor or no harm to patients
- Patient identification errors

SERIOUS INCIDENTS:

- An unexpected/unexplained patient death which falls outside the normal complications associated with a patient’s clinical management and care
- Impending litigation, suspicion of large scale theft or fraud
- Equipment failure or malfunction that causes serious harm to an individual (patient, staff, student or visitor) on NHS North Central London’s, or Independent Contractor’s premises
- A process error involving many patients, e.g. the failure of a screening programme
- Any incident that might lead to serious criminal charges, including violent attacks on either staff or patients or hostage situations
- Suspicion of a serious error or negligence by a member of staff, or contractor which could lead to public concern
- Any incident/likely to generate significant media interest
- A significant and major equipment failure that impacts upon the operational function of the organisation/business
- A serious breach of confidentiality
- Abduction of a patient
- Serious chemical or microbiological contamination or radiation incident
- Accidental or suspicious death of, or serious injury to, any individual (staff, patient, student or visitor) on NHS North Central London’s, or Independent Contractor’s premises
- A serious outbreak of an infectious disease e.g. food poisoning, transmission of an infected disease from staff members to a patient, or any incident involving a healthcare worker infected with HIV, Hepatitis B
- The suicide of any person on NHS North Central London’s, or Independent Contractor’s property
- Serious damage, which occurs on NHS North Central London’s, or Independent Contractor’s property particularly resulting in injury or disruption of services (e.g. fire, flood, power or water failure)
Appendix 6: Incident report form

Incident Reporting Form

<table>
<thead>
<tr>
<th>Incident Details</th>
<th>Incident Time (if known)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Location of Incident</td>
<td></td>
</tr>
<tr>
<td>Trust</td>
<td>Borough</td>
</tr>
<tr>
<td>Independent Contractor Type e.g. GP, Dentist etc</td>
<td>NCL Directorate</td>
</tr>
<tr>
<td>Incident location address:</td>
<td></td>
</tr>
</tbody>
</table>

Description of Event *(Enter Facts not opinions, Do not enter names of people)*:

*If the incident involved equipment/device please ensure that batch/serial/asset numbers are recorded:*

Immediate Action Taken *(Enter action taken at the time of the event or immediately after)*:

Details of Person Affected

<table>
<thead>
<tr>
<th>Surname:</th>
<th>First Name:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of Birth:</td>
<td>NHS Number: (for patients only)</td>
</tr>
</tbody>
</table>

*If an employee has been absent from work from >3 days as a result of an incident at work, the incident may need to be reported under RIDDOR. Please contact the NCL Corporate Governance Team on 0207 685 6294 if you are unsure or require support with reporting.*

Has anyone been harmed as a result of this incident?

- [ ] Near Miss This was a prevented safety incident
- [ ] No Harm The incident occurred but no-one has been harmed as a result
- [ ] Low Harm The incident has caused short term injury. Full recovery in <3 days.
- [ ] Moderate Harm* The incident has caused semi-permanent injury
- [ ] Severe Harm* The incident has caused permanent injury
- [ ] Catastrophic* An incident that leads to the death of one or more persons

*Please contact the NCL Patient Safety Team to discuss within 1 working day of incident (contact details on page 2)*

Details of the incident reporter:

<table>
<thead>
<tr>
<th>Name</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Department/Practice etc</td>
<td></td>
</tr>
<tr>
<td>Email Address</td>
<td></td>
</tr>
<tr>
<td>Telephone</td>
<td></td>
</tr>
</tbody>
</table>

Your Line Manager/ Person responsible for local incident management

What happens next?

Please pass the form to your line manager or the person responsible for incident management in your department/practice for review and investigation.

