TRUST POLICY AND PROCEDURES FOR INCIDENT REPORTING, ANALYSING, INVESTIGATING & LEARNING INCLUDING SERIOUS INCIDENTS

<table>
<thead>
<tr>
<th>Reference Number</th>
<th>Version: 2.8</th>
<th>Status</th>
<th>Author: E Oldfield</th>
<th>Job Title Clinical Lead Risk &amp; Governance</th>
</tr>
</thead>
<tbody>
<tr>
<td>POL-RKM/1448/07</td>
<td></td>
<td>Final</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Version / Amendment History

<table>
<thead>
<tr>
<th>Version</th>
<th>Date</th>
<th>Author</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Oct 2007</td>
<td>G Ogden</td>
<td>Original policy</td>
</tr>
<tr>
<td>1.1 – 2</td>
<td>Sept - Oct 2008</td>
<td>G Ogden</td>
<td>To meet NHSLA standards</td>
</tr>
<tr>
<td>2.1</td>
<td>Sept 2009</td>
<td>G Ogden</td>
<td>To include reference to Information Governance requirements</td>
</tr>
<tr>
<td>2.2</td>
<td>Dec 2009</td>
<td>G Ogden</td>
<td>Addition of maternity procedure appendix 16</td>
</tr>
<tr>
<td>2.3</td>
<td>July 2010</td>
<td>G Ogden</td>
<td>Changes in relation to SIs and Feedback Reports</td>
</tr>
<tr>
<td>2.4</td>
<td>April 2011</td>
<td>G Ogden</td>
<td>Update on Never Events &amp; Being Open Leads</td>
</tr>
<tr>
<td>2.5</td>
<td>April 2012</td>
<td>Dee Stanley-Smith</td>
<td>To comply with new policy issued by NHS Derby City PCT March 2012 as required by the contract section C part 72v2</td>
</tr>
<tr>
<td>2.6</td>
<td>2013</td>
<td>Dee Stanley-Smith</td>
<td>To comply with new policy issued by Southern Derbyshire CCG March 2013 as required by the contract section C part 72v2</td>
</tr>
<tr>
<td>2.7</td>
<td>April 2015</td>
<td>Helen Gibbs</td>
<td>Recommendation post Bowel Cancer Screening QA visit in 2013</td>
</tr>
<tr>
<td>2.8</td>
<td>May 2017</td>
<td>Ethel Oldfield</td>
<td>Revised and Updated</td>
</tr>
<tr>
<td>Intended Recipients:</td>
<td>All staff</td>
<td></td>
<td></td>
</tr>
<tr>
<td>---------------------</td>
<td>----------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Training and Dissemination:</td>
<td>Trust Induction, Periodic Compulsory Updates, Intranet</td>
<td></td>
<td></td>
</tr>
<tr>
<td>To be read in conjunction with:</td>
<td>Risk Strategy, Trust Policy &amp; Procedure for Raising Concerns at Work, Trust Policy for Health &amp; Safety, Reporting of injuries, Diseases and Dangerous Occurrences (RIDDOR) - Trust Policy &amp; Procedure, Trust Policy &amp; Procedure Being Open and Duty of Candour</td>
<td></td>
<td></td>
</tr>
<tr>
<td>In consultation with and Date:</td>
<td>Risk Committee August 2013</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>EIRA stage One Completed</th>
<th>Yes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stage Two</td>
<td>N/A</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Approving Body and Date Approved</th>
<th>Patient Safety Committee – March 2017, Quality Review Committee - April 2017, Trust Delivery Group - May 2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date of Issue</td>
<td>May 2017</td>
</tr>
<tr>
<td>Review Date and Frequency</td>
<td>2020, 3 yearly</td>
</tr>
<tr>
<td>Contact for Review</td>
<td>Clinical Lead Risk &amp; Governance</td>
</tr>
<tr>
<td>Executive Lead Signature</td>
<td>Chief Nurse &amp; Director of Patient Experience</td>
</tr>
<tr>
<td>Approving Executive Signature</td>
<td>Chief Nurse &amp; Director of Patient Experience</td>
</tr>
</tbody>
</table>
## Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incident Management Timescales</td>
<td>6</td>
</tr>
<tr>
<td>Serious Incident Flowchart</td>
<td>7</td>
</tr>
</tbody>
</table>

### Section 1

#### Introduction

<table>
<thead>
<tr>
<th>1</th>
<th>Introduction</th>
<th>8</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1</td>
<td>Purpose and Outcome</td>
<td>8</td>
</tr>
<tr>
<td>1.2</td>
<td>Definitions</td>
<td>9</td>
</tr>
<tr>
<td>1.3</td>
<td>Key Responsibilities</td>
<td>10</td>
</tr>
<tr>
<td>1.3.1</td>
<td>Trust Requirements</td>
<td>10</td>
</tr>
<tr>
<td>1.3.2</td>
<td>Clinical Commissioning Group (CCG)</td>
<td>11</td>
</tr>
<tr>
<td>1.3.3</td>
<td>MHS England Regional Team</td>
<td>11</td>
</tr>
<tr>
<td>1.3.4</td>
<td>Care Quality Committee (CQC)</td>
<td>11</td>
</tr>
<tr>
<td>1.3.5</td>
<td>Monitor</td>
<td>11</td>
</tr>
<tr>
<td>1.3.6</td>
<td>Chief Executive</td>
<td>11</td>
</tr>
<tr>
<td>1.3.7</td>
<td>Chief Nurse &amp; Director of Patient Experience and Medical Director</td>
<td>12</td>
</tr>
<tr>
<td>1.3.8</td>
<td>Divisional Nurse/Medical Directors</td>
<td>12</td>
</tr>
<tr>
<td>1.3.9</td>
<td>Head of Governance</td>
<td>12</td>
</tr>
<tr>
<td>1.3.10</td>
<td>Head of Patient Safety</td>
<td>12</td>
</tr>
<tr>
<td>1.3.11</td>
<td>Clinical Lead Risk &amp; Governance</td>
<td>12</td>
</tr>
<tr>
<td>1.3.12</td>
<td>Senior Information Risk Owner</td>
<td>12</td>
</tr>
<tr>
<td>1.3.13</td>
<td>Clinical Governance Facilitators</td>
<td>12</td>
</tr>
<tr>
<td>1.3.14</td>
<td>Departmental Managers or Nominated Deputies</td>
<td>12</td>
</tr>
<tr>
<td>1.3.15</td>
<td>The Corporate Risk and Clinical Governance Team</td>
<td>13</td>
</tr>
<tr>
<td>1.3.16</td>
<td>Health and Safety Manager</td>
<td>13</td>
</tr>
<tr>
<td>1.3.17</td>
<td>Trust Staff</td>
<td>13</td>
</tr>
<tr>
<td>1.3.18</td>
<td>Quality Review Committee</td>
<td>13</td>
</tr>
<tr>
<td>1.3.19</td>
<td>Patient Safety Committee</td>
<td>13</td>
</tr>
<tr>
<td>1.3.20</td>
<td>Incident Learning Group</td>
<td>13</td>
</tr>
<tr>
<td>1.3.21</td>
<td>Incident Quality Assurance Group</td>
<td>13</td>
</tr>
<tr>
<td>1.3.22</td>
<td>Health and Safety Committee</td>
<td>13</td>
</tr>
<tr>
<td>Section</td>
<td>Topic</td>
<td>Page</td>
</tr>
<tr>
<td>---------</td>
<td>-----------------------------------------------------------------------</td>
<td>------</td>
</tr>
<tr>
<td>Section 2</td>
<td>Incident Reporting</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Incident Reporting, Analysis, Investigation and Learning</td>
<td>15</td>
</tr>
<tr>
<td>2.1</td>
<td>What is an Incident &amp; what should be reported?</td>
<td>15</td>
</tr>
<tr>
<td>2.2</td>
<td>What to do when an incident occurs</td>
<td>16</td>
</tr>
<tr>
<td>2.3</td>
<td>Incident Reporting System - Datix</td>
<td>17</td>
</tr>
<tr>
<td>2.4</td>
<td>What happens next – Level 1, 2 &amp; 3 Sign Off including Incident Rejection</td>
<td>17</td>
</tr>
<tr>
<td>2.5</td>
<td>Levels of Harm</td>
<td>19</td>
</tr>
<tr>
<td>2.6</td>
<td>Incident Management including timescales</td>
<td>20</td>
</tr>
<tr>
<td>2.7</td>
<td>Extensions</td>
<td>21</td>
</tr>
<tr>
<td>2.8</td>
<td>Incident Categorisation &amp; Escalation</td>
<td>21</td>
</tr>
<tr>
<td>2.9</td>
<td>Analysis of Incident Themes</td>
<td>21</td>
</tr>
<tr>
<td>2.10</td>
<td>Training Requirements</td>
<td>22</td>
</tr>
<tr>
<td>2.11</td>
<td>Levels of Investigation</td>
<td>23</td>
</tr>
<tr>
<td>2.12</td>
<td>Human Factors</td>
<td>24</td>
</tr>
<tr>
<td>2.13</td>
<td>Duty of Candour/Being Open</td>
<td>24</td>
</tr>
<tr>
<td>Section 3</td>
<td>Serious Incidents</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Introduction</td>
<td>25</td>
</tr>
<tr>
<td>3.1</td>
<td>Can a Near Miss be a Serious Incident?</td>
<td>26</td>
</tr>
<tr>
<td>3.2</td>
<td>Incidents Involving Other Organisations</td>
<td>26</td>
</tr>
<tr>
<td>3.3</td>
<td>Multi-agency Investigations</td>
<td>26</td>
</tr>
<tr>
<td>3.4</td>
<td>Serious Case Reviews &amp; Safeguarding Adult Reviews</td>
<td>26</td>
</tr>
<tr>
<td>3.5</td>
<td>Deaths in Custody</td>
<td>27</td>
</tr>
<tr>
<td>3.6</td>
<td>Homicides by patients in receipt of mental health care</td>
<td>27</td>
</tr>
<tr>
<td>3.7</td>
<td>Domestic Homicide Reviews</td>
<td>27</td>
</tr>
<tr>
<td>Section</td>
<td>Title</td>
<td>Page</td>
</tr>
<tr>
<td>---------</td>
<td>----------------------------------------------------------------------</td>
<td>------</td>
</tr>
<tr>
<td>3.8</td>
<td>National Screening Incidents</td>
<td>27</td>
</tr>
<tr>
<td>3.9</td>
<td>Police/Coroner Investigations</td>
<td>28</td>
</tr>
<tr>
<td>3.10</td>
<td>Never Events</td>
<td>29</td>
</tr>
<tr>
<td>3.11</td>
<td>Information Governance Breaches</td>
<td>29</td>
</tr>
<tr>
<td>3.12</td>
<td>Pressure Ulcers</td>
<td>30</td>
</tr>
<tr>
<td>3.13</td>
<td>Healthcare Associated Infections</td>
<td>31</td>
</tr>
<tr>
<td>3.14</td>
<td>High Profile Serious Incidents</td>
<td>32</td>
</tr>
<tr>
<td>3.15</td>
<td>Communications</td>
<td>32</td>
</tr>
<tr>
<td>3.16</td>
<td>Risk Assessments</td>
<td>33</td>
</tr>
<tr>
<td>3.17</td>
<td>Action Plans &amp; Organisational Learning</td>
<td>33</td>
</tr>
<tr>
<td>3.18</td>
<td>Quality Critique of Final reports</td>
<td>34</td>
</tr>
<tr>
<td>3.19</td>
<td>Updating STEIS</td>
<td>33</td>
</tr>
<tr>
<td>3.20</td>
<td>Externally reportable incidents</td>
<td>33</td>
</tr>
<tr>
<td><strong>Section 4</strong></td>
<td>References</td>
<td></td>
</tr>
<tr>
<td><strong>Section 5</strong></td>
<td>Appendices</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Safeguarding Children Serious Incident Reporting Flowchart</td>
<td>36</td>
</tr>
<tr>
<td>2</td>
<td>Safeguarding Adults Serious Incident Reporting Flowchart</td>
<td>37</td>
</tr>
<tr>
<td>3</td>
<td>SIRI Scoring (Information Governance Breaches)</td>
<td>38</td>
</tr>
<tr>
<td>4</td>
<td>Reporting Externally</td>
<td>40</td>
</tr>
<tr>
<td>5</td>
<td>Incident Decision Tree</td>
<td>41</td>
</tr>
<tr>
<td>6</td>
<td>Taking Statement from Staff</td>
<td>42</td>
</tr>
<tr>
<td>7</td>
<td>Template Letter for Staff</td>
<td>43</td>
</tr>
<tr>
<td>8</td>
<td>Root Cause Analysis</td>
<td>44</td>
</tr>
<tr>
<td>9</td>
<td>Investigation and Reporting of a Trust Apportioned MRSA Bacteraemia</td>
<td>46</td>
</tr>
<tr>
<td>10</td>
<td>Mental Health/Learning Disability Patient 12 hour Trolley Breach</td>
<td>47</td>
</tr>
</tbody>
</table>
## Incident Management Timescales