Thank you for taking the time to report this incident.
### Risk Assessment:

<table>
<thead>
<tr>
<th>LIKELIHOOD</th>
<th>CONSEQUENCE severity / impact</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Negligible (1)</td>
</tr>
<tr>
<td>Rare (1)</td>
<td>1</td>
</tr>
<tr>
<td>Unlikely (2)</td>
<td>2</td>
</tr>
<tr>
<td>Possible (3)</td>
<td>3</td>
</tr>
<tr>
<td>Likely (4)</td>
<td>4</td>
</tr>
<tr>
<td>Almost certain (5)</td>
<td>5</td>
</tr>
</tbody>
</table>

Please indicate the risk grade of the incident (Likelihood x Severity=)

using the matrix above:

The risk grading will help identify the level of investigation required. Details can be found in the NHS North Central London’s Policy and Procedure for the reporting, investigation and management of incidents and Serious Incidents.

### Investigation Details:

Please provide details about the investigation that has been undertaken following the incident:

- [ ]

### Contributory Factors and Root Causes:

Please list any contributory factors and root causes that you have identified through your investigation of the incident:

1. [ ]
2. [ ]

Continue on a separate sheet if necessary

### Actions:

Please list any actions which have been or will be taken to reduce the impact of this incident or the risk of it happening again:

<table>
<thead>
<tr>
<th>Action Required</th>
<th>Person Responsible</th>
<th>Due Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Continue on a separate sheet if necessary

### Once completed:

Email the form to: ncl.incidents@nhs.net

Or Post: Patient Safety Team, 5th Floor, Stephenson House, 75 Hampstead Rd, London, NW1 2PL

Please contact the NCL Patient Safety Team 020 7685 6697/6200 with any queries
Appendix 7: Flowchart for Incident Identification and Management

Near Miss/Incident Occurs

Does it result in an unexpected death or major permanent harm?

Yes

Take immediate action as appropriate (make people safe etc)
Inform line manager immediately (after Hours Phone: 07623 908098) and the patient safety team on: 0207 685 6697/6530.

No

Incident Report Form completed by staff member before end of shift and forwarded to person in charge of department/area

Person in charge of dept/area to grade incident and sign off Incident Report Form within 24 hours of receipt

Grading

Green Incident (score=1-3)

Yellow Incident (score=4-6)

Amber Incident (score=8-12)
Potential Serious Incident

Red Incident (score=15-25)
Potential Serious Incident (SI)

Local management action as appropriate

Copy of incident report form forwarded to Patient Safety Team at ncl.incidents@chs.net
Patient Safety Team alerts Director of Quality & Safety

Investigation to be undertaken by local senior Manager or appropriate person. Patient Safety Team to provide advice on the process. Director of Quality & Safety to approve orange incident report within 20 working days of incident. Copy of report attached to Datix. Investigator responsible for providing copy of completed investigation to staff member who completed original incident form, and other staff as appropriate.

Reviewed at Serious Incident Monitoring Group

Reviewed at Quality & Safety Committee

Action plans implemented locally, and monitored through the Patient Safety Team, Primary Care Commissioning Group and the Serious Incident Monitoring Group
Appendix 8: Process for the Management of Potential Serious Incidents in the First 48 hours

Potential Serious incident (SI) Take immediate action as appropriate (make people safe etc)

Most senior person present immediately phones Manager responsible for incident management of that area – they inform the Patient Safety Team (or on-call manager 07623 908008). Patient Safety Manager informs Director of Quality & Safety (within 24 hours)

The Manager responsible for incident management (or on-call Manager) ensures:
1. A member of staff is identified to co-ordinate the immediate management of the incident (see the box to the right)
2. The patient(s) and/or relatives have been informed as appropriate (Being Open Process)
3. The Patient Safety Team have been informed
4. An incident form has been completed and sent to the Patient Safety Team (within 24 hours)

MANAGEMENT OF INCIDENT
Most senior member of staff present assumes initial responsibility for informing the person responsible for incident management for that area (if after hours, the on-call Manager) who will ensure a designated member of staff is responsible for the following:
1. Labelling and securing any material evidence (e.g. packaging, batch identification, broken or faulty equipment).
2. Recording readings, settings, positions of switches, valves and dials etc.
3. Taking photographs.
4. Labelling and preventing further use of equipment, product or room as appropriate.
5. Products are not to be repaired or returned to the supplier before completion of the significant incident report and obtaining advice from the Clinical Governance Team.
6. Ensuring that all observations, tests, requests, laboratory results, treatment administered, or care given are recorded, dated, signed and filled in the patients records.
7. Securing and/or photocopying the medical records and other relevant information.