### Low/No Harm Incidents

<table>
<thead>
<tr>
<th>Incident Occurs</th>
<th>Who</th>
<th>What</th>
<th>When</th>
</tr>
</thead>
<tbody>
<tr>
<td>IR1 Completed &amp; Submitted</td>
<td>Any member of staff inc students, volunteers,</td>
<td>Report the incident, factual details, not opinions</td>
<td>As soon as possible after the incident, but within 12 hours of incident recognition</td>
</tr>
<tr>
<td></td>
<td>contractors etc</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Local Sign off (Level 1 / 2 – Sister)</td>
<td>Sister/Senior Sister/Manager</td>
<td>Complete the local investigation inc level of harm, management action taken including where the patient is now, Duty of Candour if necessary</td>
<td>Local investigation should be completed within 7 working days as final sign off must be completed within 10 days of incident recognition</td>
</tr>
<tr>
<td>Management Action</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Final signed off</td>
<td>Matron/Service Manager/CGF</td>
<td>Ensure there is evidence to support the closure of the incident, learning identified &amp; no further action required</td>
<td>Incident should be finally closed within 10 days of the incident occurring unless SI or Higher level of investigation</td>
</tr>
</tbody>
</table>

### Serious Incidents

All Serious Incidents must be reported onto STEIS within 2 working days of when the incident was recognised. All investigation reports will go through internal review via IQAG (40-45 days) and must be completed within 60 days. Serious Incident reports will be sent to the Commissioner within 60 working days. These reports will be provided to the Police upon request or shared with the Coroner where necessary. On receipt of investigation reports, CCG must review and provide feedback to the Trust within 20 days. Once the report is closed by the CCG, this can be closed on Datix and shared with the family.

### Mental Health/Learning Disability Patient 12 hour Trolley Breach

All 12 hour breaches (MH/LD) in A&E are treated as Serious Incidents and undergo a joint full root cause analysis with Derbyshire Healthcare Foundation Trust and follow the process through IQAG as an SI.
**Key**
- SI – Serious Incident
- RCA – Root Cause Analysis
- ILG – Incident Learning Group
- IQAG – Incident Quality Assurance Group
- DND – Divisional Nurse Director
- HoM – Head of Midwifery
- CEO – Chief Executive Officer
- MD – Medical Director
- CN – Chief Nurse
- STEIS – Strategic Executive Information System
- CCG – Clinical Commissioning Group
- CQC – Care Quality Commission

---

**Serious Incident & Internal Investigation Flowchart**

**Incident Occurs**
- Complete Datix as soon as possible

**Potential Serious Incident or Higher Level Internal Incident**
- In hours 8:30 – 4:30 contact local Clinical Governance team or Corporate Risk
- Out of Hours, if Serious Incident, inform Senior Manager/Nurse on call

If potential SI, escalate to Corporate Risk
- Perform Duty of Candour/Being Open
- Inform DND/HoM/DMD or deputy

**Likely SI – Corporate Risk/Head of Patient Safety informs MD and CN**

SI Agreed by MD/CN - Reported onto STEIS as SI by Corporate Risk - **This must be within 48 hours of recognition of incident**

Incident Investigation Report (RCA) must be submitted to Corporate Risk for IQAG **(within 40-45 working days from incident)**

Following Executive sign off, report sent to CCG by Corporate Risk **(within 60 working days from incident)**. Await closure notice from CCG prior to offering report to patient/family

Action plans completed, Evidence attached to Datix and returned to Corporate Risk

Action plan completion monitored by IQAG
- Learning from Actions monitored up via ILG

CCG and/or CQC may request evidence of completed action plans
Section 1
Introduction to Policy

1.0 Introduction
The reporting of incidents and near-misses is a key element in the governance of the organisation. Having a system that enables the capture and analysis of incident information is the cornerstone to effective risk management and can assist in the learning of lessons, prevention of harm and improvement of performance. Incident reporting presents an important opportunity to learn from past events and ensure steps are taken to minimise recurrences.

There is overwhelming evidence that NHS organisations with a high level of incident reporting are more likely to learn and subsequently increase safety for patients, staff and visitors.

Derby Teaching Hospitals NHS Foundation Trust is required by the Southern Derbyshire Clinical Commissioning Group to adopt the requirements of CCG Policy ‘Policy for the Reporting and Management of Serious Incidents’ (January 2016) which is based on the NHS England Serious Incident Framework.
If an incident or Serious Incident occurs in Private Patients, this will be managed as per this policy, regardless if the care is NHS funded or not.

1.1 Purpose and Outcomes
This policy sets out the Trust systems processes and expectations in relation to incident reporting and learning to include the:

- Process for reporting all incidents involving staff, patients and others.
- Process for reporting to external agencies.
- Process for investigating incidents according to level of risk.
- Process for involving and communicating with internal and external stakeholders to share safety lessons.
- Process for the aggregated analysis of incidents, complaints and claims.
- Process by which the organisation ensures local and organisational learning and changes in practice resulting from individual incidents and aggregated analysis.
- Process for ensuring communication is open, honest, occurs as soon as possible and is well documented.
- Training requirements for staff.

Compliance with this policy will ensure that incidents are systematically identified, recorded, reported to management and appropriately investigated resulting in learning and thus improving safety for future patients, staff and visitors.
1.2 Definitions Used

| **Being Open** | The Trust has an open and transparent culture and this refers to the process for communicating adverse events with patients and their carers, staff and visitors, regardless of the level of harm. |
| **Commissioner** | The Clinical Commissioning Groups (CCGs) who undertake the commissioning function. |
| **Duty of Candour** | There is a statutory and a professional obligation to undertake Duty of Candour when a patient suffers moderate harm or more. This means patients/their family must be informed of what has happened, apologise that something has happened to them, investigate where necessary and follow up with a written apology. See Duty of Candour Policy on Flo. |
| **HSE** | Health and Safety Executive. |
| **Incident:** | An event or circumstance which could have resulted, 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. |
| **Never Events** | Never Events are serious incidents that are wholly preventable, as guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and should have been implemented by all healthcare providers. Click here for full list of Never Events. |
| **NPSA** | National Patient Safety Agency (now NHS Improvement but much of the terminology used is from the NPSA). |
| **RIDDOR:** | Reporting of Injuries, Diseases and Dangerous Occurrences Regulations. |
| **Root Cause Analysis (RCA)** | 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. |
| **Serious Incident** | Serious Incidents (SI) are events in health care where the potential for learning is so great, or the consequences to patients, families and carers, staff or organisations are so significant, that they warrant using additional resources to mount a comprehensive response. Serious incidents can extend beyond incidents which affect patients directly and include incidents which may indirectly impact patient safety or an organisation’s ability to deliver ongoing healthcare. It also includes allegations of abuse, adverse media coverage and/or one of the core set of Never Events. Where it is unclear if an incidents fulfils the criteria for an SI, an open and honest discussion with Divisional and Corporate Risk is required. |
The Department of Health Strategic Executive Information System (STEIS) database – Serious Incident system enables electronic logging, tracking and reporting of Serious Incidents and national learning.

**Unexpected death**

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

### 1.3 Key Responsibilities/Duties

#### 1.3.1 Trust Requirements

All patient safety incidents, including no or low harm incidents, must be reported onto Datix, which is then uploaded into the National Reporting and Learning System by the Corporate Risk Team. Incidents must be reported on Datix within 12 hours of recognition of the incident.

The primary responsibility of the trust in relation to incidents is to the people who are affected and/or their families/carers. The key organisational accountability for serious incident management is from the Trust to the commissioner.

All Serious incidents are reported to the commissioner via the STEIS system

**All incidents should be reported as soon as possible after the incident occurred.**

**All serious incidents must be reported onto STEIS within 2 working days of recognising the incident.**

The Trust has a robust governance process, with executive oversight, in place, to identify and manage serious incidents, ensuring that any identified risks are mitigated, lessons are learned and action plans implemented in a timely manner.

In addition to an Executive Lead identified to manage the SI process, the Trust is required to nominate an appropriate senior member of staff to be the main contact with the Commissioner. This is the Head Patient Safety. In their absence, including out of hours, a suitable deputy will be available (e.g. Director on call).

An audit trail must be maintained so that this information can be provided on a ‘need to know’ basis when required.
1.3.2 Clinical Commissioning Group
Commissioners will receive notification of incidents via the STEIS system and are responsible for the closure of the incident following review of the final Root Cause Analysis. The commissioner can request a 72 hour report for any serious incident. The commissioner must have a robust governance process in place to manage serious incidents, with executive oversight, in order to gain assurance that the provider organisations have undertaken a robust investigation with appropriate recommendations and actions. The commissioner will only grant extensions for submission of final reports under exceptional circumstances.

On receipt of investigation reports, commissioners must review and provide feedback to the provider within 20 calendar days. The commissioner will provide a realistic turnaround timescale for any investigation report that requires re-submission. Once an updated report is submitted the commissioner has a further 20 working days to provide feedback and close the incident. The commissioner is responsible for updating STEIS including delays to closure.

The commissioner will provide assurance / exception reports relating to delays in submission / closure to the NHS England Regional Team as requested. The commissioner will monitor action plan implementation by requesting additional evidence as required or through quality visits. Commissioners have a responsibility to inform associate commissioners of any Serious Incidents relating to patients in their CCG locality.

1.3.3 NHS England Regional Team
NHS England maintains oversight and surveillance of serious incident management within NHS-funded care and ensures that CCGs have systems in place to appropriately manage serious incidents for the care they commission. They are responsible for reviewing trends, analysing quality and identifying issues of concern.

NHS England are responsible for the decision making process in relation to homicides committed by mental health patients.

1.3.4 Care Quality Commission (CQC)
The CQC has a role in encouraging improvement and may use the details of incident reports, investigations and action plans to monitor an organisation’s compliance with essential standards of quality and safety, to assess risks to quality and to respond accordingly.

1.3.5 NHS Improvement
NHS Improvement (NHSI) will use the details of serious incident reports, investigations and action plans to monitor a Foundation Trust’s compliance with essential standards of quality and safety and their licence terms.

1.3.6 The Chief Executive
The Chief Executive will identify an Executive Lead and delegate responsibility for the management of incidents.
1.3.7 The Chief Nurse and Director of Patient Experience and the Executive Medical Director
The Chief Nurse and Director of Patient Experience is the Executive Lead and is required to implement an effective risk management system, providing staff with a clear framework for prompt incident reporting, including training and support ensuring that appropriate actions are taking place, that risk is mitigated and there is a strong culture of learning and improvement. They or their nominated deputy will agree with the Medical Director Serious Incidents as defined within the policy for reporting to the Commissioners.

1.3.8 Divisional Nurse Directors/Head of Midwifery/Divisional Medical Directors/Divisional Director
Are responsible for ensuring the Divisional structure supports the systems for identifying, recording, reporting to management, appropriately investigating and learning from incidents. They or their nominated deputy will act as Chair at Local Reviews of Serious Incidents or incidents requiring higher level of internal investigation.

1.3.9 The Head of Clinical Governance
Is responsible for ensuring the functioning of the Corporate systems detailed within this policy in support of the identifying, recording and reporting to management.

1.3.10 Head of Patient Safety
Is the Senior Manager who will be the main contact with the Commissioner with regard to serious incidents. In their absence, including out of hours, a suitable deputy will be available (e.g. a senior member of the Risk and Clinical Governance team or the Director on call when out of hours).

1.3.11 Clinical lead Risk & Governance
Is responsible for ensuring clinical incidents are escalated and reported in a timely and appropriate manner and in conjunction with the Head of Governance, will have corporate responsibility for ensuring the Trust meets all national and local requirements around clinical risk management and patient safety, working closely with the Head of Patient Safety to ensure that adequate systems and processes are in place for the continuous effective management of clinical risk.

1.3.12 Senior Information Risk Owner (SIRO)
Is responsible for ownership of information risk across the Trust and for ensuring the Board is adequately briefed on information security risks and incidents.

1.3.13 Clinical Governance Facilitators
Are responsible for ensuring that incidents are systematically identified, recorded, reported to management, appropriately investigated and that learning occurs and feedback is given at Business Unit/Divisional level. They or their nominated deputy will act as Chair at appropriate incident review meetings.

1.3.14 Departmental Managers or Nominated Deputies (Level 1, Level 2 & Level 3/ Final Sign offs)
Are responsible for ensuring staff report incidents, categorising incidents in accordance with this policy, investigating incidents, escalating incidents where necessary according to the incident categorisation and providing feedback to reporting staff.
1.3.15 The Corporate Risk and Governance Team
Undertake the Corporate collation and analysis of incidents, liaise with external and internal stakeholders where necessary, generate trend reports of incident types/themes and maintain a database of incidents requiring further investigation in support of Incident Quality Assurance Group & Incident Learning Group.

1.3.16 Health and Safety Manager
The Health and Safety Manager is responsible for ensuring RIDDOR reportable incidents are reported to the Health and Safety Executive (HSE). The Health and Safety Manager may be called to assist staff and managers following an accident/incident.

1.3.17 Trust Staff
All staff are responsible for reporting incidents in accordance with this policy and requesting feedback. **This includes:**
- Students & Trainees
- Visitors
- Agency staff & Contractors
- Volunteers

1.3.18 Quality Review Committee
Will receive a report from Patient Safety Committee on emerging themes and issues for escalation identified through incident reporting

1.3.19 Patient Safety Committee
Will receive reports from the Incident Learning Group (IRG/ILG) in relation to compliance with undertaking investigations, subsequently implementing actions and exploring themes arising from investigations.

1.3.20 Incident Learning Group (ILG)
Will provide a forum to review and ensure that action is taken to escalate and investigate the high risk incidents, inquests and claims and other issues raised internally or by external organisations (e.g. discharge reports from the CQC) in compliance with Trust Processes and Policies. Emphasis will be given to the identification and dissemination of organisational learning.

1.3.21 Incident Quality Assurance Group (IQAG)
A forum to demonstrate assurance of in-depth, thorough investigations, ensuring that processes are reviewed, that action plans are succinct and effective and that the findings are shared appropriately
This group is a sub-group of the Trust Incident Learning Group

1.3.22 Health and Safety Committees
Will meet bi-monthly and is chaired by the Executive Director of Workforce Management. These committees will fulfil their functions in line with their terms of reference.

1.3.23 Patient Experience Committee
Will receive, review and approve presentations and Action Plans from Divisions in relation to actions being taken in response to the aggregate reports for incidents, complaints and claims.
1.3.24 Business Unit Risk Groups
Will monitor trends in incidents, discuss and review all incidents and review Root Cause Analysis. Learning and trends are fed back to the Divisional Risk & Governance Groups.

1.3.25 Divisional Risk/Governance Groups
Trends from incidents and RCAs are escalated to the Divisional Risk/Governance Groups. Following a Serious Incident, these groups will review all related risk assessments and update the risk register.

1.3.26 Risk & Compliance Committee
The Risk & Compliance Committee will monitor the Risk Register and escalate high and extreme risks to the Management Executive.

1.3.27 Infection Prevention & Control Committee (IPCC)
The IPCC is a sub-committee of the Quality review committee. The IPCC meets on a monthly basis and oversees all Infection prevention and control issues in the Trust and receive root cause analysis investigation findings and disseminate the learning across the Trust.

1.3.28 Monitoring / Key Performance Indicators

<table>
<thead>
<tr>
<th>Key control</th>
<th>Evidence</th>
<th>Frequency</th>
<th>Responsible Lead</th>
</tr>
</thead>
<tbody>
<tr>
<td>All SI and higher level Internal Investigations will be completed within the</td>
<td>Report to Incident Learning Group &amp; Patient Safety Committee</td>
<td>Quarterly</td>
<td>Head of Patient Safety</td>
</tr>
<tr>
<td>required 60 working day timescale</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trust-wide lessons learned from SIs will be implemented within the</td>
<td>This is monitored weekly at IQAG and via quarterly report to ILG from</td>
<td>Quarterly</td>
<td>Clinical Governance Facilitators</td>
</tr>
<tr>
<td>designated timescales</td>
<td>Divisions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Divisional Lessons learned from SIs will be implemented within the</td>
<td>This is monitored via quarterly report to ILG from Divisions</td>
<td>Quarterly</td>
<td>Clinical Governance Facilitators</td>
</tr>
<tr>
<td>designated timescales</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Local identification and management of risks with appropriate re-assessment</td>
<td>This is monitored via quarterly report to ILG and PSC from Divisions</td>
<td>Quarterly</td>
<td>Clinical Governance Facilitators</td>
</tr>
<tr>
<td>Review of incident reporting data held within the Datix system in relation</td>
<td>This is monitored via monthly corporate trawl – trends are picked up and</td>
<td>Quarterly</td>
<td>Corporate Risk and ILG</td>
</tr>
<tr>
<td>to the type of incident reported, reporting by all areas and staff groups,</td>
<td>fed into ILG for consideration of a task &amp; finish group</td>
<td></td>
<td></td>
</tr>
<tr>
<td>the grading and theming of incidents</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Section 2
Incident Reporting

2. Incident Reporting, Analysis, Investigation and Learning

“People make errors, which lead to accidents. Accidents lead to deaths. The standard solution is to blame the people involved. If we find out who made the errors and punish them, we solve the problem, right? Wrong. The problem is seldom the fault of an individual; it is the fault of the system. Change the people without changing the system and the problems will continue.”