The Patient Safety Manager:
1. Ensures that the incident has been reported on Datix, and STEIS (if required)
2. Informs the Director of Quality & Safety that a potential SI has occurred.
3. Provides advice and support

The Director of Quality & Safety:
1. in discussion with relevant experts/stakeholders will agree an incident status – i.e. whether to formally declare a SI (within 48 hours).
2. Identifies a Lead Investigator
3. Selects an Executive Panel to oversee the investigation.
4. ensures, and informs, relevant stakeholders that an incident has occurred

Is it an SI?

Follow procedure for Orange incidents

Follow process for RCA investigation

Yes

No
## Amber Adverse Incident Investigation Template

<table>
<thead>
<tr>
<th>STEIS No. (if applicable)</th>
<th>Datix Incident No.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Incident date/Time</th>
<th>Date of Report</th>
<th>Location</th>
<th>Author</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Description of incident (including immediate action taken):** Include medical/ patient history where relevant. Include other factors where relevant (staffing mix etc)

**Outcome of incident** Include actual harm to patient/ staff/ visitor and the present condition (whether now recovered, etc. Include details of damage to property/ reputation where appropriate

**Summary chronology:** (Attach full chronology where necessary)

<table>
<thead>
<tr>
<th>Action</th>
<th>Strength of action in reducing risk (strong/ medium/ weak)</th>
<th>By Whom/When</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Root Causes

1. 
2. 

### Contributory Factors

1. 
2. 

### Actions to address numbered root causes

<table>
<thead>
<tr>
<th>Root Cause</th>
<th>Action</th>
<th>Strength of action in reducing risk (strong/ medium/ weak)</th>
<th>By Whom/When</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Incident closed and action plan agreed by Serious Incident Monitoring Group
  - Date: 

- Action plan review by Serious Incident Monitoring Group
  - Date: 

- Feedback given to all staff concerned
  - Date: 
  
- Patient/ relatives informed (refer to NPSA Being Open
  - Date: 
  
- Risk recorded on Risk Register (where relevant)*
  - Date: 

*Root causes that pose risk and cannot be resolved by action in the short-term must be placed on the relevant Risk Register or Trust-wide Risk Register (for Trust-wide risks)
## Root Cause Analysis Investigation Report

<table>
<thead>
<tr>
<th>Incident Investigation Title:</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Incident Date:</td>
<td></td>
</tr>
<tr>
<td>Incident Number:</td>
<td></td>
</tr>
<tr>
<td>Author(s) and Job Titles</td>
<td></td>
</tr>
<tr>
<td>Investigation Report Date:</td>
<td></td>
</tr>
</tbody>
</table>
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**Executive Summary**

Complete this summary AFTER the main report has been written. This forms an important precise of the report.

- **Brief incident description:**
  - Incident date:
  - Incident type:
    - Healthcare Specialty:
  - Actual effect on patient and/or service:
  - Actual severity of incident:

<table>
<thead>
<tr>
<th>Level of investigation conducted</th>
</tr>
</thead>
<tbody>
<tr>
<td>Involvement and support of the patient and/or relatives</td>
</tr>
<tr>
<td>Detection of the incident</td>
</tr>
<tr>
<td>Care and service delivery problems</td>
</tr>
<tr>
<td>Contributory factors</td>
</tr>
<tr>
<td>Root causes</td>
</tr>
<tr>
<td>Lessons learned</td>
</tr>
<tr>
<td>Recommendations</td>
</tr>
<tr>
<td>Arrangements for sharing learning</td>
</tr>
</tbody>
</table>
MAIN REPORT:

Incident description and consequences

Incident description:

Incident date:

Incident type:

Specialty:

Actual effect on patient:

Actual severity of the incident:

Pre-investigation risk assessment

<table>
<thead>
<tr>
<th>A</th>
<th>B</th>
<th>C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Potential Severity (1-5)</td>
<td>Likelihood of recurrence at that severity (1-5)</td>
<td>Risk Rating (C = A x B)</td>
</tr>
</tbody>
</table>

Background and context

Add text here

Terms of reference

Guide provided below. Amend this to build your own. Add only a summary to the body of the report.