Don Norman
Author, the Design of Everyday Things

An open and just culture is one in which incidents and failures are openly and honestly discussed by staff, patients and families, creating an environment where the causes of serious incidents can be established and lessons can be widely learned. The Trust has a ‘just culture’, this means that learning and accountability are balanced and the focus of incident reporting and investigation is on learning and sharing the learning across the Trust to increase patient safety and staff wellbeing.

2.1 What is an Incident & what should be reported?
All staff must report any adverse incident which has the potential to produce unexpected or unwanted effects, or any incident which has a consequence or a learning point.

All incident should be reported as soon as possible, but within 12 hours
An incident is described as:
Any unintended or unexpected incident which could have, or did, lead to harm for one or more patients or
Any event that gives (or may give) rise to personal injury or to property loss or damage. This covers a broad range of events, some examples of which are given below:

Clinical Incidents / Near Misses
- Delays to treatment / care
- Incorrect patient identification
- Inadequate / incomplete health records
- Failure to obtain valid consent
- Inadequate observations / checks undertaken
- Medical devices failure / availability
- Tissue damage
- Significant or unexpected complications of a clinical procedure / treatment
- Hospitalisation of patients undergoing research trials
- Unexpected death*

*Incidents resulting in unexpected death or serious injury must always be reported immediately to a senior member of staff (usually to include Line Manager and named or on-call Consultant as appropriate).

Medication Error / Near Misses
- Prescription errors
- Administration errors
- Inadequate storage
Patient Falls
- All patient falls must be reported as an incident.
- All inpatient falls resulting in a fracture will be escalated and investigated with a full root cause analysis and report.

Pressure Ulcers
- All Grade 2, 3 & 4. Are to be reported. All grades 3 and 4 pressure ulcers must be managed as Serious Incidents - see Tissue Viability Prevention of Pressure Ulcers on Flo for further guidance.
- Admitted with pressure ulcers
- Hospital acquired pressure ulcers
- Deteriorated whilst in-patient

Personal Accidents / Near Misses (May be RIDDOR reportable)
- Visitor / Staff Slips, trips and falls
- Needlestick / inoculation injuries
- Back injury or any musculoskeletal injury

Occupational Ill Health
- Occupationally acquired infection
- Occupationally acquired dermatitis

Violence, Abuse and Harassment
- Verbal abuse
- Racial / sexual harassment
- Physical assault
- Allegation of Abuse

Security Incident
- Absconded patients
- Breach of confidential information (Information Governance)
- Theft / damage to Trust or personal property (including fraud)

NB All incidents involving theft must be reported to Security

Incidents not only cover events where harm has been caused but also those where a hazard is identified but no harm has occurred, either due to luck or an error being realised in time and measures being taken to prevent harm occurring. These are often referred to as near misses or no harm incidents. These are reported in the same way as incidents resulting in harm as it is expected that for every incident where harm occurs there will be many where no harm is caused therefore these incidents can provide a wealth of learning information.

2.2 What to do when an Incident occurs
Some incidents will require prompt and specific action to deal with the problem. This may include the following:
- Ensure the patient is safe – medical assistance may be required
- Ensure that patients, staff, visitors and others, are protected from the risk if required
- Comply with ‘Being Open’ and, if appropriate, the Duty of Candour requirements
- Notifying senior members of staff on duty
• If equipment / machinery is involved, removing it from service (marking it clearly ‘out of order’) and arrange its repair or removal – make note of the model number to ensure it can be traced and fixed.
• Recording the action taken in the patient’s care records. Records might not be at hand, but they should be found and either tracked or made secure.
• Member of staff to report the incident via the incident reporting system (Datix)
  If necessary, request that all those who observed what happened prepare a witness statement as soon after the event as possible.

Incidents resulting in unexpected death or serious injury must always be reported immediately to a senior member of staff (usually to include Line Manager and named or on-call Consultant as appropriate)

2.3 Incident Reporting System – Datix

An electronic incident form (IR1) must be accurately completed and submitted for all incidents via the Datix electronic incident reporting system. Datix is accessed via the Flo Home page. If patient related incident, patient details must be recorded on the incident form. Should the intranet not be available, paper forms will be completed and delivered to the Risk and Clinical Governance Team within 2 working days. The Risk and Clinical Governance administrator(s) will input the information onto the DATIX system on the day of receipt.

All identified serious incidents must be notified to the relevant bodies without delay and within two working days of becoming aware of the incident occurring. If there is a delay in reporting the incident, a rationale must be recorded on STEIS by the Risk and Governance Office (See Serious Incident Section below)

Any media issue that is not related to a serious incident must not be reported through STEIS but through relevant communication teams.

2.4 What happens next including local sign off – Level 1 & Level 2

The identified manager and senior staff in the location or clinical area receive a notification that an incident has occurred. Some specific incidents are also sent to specialist areas e.g Tissue Viability.

NB: Please ensure the incident is reported for the area where the incident occurred, rather than where the patient (or you) are currently based e.g you and that patient are currently on Ward X, however you are reporting an incident that occurred on Ward Y – The senior staff on ward Y need to manage the incident

The Level 1 & Level 2 sign off(s) for the location where the incident occurred will log in to the Datix system. They will review the details, filling in any further detail, including the level of harm to the patient (see below). If the harm if moderate or above, Duty of Candour applies.

The Level 1 sign off is required to ‘finish the story’ – what is the outcome to the patient, and ensure all the information is correctly filled in. You may need to discuss the incident with the staff involved, and/or the patient, in order to obtain all the details and evaluate the need for escalation if necessary.

If the patient has suffered severe harm, the incident will require escalation to the Divisional Clinical Governance Team and Corporate Risk Team. This will be discussed and escalated, if necessary, to the Chief Nurse and Medical Director. If the incident meets the criteria for sever harm, the incident will be placed on STEIS as a Serious Incident (SI)
For incidents which do not reach the threshold for Serious Incidents, the Level 1 sign off should carry out an investigation of a scale and scope which is proportionate to the incident to ensure that resources are effectively used and conducted to identify:

- The cause of the incident
- Whether the incident can be prevented from occurring again
- The action taken to manage the incident
- Whether the actions taken were suitable and sufficient to manage the incident effectively
- Any post incident actions, including further management, learning and changes to systems and practices which may prevent or mitigate a future occurrence.

Any investigation should be of a suitable thoroughness to achieve the aims above. The investigation should be based upon the Root Cause Analysis process, and may range from simple fact finding to a full investigation.

The Level 1 sign off is to summarise the findings of the investigation on the actions taken section of the incident reporting system.

**Level 3/Final Sign Off**

Matrons, DNDS/HoM, CGFs will review all of the above and if all the information is correct and they believe the actions and learning are appropriate, this can be closed off, unless the incident is undergoing a full Root Cause Analysis for ‘Internal Incident Requiring Higher Level of Investigation’, or a ‘Serious Incident’ – the incident must be remain ‘under review’ until the report has been finalised and closed. There must be information/evidence on the system to support the incident being closed.

Expert advice (usually by consulting more senior staff or specialist e.g. Infection Control, Tissue Viability, Back Care Advisor, Health and Safety Manager, etc) should be sought when necessary and wherever practicable a consensus view should be arrived at by two or more persons with relevant knowledge.

For additional advice/support consult Risk Services for patient related incidents and the Health and Safety Manager for staff related incidents.

**Rejection of Incidents**

If the Sign Offs feel that an incident should be rejected, this should be discussed with the Clinical Governance Team for Division/Business Unit or the Corporate Risk team.

Incidents can only be rejected by the Clinical Governance Facilitators/Advisors or the Corporate Risk Team.
### Levels of harm

**Patient Related Incidents: NPSA Levels of Harm**

The levels of harm used for patient safety incident are defined by the National Patient Safety Agency (NPSA) and the Trust use these definitions for Patient related incidents.

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>No harm</td>
<td>Impact prevented – any patient safety incident that had the potential to cause harm but was prevented, resulting in no harm to people</td>
</tr>
<tr>
<td></td>
<td>Impact not prevented – any patient safety incident that ran to completion but no harm occurred to people receiving care</td>
</tr>
<tr>
<td>Low</td>
<td>Any patient safety incident that required extra observation or minor treatment and caused minimal harm, to one or more persons receiving care</td>
</tr>
<tr>
<td>Moderate</td>
<td>Any patient safety incident that resulted in a moderate increase in treatment (e.g increase in length of hospital stay by 4-15 days) and which caused significant but not permanent harm, to one or more persons receiving care</td>
</tr>
</tbody>
</table>
| Severe         | Any patient safety incident that appears to have resulted in permanent harm to one or more persons receiving care.  
|                | - Chronic pain is continuous, long term pain of more than 12 weeks or pain that remains after the time that healing would have thought to have occurred, after trauma or surgery |
|                | - Psychological harm is an impairment to sensory, motor or intellectual function or impairment to normal working or personal life which is not likely to be temporary (i.e. has lasted, or is likely to last, for a continuous period of at least 28 days) |
| Death          | Any patient safety incident that directly resulted in the death of one or more persons receiving care. |

**Non-Patient related incidents (e.g staff related incidents) This is also used for Risk Assessments**

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Negligible</td>
<td>- Minimal injury requiring no/minimal intervention or treatment.</td>
</tr>
<tr>
<td></td>
<td>- No time off work</td>
</tr>
<tr>
<td>Minor</td>
<td>- Minor injury or illness, requiring minor intervention</td>
</tr>
<tr>
<td></td>
<td>- Requiring time off work for &gt;3 days</td>
</tr>
<tr>
<td></td>
<td>- Increase in length of hospital stay by 1-3 days</td>
</tr>
<tr>
<td>Moderate</td>
<td>- Moderate injury requiring professional intervention</td>
</tr>
<tr>
<td></td>
<td>- Requiring time off work for 4-14 days</td>
</tr>
<tr>
<td></td>
<td>- Increase in length of hospital stay by 4-15 days</td>
</tr>
<tr>
<td></td>
<td>- RIDDOR/agency reportable incident</td>
</tr>
<tr>
<td></td>
<td>- An event which impacts on a small number of patients</td>
</tr>
<tr>
<td>Major</td>
<td>- Major injury leading to long-term incapacity/disability</td>
</tr>
<tr>
<td></td>
<td>- Requiring time off work for &gt;14 days</td>
</tr>
<tr>
<td></td>
<td>- Increase in length of hospital stay by &gt;15 days</td>
</tr>
<tr>
<td></td>
<td>- Mismanagement of patient care with long-term effects</td>
</tr>
<tr>
<td>Catastrophic</td>
<td>- Incident leading to death</td>
</tr>
<tr>
<td></td>
<td>- Multiple permanent injuries or irreversible health effects</td>
</tr>
<tr>
<td></td>
<td>- An event which impacts on a large number of patients</td>
</tr>
</tbody>
</table>
2.6 Incident Management including Timescales

Incidents should be recorded as soon as practicable, but within 12 hours of the incident occurring or staff becoming aware of it.

Upon receipt of the email notification of an incident occurrence, the Level 1 sign off should review the incident and contact the manager to discuss the incident, or to provide advice on how to proceed, within 10 working days.

The completion of the investigation and closure of the incident on the reporting system (Datix) by the Level 2 sign off should take no longer than 10 working days.

The 10 day closure target can be extended if:

- The incident investigation is complex
- The incident is subject to the Serious Incident process (60 working days)
- An internal or external investigation is underway
- The incident is under the control of the Police or Coroner
- Another statutory body has control of the incident investigation

<table>
<thead>
<tr>
<th>Incident Management</th>
<th>Low/No Harm Incidents</th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Incident Occurs</td>
<td>Who</td>
<td>What</td>
<td>When</td>
</tr>
<tr>
<td>IR1 Completed &amp; Submitted</td>
<td>Any member of staff inc students, volunteers, contractors etc</td>
<td>Report the incident, factual details, not opinions</td>
<td>As soon as possible after the incident, but within 12 hours</td>
</tr>
<tr>
<td>Local Sign off (Level 1 / 2 – Sister) Management Action</td>
<td>Sister/Senior Sister/Manager</td>
<td>Complete the local investigation inc level of harm, management action taken including where the patient is now, Duty of Candour if necessary</td>
<td>Local investigation should be completed within 7 working days as final sign off must be completed within 10 days</td>
</tr>
<tr>
<td>Final signed off</td>
<td>Matron/Service Manager/CGF/A or Corporate Risk</td>
<td>Ensure there is evidence to support the closure of the incident, learning identified &amp; no further action required</td>
<td>Incident should be finally closed within 10 days of the incident occurring unless SI or Higher level of investigation</td>
</tr>
</tbody>
</table>

Serious Incidents

All Serious Incidents must be reported onto STEIS within 2 working days of when the incident was recognised.

All investigation reports will go through internal review via IQAG (40-45 days) and must be completed within 60 days.

Serious Incident reports will be sent to the Commissioner within 60 working days.

These reports will be provided to the Police or the Coroner upon request where necessary.

On receipt of investigation reports, CCG must review and provide feedback to the Trust within 20 days. Once the report is closed by the CCG, this can be closed on Datix and shared with the family.
2.7 Extensions
Extensions for Serious Incidents may be requested in accordance with the Commissioner’s set extension criteria via the Corporate Risk Office. These extension requests are considered by the Commissioner and agreed on a case by case basis. All extension requests will be considered by a senior member of the Corporate Risk Team and will only be put forward in extreme cases as it is the intention of the Trust to submit all SI Reports in line with the timescale above.

2.8 Incident Categorisation and Escalation
Incidents are divided into 2 groups.

1. Incidents that are not externally reportable under the criteria laid out in this Policy:
   - Incidents requiring a higher level of investigation (requiring a root cause analysis with an internal report to the Trust Incident Quality Assurance Group)
   - Minor incidents not requiring root cause analysis or an internal report – these are managed locally
   - Trending/Learning – where trends or themes are found, the Incident Review/Learning Group (ILG) will instigate appropriate groups to review the processes across the Trust, develop an action plan and share the learning via ILG and Patient Safety Committee.

2. Serious Incidents that are externally reportable e.g Serious Incidents and Never Events (See Section 2 below)

Not all incidents need to be investigated to the same extent or depth. Categorising incidents according to the actual impact and the likelihood of the incident recurring to patients/visitors/staff and the organisation establishes the level of local investigation and causal analysis that should be carried out.

For root cause analysis guidance, see Appendix 7
Level 1 & Level 2 Sign Offs are responsible for the grading of the incident. Those requiring escalating should be done so as soon as possible and must be escalated to Corporate Risk & reported on STEIS within 48 hours of the incident being recognised.

2.9 Analysis of Incident Themes
Once received by Risk Services, incidents will be themed and detailed on a central database to enable further analysis.
Risk reports will be produced and reported quarterly to Patient Safety Committee. These reports will cover:
Divisional:
- Incident trend for all incidents, patient related incidents and staff related incidents.
- Incident trend against nationally identified categories within the National Reporting & Learning System.

Incident trends are taken to Incident Learning Group for discussion and further action, in the form of Task & Finish Groups or allocation to already established groups e.g Insulin Safety
Group, Falls Group etc.
The Task & Finish Groups feedback to the ILG learning shared across the Divisions.

2.10 **Training Requirements for Staff**
Information is provided to all staff on induction and information is available on the Datix home page and guidance on reporting.
Training is available on Root Cause Analysis via the learning hub for staff leading investigations (incident or complaints)

2.11 **Levels of Investigation**
Investigations should be focused on learning and improvement. They should not attribute blame or liability for the causation of safety issues. Everyone who is involved should have the opportunity to contribute to the investigation, including patients and families.

All incidents should have an investigation, whether local or RCA, which will address the following:
- What happened?
- How did it happen?
- Why did it happen?
- Identify good practice
- Actions taken

Templates for reports are available on Flo, from your Clinical Governance Team or the Corporate Risk Team.

<table>
<thead>
<tr>
<th>Local Investigation (to be completed on Datix)</th>
<th>RCA Level 1 Internal Requiring Higher Level of Investigation</th>
<th>RCA Level 2 Serious Incidents</th>
<th>RCA Level 3 Independent Investigation</th>
</tr>
</thead>
<tbody>
<tr>
<td>- The cause of the incident</td>
<td>- Usually, no, low or moderate harm</td>
<td>Commonly conducted for actual or potential 'severe harm or death\n- Includes a thorough and credible investigation</td>
<td>Conducted and commissioned by those independent to the Trust</td>
</tr>
<tr>
<td>- Whether the incident can be prevented from occurring again</td>
<td>- If a patient is directly affected, they/relative/carer should be involved.</td>
<td>• Conducted to a high level of detail,</td>
<td></td>
</tr>
<tr>
<td>- The action taken to manage the incident</td>
<td>- Includes plans for shared learning –locally and/or nationally as appropriate</td>
<td>• Includes use of appropriate analytical tools (e.g. tabular timeline, contributory factors framework, change analysis, barrier analysis).</td>
<td></td>
</tr>
<tr>
<td>- Whether the actions taken were suitable and sufficient to manage the incident effectively</td>
<td></td>
<td>• Normally conducted by a multidisciplinary team, or involves experts/expert opinion/independent advice or specialist investigator(s).</td>
<td></td>
</tr>
<tr>
<td>- Any post incident actions, including further management, learning and changes to systems and practices which may prevent or mitigate a future</td>
<td></td>
<td>• Should be conducted by staff not involved in the incident, locality or directorate in which it occurred.</td>
<td></td>
</tr>
</tbody>
</table>

Policy & Procedures for Incident Reporting, Analysing, Investigating & Learning
April 2017
Page 22 of 47
occurrence.

| an offer to patient/relative/carer of links to independent representation or advocacy services.  
| May require management of the media via the organisation’s communications department.  
| Includes robust recommendations for shared learning, locally and/or nationally as appropriate |

2.12 **Human Factors in Incident Investigation in Healthcare**

Human factors is the science of understanding human performance within a given system. Translated into a healthcare context, human factors has been defined as:

> “Enhancing clinical performance through an understanding of the effects of teamwork, tasks, equipment, workspace, culture, organization on human behaviour and abilities, and application of that knowledge in clinical settings.”

Developing healthcare systems that are founded on human factors principles can positively impact on safety by:

- Reduction of harm through better design of healthcare systems and equipment
- Understanding why healthcare staff make errors and how ‘systems factors’ threaten patient safety
- Improving the safety culture of teams and organisations
- Enhancing teamwork and improving communication between healthcare staff.
- Improving how we learn when things go wrong by improving current approaches to incident investigation
- Predicting ‘what could go wrong’ in the design of new hospitals and healthcare processes, for example, through the application of cognitive task analysis, prospective risk assessment tools, workload assessments etc

Although it may be difficult to quantify, complex system issues such as the influence of culture, non-technical skills and behaviours of senior staff should be considered in the investigation process. Consider the following:

- Cognition and Workload
- Distractions
- The physical environment
- Teamwork
- Policy & process
- Products or Devices used


2.13 **Duty Of Candour & Being Open**

The principles of honesty, openness and transparency must be applied. Being open when things go wrong is key to the partnership between patients and those who provide their care. Openness about what happened and discussing patient safety incidents promptly, fully and compassionately can help patients cope better with the after-effects.
When a patient has been harmed (moderate, severe or death), Duty of Candour becomes a legal and professional obligation. Patients, families / carers must be informed of the incident and investigation. They should be given the opportunity to express any concerns and questions which should then be reflected in the terms of reference. Evidence should be gathered from patients, families / carers if appropriate. They should be given access to any findings of the investigation and have the opportunity to respond / comment. The standards of CQC regulation 20, March 2015 can be found here.