<table>
<thead>
<tr>
<th>Purpose</th>
<th>To identify the root causes and key learning from an incident and use this information to significantly reduce the likelihood of future harm to patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>Objectives</td>
<td>To establish the facts i.e. what happened (effect), to whom, when, where, how and why (root causes)</td>
</tr>
<tr>
<td>To establish whether failings occurred in care or treatment</td>
<td></td>
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<tr>
<td>To look for improvements rather than to apportion blame</td>
<td></td>
</tr>
<tr>
<td>To establish how recurrence may be reduced or eliminated</td>
<td></td>
</tr>
<tr>
<td>To formulate recommendations and an action plan</td>
<td></td>
</tr>
<tr>
<td>To provide a report and record of the investigation process &amp; outcome</td>
<td></td>
</tr>
<tr>
<td>To provide a means of sharing learning from the incident</td>
<td></td>
</tr>
<tr>
<td>To identify routes of sharing learning from the incident</td>
<td></td>
</tr>
<tr>
<td>Key questions/issues to be addressed</td>
<td>...specific to this incident or incident type</td>
</tr>
<tr>
<td>Key Deliverables</td>
<td>Investigation Report, Action Plan, Implementation of Actions</td>
</tr>
</tbody>
</table>
### Scope (investigation start & end points)

**Investigation type, process and methods used**
- Single or Multi-incident investigation
- Gathering information e.g. Interviews
- Incident Mapping e.g. Tabular timeline
- Identifying Care and service delivery problems e.g. Change analysis
- Identifying contributory factors & root causes e.g. Fishbone diagrams
- Generating solutions e.g. Barrier analysis

### Arrangements for communication, monitoring, evaluation and action

**Investigation Commissioner**

**Investigation team**
Names, Roles, Qualifications, Departments

**Resources**

**Involvement of other organisations**

**Stakeholders/audience**

**Investigation timescales/schedule**

### Level of investigation
Add text here

### Involvement and support of patient and relatives
Add text here

### Involvement and support provided for staff involved
Add text here

### Information and evidence gathered
Add text here
FINDINGS:

Chronology of events

<table>
<thead>
<tr>
<th>Date &amp; Time</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
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<td></td>
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<td></td>
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<tr>
<td></td>
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</tr>
</tbody>
</table>

Detection of incident
Add text here

Notable practice
Add text here

Care and service delivery problems
Add text here

Contributory factors
Add text here

Root causes
Add text here

Lessons learned
Add text here

Post-investigation risk assessment

<table>
<thead>
<tr>
<th>A</th>
<th>B</th>
<th>C</th>
</tr>
</thead>
<tbody>
<tr>
<td>Potential Severity (1-5)</td>
<td>Likelihood of recurrence at that severity (1-5)</td>
<td>Risk Rating (C = A x B)</td>
</tr>
</tbody>
</table>
CONCLUSIONS:

Recommendations
Add text here

Arrangements for Shared Learning
Add text here

Distribution List
Add text here

Appendices
Add text here

Action Plan
See also 'Types of Preventative Actions Planned' - tool at [www.npsa.nhs.uk/rca](http://www.npsa.nhs.uk/rca)

<table>
<thead>
<tr>
<th>Action 1</th>
<th>Action 2</th>
<th>Action 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Root CAUSE</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EFFECT on Patient</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Recommendation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Action to Address Root Cause</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Level for Action</td>
<td>(Org, Direct, Team)</td>
<td></td>
</tr>
<tr>
<td>Implementation by:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Target Date for Implementation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Additional Resources Required</td>
<td>(Time, money, other)</td>
<td></td>
</tr>
<tr>
<td>Evidence of Progress and Completion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Monitoring &amp; Evaluation Arrangements</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sign off - action completed date:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sign off by:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Appendix 11: Flowchart for the Identification of Information Governance Incidents

Recognising and reporting actual or suspected Information Governance incidents or near misses

Has there been any actual or suspected breach, loss or tampering of patient confidentiality, integrity or availability of any data or service?

NO

Has there been or is it suspected that there has been a loss or theft of any NHS NCL, Network or LHP device?

NO

Has there been any actual or suspected breach or loss of any patient records or patient information?

NO

Has there been any actual or suspected breach or loss of any patient records or patient information of any sort?

NO

Has there been any unauthorised access or suspected unauthorised access to patient information?

NO

Has there been any actual or suspected tampering of any of NHS NCL’s, Networks’ or LHP’s information systems in any way?

NO

Has there been any actual or suspected tampering of any patient data or information?

NO

Has there been any actual or suspected loss of any service or access to patient data?

NO

Do you still have concern that you may need to report a suspected information governance or information security incident?

NO

No further action

YES


If you have any queries contact the NHS North Central London Patient Safety Manager email: ncl.incidents@nhs.net or qualityandsafety@nclondon.nhs.uk

Contact the Information Governance Team on 020 7685 6295 or via email: information.governance@nclondon.nhs.uk for further information
Appendix 12: Management of Information Governance Incidents

Information Governance Incident or Near Miss Reporting & Escalation Process
NHS North Central London, Networks, London Health Programmes

Information governance incident or near miss - inform your Manager, Practice manager, IG Lead or the designated person in your department/practice as soon as possible.

If you are unsure if it is an incident, check the "Recognising & Reporting IG incidents" flowchart.

Reporting manager to complete incident report on Datix
and inform your line manager in person or by telephone

If you have any queries, contact the NHS North Central London
ncl.incidents@nhs.net or qualityandsafety@nclondon.nhs.uk
Tel: 020 7527 1402 or 020 3316 1014

Within 24 hours

Datix report to Corporate Governance Facilitator & Information Security Officer

NHS North Central London Corporate Governance Facilitator
Simon Gaskell
Simon.gaskell@nclondon.nhs.uk
Tel: 020 7685 6294

Within 48 hours

Report cascaded to:
• IG Manager, NHS North Central London
• Head of Corporate Governance, NHS North Central London
• Caldicott Guardian, NHS North Central London
• SIRO, NHS North Central London

• IG Manager – Peter Conoulty
Peter.Conoulty@nclondon.nhs.uk or Peter.Conoulty@nhs.net

• Head of Corporate Governance – Victoria Grimsell
victoria.grimsell@nclondon.nhs.uk

• Caldicott Guardian – Douglas Russell
douglas.russell@nclondon.nhs.uk

• SIRO – Sarah Price
sarah.price@nclondon.nhs.uk

USEFUL CONTACTS
Patient Services – ncl.incidents@nhs.net or qualityandsafety@nclondon.nhs.uk – 020 7527 1333
Corporate Governance Facilitator - Simon Gaskell simon.gaskell@nclondon.nhs.uk – 020 7685 6294
Suspected IG security incidence or concern
information.governance@nclondon.nhs.uk or 020 7685 6294
www.ncl.nhs.uk
Appendix 13: RIDDOR Reportable Incidents

1. Any fracture, other than to the fingers, thumbs or toes.
2. Any amputation.
3. Dislocation of the shoulder, hip, knee or spine.
4. Loss of sight (whether temporary or permanent).
5. A chemical or hot metal burn to the eye, or any penetrating injury to the eye.
6. Any injury resulting in from electrical shock or electric burn (including any electrical
   burn caused by arcing or arcing products) leading to unconsciousness or requiring
   resuscitation or admittance to hospital for more than 24 hours.
7. Any other injury:-
   a) leading to hypothermia, heat-induced illness or to unconsciousness,
   b) requiring resuscitation, or
   c) requiring admittance to hospital for more than 24 hours.
8. Loss of consciousness caused by asphyxia or by exposure to a harmful substance or
   biological agent.
9. Any of the following conditions which result from the absorption of any substance by
   inhalation, ingestion or through the skin:
   a) acute illness requiring medical treatment or
   b) loss of consciousness.
10. Acute illness which requires medical treatment where there is reason to believe that
    this resulted from exposure to a biological agent or its toxins or infected material
11. Collapse, overturning or failure of load-bearing parts of lifts and lifting equipment.
12. An accident connected with work (including an act of physical violence), which results
    in the injured person being away from work or unable to do the full range of their
    normal duties for more than three days.
Appendix 14: Executive Panel Generic Terms of Reference Template