The Trust Policy for Duty of Candour can be found on Flo (click here)
Section 3
Serious Incidents

3. Introduction
A Serious Incident is an event that causes severe harm or unexpected or avoidable death, where there is a potential for learning and warrants a comprehensive response. The occurrence of a serious incident demonstrates weaknesses in a system or process that need to be addressed to prevent future incidents.

In broad terms, serious incidents are events in health care where the potential for learning is so great, or the consequences to patients, families and carers, staff or organisations are so significant, that they warrant using additional resources to mount a comprehensive response. Serious incidents can extend beyond incidents which affect patients directly and include incidents which may indirectly impact patient safety or an organisation’s ability to deliver ongoing healthcare. There is no definitive list of events/incidents that constitute a serious incident, however NHS England have given some guidance on when a Serious Incident must be declared, however each incident will be reviewed on a case by case basis.

Serious Incidents Include:
- Acts and/or omissions occurring as part of healthcare (including in the community) that result in:
  - Unexpected or avoidable death of one or more people. This includes
    - suicide/self-inflicted death; and
    - homicide by a person in receipt of mental health care within the recent past
  - Unexpected or avoidable injury to one or more people that has resulted in serious harm
  - Unexpected or avoidable injury to one or more people that requires further treatment by a healthcare professional in order to prevent the death of the service user; or serious harm
  - Actual or alleged abuse; sexual abuse, physical or psychological ill-treatment, or acts of omission which constitute neglect, exploitation, financial or material abuse, discriminative and organisational abuse, self-neglect, domestic abuse, human trafficking and modern day slavery where healthcare did not take appropriate action/intervention to safeguard against such abuse occurring or where abuse occurred during the provision of our care. This includes abuse that resulted in (or was identified through) a Serious Case Review (SCR), Safeguarding Adult Review (SAR), Safeguarding Adult Enquiry or other externally-led investigation, where delivery of our care caused/contributed towards the incident.
- A Never Event - all Never Events are defined as serious incidents although not all Never Events necessarily result in serious harm or death.
- An incident (or series of incidents) that prevents, or threatens to prevent, an organisation’s ability to continue to deliver an acceptable quality of healthcare services, including (but not limited to) the following:
- Failures in the security, integrity, accuracy or availability of information often described as data loss and/or information governance related issues
- Property damage;
- Security breach/concern
- Incidents in population-wide healthcare activities like screening and immunisation programmes where the potential for harm may extend to a large population;
- Inappropriate enforcement/care under the Mental Health Act (1983) and the Mental Capacity Act (2005) including Mental Capacity Act, Deprivation of Liberty Safeguards (MCA DOLS);
- Systematic failure to provide an acceptable standard of safe care (this may include incidents, or series of incidents, which necessitate ward/ unit closure or suspension of services); or
- Activation of Major Incident Plan (by provider, commissioner or relevant agency)
- Major loss of confidence in the service, including prolonged adverse media coverage or public concern about the quality of healthcare or an organisation

3.1 Can a Near Miss be a Serious Incident
It may be appropriate for a ‘near miss’ to be classed as a serious incident because the outcome of an incident does not always reflect the potential severity of harm that could be caused should the incident (or a similar incident) occur again. Deciding whether or not a ‘near miss’ should be classified as a serious incident should therefore be based on an assessment of risk that considers:
- The likelihood of the incident occurring again if current systems/process remain unchanged; and
- The potential for harm to staff, patients, and the organisation should the incident occur again.

This does not mean that every ‘near miss’ should be reported as a serious incident but, where there is a significant existing risk of system failure and serious harm, the serious incident process should be used to understand and mitigate that risk. Please contact the Corporate Risk team to discuss if you are unsure.

3.2 Incidents involving other organisations?
If a serious incident or near miss is identified by an organisation that occurred whilst under the care of another provider, then that organisation must take action to ensure that the relevant provider and commissioner are informed.

3.3 Multi-agency investigations
If an incident occurs that involves multiple organisations then the provider who identifies the occurrence should report onto STEIS and co-ordinate the investigation. If there is a dispute over which organisation should lead the investigation the final decision should be made by the commissioner.

3.4 Serious Case Reviews (SCR) and Safeguarding Adult Reviews (SAR)
The Local Authority via the Local Safeguarding Children Board (LSCB) or Local Safeguarding Adult Board (LSAB) has a statutory duty to investigate certain types of safeguarding incidents/ concerns. With regard to safeguarding children Working
Together to Safeguard Children (2015) the LSCB is required to commission a SCR under:
Regulation 5 of the Local Safeguarding Children Boards Regulations 2006 in cases where;
   (a) abuse or neglect of a child is known or suspected; and
   (b) either: (i) the child has died; or
         (ii) the child has been seriously harmed and there is cause for concern as to the way in which the authority, their Board partners or other relevant persons have worked together to safeguard the child.

The Care and Support Statutory Guidance (updated 2017) identifies that in paragraphs 14.162 and 14.163 that the SABs must arrange a SAR when an adult in its area dies as a result of abuse or neglect, whether known or suspected, and there is concern that partner agencies could have worked more effectively to protect the adult.
And additionally that SABs must also arrange a SAR if an adult in its area has not died, but the SAB knows or suspects that the adult has experienced serious abuse or neglect.

Healthcare providers must contribute towards SCRs / SARs And ensure that learning and recommendations are disseminated, actioned and implemented and seek assurance that this is so.
**Further detail can be found in Section 1.5.2 of the Serious Incident Framework (2015).**

A Safeguarding Children flowchart is available at Appendix 1
A Safeguarding Adults flowchart is available at Appendix 2

### 3.5 Deaths in Custody – where health provision is delivered by the NHS
In prison and police custody, any death will be referred to the Prison and Probation Ombudsman (PPO) or the Independent Police Complaints Commission (IPCC) who are responsible for carrying out the relevant investigations. Healthcare providers must fully support these investigations where required to do so. This includes prisoners under escort whilst in hospital.

### 3.6 Homicides by patients in receipt of mental health care
NHS England’s Regional investigation team will consider, and if appropriate, commission an independent investigation if a patient has been under a Care Programme Approach (CPA) or in receipt of mental health services in the last 6 months.
**Full details of the Standard Operating Model can be found in Appendix 1 and 3 of the [Serious Incident Framework (2015)](#).**

### 3.7 Domestic Homicide Reviews
Community Safety Partnerships are responsible for undertaking a DHR under Home Office statutory guidance section 9(3) of the Domestic Violence, Crime and Victims Act 2004 (the 2004 Act) where the death of a person aged 16 or over has, or appears to have, resulted from violence, abuse or neglect by a relative, household member or someone he or she has been in an intimate relationship with. The Domestic Violence, Crime and Victims Act (2004) requires provider organisations to respond to requests for Individual Management Reports (IMR) in a timely manner, reflecting on any learning which might be
gained from the issues raised in the IMR. The IMR must be completed by a third party, rather than any persons involved in the care of the victim, perpetrator or family members.

Further detail can be found in Appendix 4 of the Serious Incident Framework (2015).

3.8 National Screening Incidents
Screening safety incidents include:
- any unintended or unexpected incident(s), acts of commission or acts of omission that occur in the delivery of an NHS screening programme that could have or did lead to harm to one or more persons participating in the screening programme, or to staff working in the screening programme
- harm or a risk of harm because one or more persons eligible for screening are not offered screening.

Serious Incidents in NHS National Screening Programmes must be managed in line with the guidance: Managing Safety Incidents in National Screening Programmes.

Screening and immunisation teams, led by the Screening and Immunisation Lead (SIL), will work closely with providers and the screening quality assurance service to oversee the management of screening safety incidents and serious incidents. Embedded within NHS England at sub-regional level they will utilise commissioning mechanisms to ensure that providers follow this guidance and QA advice is acted upon.

3.9 Police / Coroner Investigations
Wherever possible, serious incident investigations should continue alongside criminal proceedings but this should be considered in discussion with the police. In exceptional cases (i.e. following a formal request by police, Coroner or judge) the investigation may be put on hold and this should be discussed with those involved.

The Department of Health Memorandum of Understanding: investigating patient safety incidents involving unexpected death or serious untoward harm (2006) provides a source for reference where a serious incident occurs and an investigation is also required by the police, the Health and Safety Executive and/or the Coroner. Serious Incident reports will be shared with the Police and the Coroner where necessary.

3.10 Never Events
Never Events are serious incidents that are wholly preventable, as guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and should have been implemented by all healthcare providers.

Each Never Event type has the potential to cause serious patient harm or death. However, serious harm or death is not required to have happened as a result of a specific incident occurrence for that incident to be categorised as a Never Event.