Terms of reference
Serious Incident Investigation
Steis number:

Executive panel membership:

Role of the Executive panel
The panel will:

- Ensure a thorough, objective and robust investigation is carried out
- Review the investigation as it progresses
- Review and approve the draft report
- Review approve modify or reject the draft recommendations
- Ensure recommendations from the report are distilled into specific action points with designated senior management leads and deadlines to:
  
  a) Ensure that ………………………………… going forward is fit for purpose and reflects the learning from this investigation
  b) Mitigate or eliminate (if possible) the risk of a similar incident occurring in any part of NCL NHS Cluster during the current transitional period
  c) Ensure that organisational/departmental/individual learning is acknowledged and addressed appropriately

- Ensure and be satisfied that there are sufficiently robust monitoring arrangements in place for the above action points in order to be able to be able to provide the Board with the required level of assurance in this regard.

Investigating Team membership:

The objectives of the investigating team are:

- To establish a chronology of facts and events
- To examine, as part of the analysis, the above a) against accepted best practice and any national guidance or relevant organisational policy and b) against the working practices of the service during the period under investigation.
- To establish from the above the root causes and contributory factors that led to the Serious Incident.
- To establish if, where and at what level(s) there were missed opportunities for problems within the service to be recognised, escalated and the appropriate action taken.

The investigating team will:
• Ensure that the investigation adheres to Being Open policy
• Identify the key persons to be interviewed
• Provide all staff that are interviewed the opportunity to review and agree the transcript of their interview
• Update the executive panel regularly on progress
• Ensure that the lead Director is informed of any serious concerns that arise during the investigation
• Develop a draft report using the NPSA template within 30 days of commencement of investigation for comment/approval by the Executive Panel
• Include within the above report a set of actionable recommendations for service improvement and reduction or elimination of the risk of a recurrence
• Produce a final draft report for presentation to the Quality and Safety Committee; incorporate any comments from the committee into the final report for submission to NHS London
• Ensure feedback is given to the staff involved
• Ensure confidentiality is maintained throughout the process
Appendix 15: Media Interest Guidance for Serious Incidents

Serious incidents (SIs) notification which may be of media interest

Purpose

The purpose of this guidance is to assist you in identifying SIs which may be of media interest and require escalation to senior members of staff.

Method

The majority of serious incidents are received via NHS London on Steis forms. However, some SIs are received via e-mail on nhs.net account. The forms are assessed by the Patient Safety Manager or Patient Safety Co-ordinator to identify if there are other concerns, or if it is likely to be of media interest.

At times the reporter has already identified that the incident is likely to be of media interest and has included a media briefing within the incident form.

Criteria

The following criteria should be used to identify if an SI is likely to be of media interest. Please note this is not an exhaustive list and each case should be assessed on its own merits. If there are any doubts please contact Shindi Dhillon, James Gleed, Diane Curbishley or Alison Pointu.

- Criminal activity eg. Member of staff accused of a crime
- Abscond and death of a patient
- Current topic in media
- Serious assault
- Homicide
- Suicides – usually occurred in a public place
- Incident that has affected a large number of people
- Ward/Unit/Hospital closure
- Involves Councillor, MP, Celebrity & GPs
- Safeguarding- serious harm or death- involves Haringey
- Whistleblowing
- Medical negligence resulting in serious harm/death
- Equipment failure resulting in death
- Increased death rate in any one area
- Escape of prisoner

Action

A summary of the incident together with the media briefing, if included, and any other relevant information should be sent to Director of Quality, appropriate Borough Director, NCL Communications and senior members of the Patient Safety Team. The Director of Quality will escalate information to Chair and CEO.

Contact

For further information please contact Patient Safety on Telephone No. 020 3316 1014 /020 7527 1402.

24/11/2011