Penalties may be incurred for Never Events as per the NHS Standard Contract. Further Information is available in the Revised Never Events Framework (2015)
### Never Events List 2015/2016

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Wrong site surgery</td>
</tr>
<tr>
<td>2</td>
<td>Wrong implant / prosthesis</td>
</tr>
<tr>
<td>3</td>
<td>Retained foreign object post-procedure</td>
</tr>
<tr>
<td>4</td>
<td>Mis-selection of a strong Potassium containing solution</td>
</tr>
<tr>
<td>5</td>
<td>Wrong route administration of medication</td>
</tr>
<tr>
<td>6</td>
<td>Overdose of Insulin due to abbreviations or incorrect device</td>
</tr>
<tr>
<td>7</td>
<td>Overdose of Methotrexate for non-cancer treatment</td>
</tr>
<tr>
<td>8</td>
<td>Mis-selection of high strength Midazolam during conscious sedation</td>
</tr>
<tr>
<td>9</td>
<td>Failure to install functional collapsible shower or curtains rails (Mental Health only)</td>
</tr>
<tr>
<td>10</td>
<td>Falls from poorly restricted windows</td>
</tr>
<tr>
<td>11</td>
<td>Chest or neck entrapment in bed rails</td>
</tr>
<tr>
<td>12</td>
<td>Transfusion or transplantation of ABO-compatible blood components or organs</td>
</tr>
<tr>
<td>13</td>
<td>Misplaced oro- or naso-gastric tubes</td>
</tr>
<tr>
<td>14</td>
<td>Scalding of patients</td>
</tr>
</tbody>
</table>

### 3.11 Information Governance breaches


All IG incidents should be reported using the Information Governance Toolkit within 24 hours (by the Information Governance Team). [www.igt.hscic.gov.uk/](http://www.igt.hscic.gov.uk/)

All level 2 incidents are also to be reported on STEIS.

There is no simple definition to describe Information Governance related Serious Incident Requiring Investigation (IG SIRI) but the following can be used as a guide:
- This type of incident will typically breach one of the principles of the Data Protection Act and/or the Common Law of Confidentiality.
• This includes unlawful disclosure or misuse of confidential data, recording or sharing of inaccurate data, information security breaches and inappropriate invasion of people’s privacy.
• Personal data breaches which could lead to identity fraud or have other significant impact on individuals.
• Applies irrespective of the media involved and includes both electronic media and paper records.
• When lost data is protected eg. by appropriate encryption, so that no individuals data can be accessed, then there is no data breach
• When the data is protected but there is a risk of individuals being identified then this remains and incident and should be reported. The sensitivity factors within the IG Incident Reporting Tool will reflect that the risk is low.
• A Cyber-related incident is anything that could (or has) compromised information assets within Cyberspace which could include (refer to guidance for further definitions):
  o Denial of Service attacks
  o Phishing emails
  o Social Media Disclosures
  o Web site defacement
  o Malicious Internal damage
  o Spoof website
  o Cyber Bullying

Information Governance grading guidance is available in Appendix 3

3.12 Pressure Ulcers

Reporting of pressure ulcers should follow the current guidance from the Derbyshire Wide Pressure Ulcer Group and Regional Serious Incident Group

**Avoidable pressure ulcers** – the person receiving care developed a pressure ulcer and the provider of care did not do one of the following:
- evaluate the person’s clinical condition and pressure ulcer risk factors;
- plan and implement interventions that are consistent with the persons needs and goals, and recognised standards of practice;
- monitor and evaluate the impact of the interventions; or
- revise the interventions as appropriate.

**Unavoidable pressure ulcers** - the person receiving care developed a pressure ulcer even though the provider of the care had:
- evaluated the person’s clinical condition and pressure ulcer risk factors;
- planned and implemented interventions that are consistent with the persons needs and goals and recognised standards of practice;
- monitored and evaluated the impact of the interventions and revised the approaches as appropriate; or
- the individual person refused to adhere to prevention strategies in spite of education of the consequences of non-adherence
**Lapse in care** – care was not delivered according the prevention plan or there was a lapse in process ie. Risk assessments etc. not completed according to policy. A lapse in care can be associated with both avoidable and unavoidable pressure ulcers.

**Moisture lesions** – redness or partial thickness skin loss involving the epidermis, dermis or both caused by excessive moisture to the skin from urine, faeces or sweat. These lesions are not usually associated with a bony prominence. They can be seen alongside a pressure ulcer of any grade.

**Suspected Deep tissue Injury (SDTI)** - Purple or maroon localized area of discolored intact skin or blood-filled blister due to damage of underlying soft tissue from pressure and/or shear. The area may be preceded by tissue that is painful, firm, mushy, boggy, warmer or cooler as compared to adjacent tissue. Deep tissue injury may be difficult to detect in individuals with dark skin tones. Evolution may include a thin blister over a dark wound bed. The wound may further evolve and become covered by thin eschar. Evolution may be rapid exposing additional layers of tissue even with optimal treatment. (NPUAP/EPUAP, 2014)

SDTI’s do not need reporting on STEIS but must be reported and monitored internally. Should the SDTI develop into a grade 3 pressure ulcer it will then be reported on STEIS.

**Skin changes at life’s end (SCALE)** – Physiological changes that occur as a result of the dying process (days to weeks) may affect the skin and soft tissues and may manifest as observable (objective) changes in skin colour, turgor, or integrity, or as subjective symptoms such as localized pain. These changes can be unavoidable and may occur with the application of appropriate interventions that meet or exceed the standard of care. Skin changes at life’s end are a reflection of compromised skin (reduced soft tissue perfusion, decreased tolerance to external insults, and impaired removal of metabolic wastes. (SCALE Expert Panel, 2009):


These incidents are still reported as SI’s but only a SCALE statement written by a Tissue Viability Nurse needs to be submitted to confirm that all appropriate interventions have been put in place (see definition of unavoidable ulcers).

See Trust Pressure Ulcer Policy on Flo for further details.

### 3.13 Healthcare Associated Infections (see Appendix 9 for MRSA Flowchart)

#### 3.13.1 MRSA

All MRSA bacteraemia cases attributed to Derby Teaching Hospitals will be reported as a serious incident via the Datix system and onto the lead Clinical Commissioning Group (CCG) through a dedicated reporting system. Derby Teaching Hospitals will only report those MRSA bacteraemia cases that are attributed to DTHFT. The Infection Prevention and Control Team will refer all MRSA bacteraemia cases not attributed to the Acute Trust to the relevant CCG infection prevention and control team for investigation. All MRSA bacteraemia cases will have a Root Cause Analysis (RCA) undertaken, following the Department of Health’s post infection review (PIR) process

#### 3.13.2 Clostridium difficile

Clostridium difficile is reported as an SI when:
• Classified as 1a and 1b on the death certificate where it is clear Clostridium difficile has made a significant contribution to the cause of death.

• Cases where a serious complication including colectomy arise due to Clostridium difficile

• All Clostridium difficile deaths recorded on part 1 of the death certificate, or those patients who have surgery as a result of their C.diff infection are identified as a serious incident (SI) and will have a Root Cause Analysis (RCA) undertaken, involving, but not limited to, representative from the medical and nursing teams caring for the patient, Division Nurse Director, Infection Prevention and Control.

• If a Clostridium difficile (C.diff) infection is identified as a SI, the Trust will report to the CCG via the dedicated reporting system as a serious incident (via Risk).

• Derby Teaching Hospitals will only report the serious incidents when the case has been attributed to DTHFT. The Infection Prevention and Control team will refer all cases not attributed to the Acute Trust to the relevant CCG Infection Prevention and Control team for reporting and investigation

3.13.3 Hospital and Community based infection outbreaks
Outbreaks must be reported as an SI if they;
• Result in a high mortality for staff, patients or the community
• Involve highly virulent and transmissible organisms
• Require control measures that have an impact on the care of other patients, including limitation of access to healthcare services or where business continuity will be affected
• Involve infected healthcare workers or patient incidents necessitating consideration of a look back investigation (e.g. TB, vCJD, blood borne infections)

3.13.4 Norovirus
Norovirus must be reported as an SI if:
• One or more wards are closed due to Norovirus
• An outbreak meeting has been called.

3.13.5 Ward Closure due to infection Outbreak
Any ward closure related to suspected or confirmed infections, e.g. Norovirus will reported as a serious incident via the Datix system, by the IPCT and onto the lead Clinical Commissioning Group (CCG) through a dedicated reporting system. The IPCT will monitor the outbreak and provide the final report on the actions taken. All bay or ward closures will be reported to Public Health England by the IPCT via the PHE Norovirus voluntary reporting system but are not reported as a serious incident.

3.14 High Profile Serious Incidents
High profile SIs, such as incidents where the Trust Major Accident Plan is activated or where there is significant media interest or significant external agencies interest, may need to be reported to the Commissioner immediately. This will require the involvement and authorisation of the Director of Patient Experience and Chief Nurse and the Medical Director or their deputies. They will also be responsible for escalating the incident to other Executives in a timely manner. If this occurs out of hours the incident can be reported to the Commissioner/Director on Call. This can only be done by the Senior Executive on call for the Trust and may require the involvement of other Trust Executives.

3.15 Communications
Where appropriate the Chief Nurse and Director of Patient Experience or the Medical
Director (or nominated deputy) will:

- Inform the Chief Executive at an early stage.
- Agree with local senior staff on duty, the nature and extent of the required communication with patients, relatives and staff and identify responsibilities of individual staff accordingly.
- Ensure that patients/next of kin/staff involved, are informed before the media.
- Brief the Head of Communications, who will prepare a “press brief” for approval by the Director of Patient Experience and Chief Nurse.
- With the Head of Communications will assess the potential for multiple enquiries and agree actions as per Trust Policy for Dealing with Multiple Enquiries.
- Maintain a record of the timing and rationale of decisions taken.
- Report SI notification to the next Trust Board meeting.

The Head of Communications will continue to advise and provide support on internal and external communications

### 3.16 Risk Assessments

Following a Serious Incident, as with all untoward incidents and near misses, all related risk assessments must be reviewed by the Division’s Governance Group and the Risk Register updated accordingly. This is the responsibility of the Clinical Governance Facilitators and it will be monitored by the Risk & Compliance Committee.

### 3.17 Action Plans, Local and Organisational Learning

All investigation reports will include an Action Plan. This is part of the Incident Report Template which is available from the Corporate Risk Office or the local Clinical Governance Team. Each investigation will provide an action plan to, where possible, reduced the risk of recurrence, addressing causative factors, both latent and active failures.

Each recommendation determined by an investigation should have a corresponding action with a clear deadline and responsible person allocated. Implementation and completion of action plans will be monitored through IQAG.

The Commissioner will review all submitted investigations within 20 working days and feedback their findings to the Trust via the Corporate Risk Team who will forward any feedback received to the report author(s) and/or the relevant Clinical Governance Facilitator. The Corporate Risk Team will co-ordinate the capture and response to the Commissioner where requests for further information and or/development is required within agreed timescales.

The lead investigator will ensure that any relevant patient safety alerts (such as Central Alert System [CAS] or NPSA Rapid Response Reports [RRR]) have been referenced and considered.

The Trust will confirm completion of the action plan by email to the commissioner.

Evidence of completion of action plans is requested by the Corporate Risk team prior to
final sign off of action plan – all appropriate evidence must be attached to Datix (or its equivalent). Action plan learning from Serious Incidents and Never Events are monitored via ILG and the Divisional Governance teams are required to provide audit reports and other evidence of actions visions will be required to present their Action Plans resulting from the Division Feedback reports to the Trust Patient Experience & Engagement Group on a quarterly basis.

3.18 Quality Critique of Final Reports
The Incident Quality Assurance Group (IQAG) is responsible for ensuring that external reports are accurate and fit for purpose. The critique function is carried out by IQAG which is a sub group of Incident Learning Group (ILG). ILG is also responsible for identifying learning changes to practice by commissioning work to bring about organisational change.

3.19 Updating STEIS with Investigation Outcomes
When the investigation has been completed and when the incident has been reviewed by IQAG, the Corporate Risk and Governance Office will update the ‘root causes and lessons learned section of STEIS. The information provided should include key details of the investigation including an overview of the incident, findings, contributory factors, root causes, recommendations and actions.

3.20 Externally Reportable Incidents
Certain incidents require reporting to external agencies in addition to the Commissioning Organisation, detail of such incidents and responsibilities for reporting are included in Appendix 4.
Section 4

References


Mental Capacity Act, including all trust Documents http://flo/depts/nonclinical/mental-capacity/


Policy for the Reporting and Management of Serious Incidents, Southern Derbyshire Clinical Commissioning Group (January 2016)

 Organisation identifies incident which may meet threshold for SCR or SI

Inform Trust Safeguarding Lead (TSL)

Where TSL thinks incident is likely to meet threshold for SCR, TSL to inform the CCG Designated professional and the Safeguarding Children’s Board Serious Case Review Panel (SCRP) for review at the next meeting

If SCR does not agree that meets the threshold for SCR to commence SI

If SCRP agrees threshold is met, it will agree the ToR and timescales for the review

Trust Individual Management review will be authored by TSL, signed off by Chief Nurse and learning / recommendations disseminated via the Trust Safeguarding Committee
Appendix 2
Safeguarding Adults Serious Incident Reporting Flowchart

Reported as a Serious Incident on STEIS
1. Definition/type of Safeguarding
2. Immediate actions to Safeguard person & to stop reoccurrence
3. Immediate actions to Safeguard family, carers, staff, general public & to stop reoccurrence
4. What is your Safeguarding action plan? To include:
   - Referral to social care if indicated
   - Referral for Serious Case Review if indicated
5. Has this risk been confidentially shared with other commissioners?

Purpose: Provider/Commissioner reports to assure about person & others safety and the SIRI process

Updates from CCG / Provider on STEIS
1. Are you assured the person is safe?
2. Are you assured others are safe?
3. Are you assured the Safeguarding action plan is safe and robust?

Purpose: Assurance of ongoing safety & plan to resolve

SI open over 45 days (or 60 days if applicable)
1. Why is this still open?
2. What are the issues?
3. What is the plan to resolve & close?

Request to close SI
1. Is the RCA complete?
2. What lessons have been learned?
   - To support the individual
   - To support family, carers, staff, public
   - Across the organisation
     - Operationally
     - Strategically
   - Multi agency

Sharing Learning
1. Types of Safeguarding
2. People – LD, Dementia etc.
3. Themes
4. Good practice
5. Changes in Practice

Communication:
Safeguarding Leads, DoN, Patient Safety Leads, Commissioning for Quality, LSAB, Clinical Commissioning Groups, NHS CB, PHE
SERIOUS INCIDENT REQUIRING INVESTIGATION (SIRI) SCORING SYSTEM

Under the new SIRI scoring system the scale and sensitivity of an incident needs to be established before determining whether it needs reporting to the Information Commissioners Office (ICO) and Department of Health (DoH).

For each category, as detailed in the tables below e.g. No clinical data at risk (Table 2), that applies to the incident you add or minus a point depending on the instruction in the score column.

The total score will determine whether the incident needs reporting.

Incidences that score **one or less** do not have to be reported

Incidences that score **two or more** do have to be reported

### Step One: Establishing scale of incident

<table>
<thead>
<tr>
<th>Score</th>
<th>Table One - Number of individuals affected</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>10 or less individuals</td>
</tr>
<tr>
<td>+1</td>
<td>11 – 100 individuals</td>
</tr>
<tr>
<td>+2</td>
<td>101 – 1000 individuals</td>
</tr>
<tr>
<td>+3</td>
<td>1,001 or more individuals</td>
</tr>
</tbody>
</table>

### Step Two: Identifying the nature and sensitivity of incident

<table>
<thead>
<tr>
<th>Score</th>
<th>Table Two - Low Sensitivity</th>
</tr>
</thead>
<tbody>
<tr>
<td>-1 for each</td>
<td>No clinical data at risk</td>
</tr>
<tr>
<td></td>
<td>Limited demographic data e.g. No PID</td>
</tr>
<tr>
<td></td>
<td>Security controls/difficulty to access data partially mitigates risks</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Score</th>
<th>Table Three - Medium Sensitivity</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 for each</td>
<td>Basic demographic data at risk e.g. equivalent to telephone</td>
</tr>
<tr>
<td></td>
<td>Limited clinical information at risk e.g. clinic attendance, ward handover sheet</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Score</th>
<th>Table Four - High Sensitivity</th>
</tr>
</thead>
<tbody>
<tr>
<td>+1 for each</td>
<td>Detailed clinical information at risk e.g. case notes</td>
</tr>
<tr>
<td></td>
<td>Particularly sensitive information at risk e.g. HIV, STD, Mental</td>
</tr>
<tr>
<td></td>
<td>One or more previous incidences of a similar type in past 12</td>
</tr>
<tr>
<td></td>
<td>Failure to securely encrypt mobile technology or other obvious</td>
</tr>
<tr>
<td></td>
<td>Celebrity involved or other newsworthy aspects or media interest</td>
</tr>
<tr>
<td></td>
<td>A complaint has been made to the Information Commissioner</td>
</tr>
<tr>
<td></td>
<td>Individuals affected are likely to suffer significant distress or</td>
</tr>
<tr>
<td></td>
<td>Individuals affected have been placed at risk of physical harm</td>
</tr>
<tr>
<td></td>
<td>Individuals affected may suffer significant detriment e.g. financial</td>
</tr>
<tr>
<td></td>
<td>Incident has incurred or risked incurring a clinical untoward</td>
</tr>
</tbody>
</table>
Step 3: Where adjusted scale indicates that the incident is level 2, the incident will be reported to the ICO and DH automatically via the IG Incident Reporting Tool.

<table>
<thead>
<tr>
<th>Final Score</th>
<th>Level of SIRI</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 or less</td>
<td>Level 1 IG SIRI (Not Reportable)</td>
</tr>
<tr>
<td>2 or more</td>
<td>Level 2 IG SIRI (Reportable)</td>
</tr>
</tbody>
</table>

Example:
Information about a child and the circumstances of an associated child protection plan has been faxed to the wrong address.

<table>
<thead>
<tr>
<th>Baseline scale factor</th>
<th>Sensitivity Factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>-1 No clinical data at risk</td>
</tr>
<tr>
<td></td>
<td>0 Basic demographic data</td>
</tr>
<tr>
<td></td>
<td>+1 Sensitive information</td>
</tr>
<tr>
<td></td>
<td>+1 Information may cause distress</td>
</tr>
</tbody>
</table>

Final scale point 1 so this is a level 1 SIRI and not reportable

Subsequent to incident above the same error is made again and the recipient this time informs the Trust she has complained to the ICO.

<table>
<thead>
<tr>
<th>Baseline scale factor</th>
<th>Sensitivity Factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>-1 No clinical data at risk</td>
</tr>
<tr>
<td></td>
<td>0 Basic demographic data</td>
</tr>
<tr>
<td></td>
<td>+1 Sensitive information</td>
</tr>
<tr>
<td></td>
<td>+1 Information may cause distress</td>
</tr>
<tr>
<td></td>
<td>+1 Repeat incident</td>
</tr>
<tr>
<td></td>
<td>+1 Complaint to ICO</td>
</tr>
</tbody>
</table>

Final scale point 3 so this is a level 2 reportable SIRI

A member of staff took a ward handover sheet home by mistake and disposed of it in a public waste bin where it was found by a member of the public. 19 individual’s details were included.

<table>
<thead>
<tr>
<th>Baseline scale factor</th>
<th>Sensitivity Factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>-1 Limited demographic data</td>
</tr>
<tr>
<td></td>
<td>0 Limited clinical information</td>
</tr>
<tr>
<td></td>
<td>+1 Security failure re disposal of data</td>
</tr>
</tbody>
</table>

Final scale point 1 so this is a level 1 SIRI and not reportable

Loss of an individual’s medical records. The records were found to be missing when the patient concerned made a subject access request.

<table>
<thead>
<tr>
<th>Baseline scale factor</th>
<th>Sensitivity Factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0 Basic demographic data</td>
</tr>
<tr>
<td></td>
<td>+1 Detailed clinical information</td>
</tr>
<tr>
<td></td>
<td>+1 Patient distressed</td>
</tr>
<tr>
<td></td>
<td>+1 Complaint to ICO</td>
</tr>
</tbody>
</table>

Final scale point 3 so this is a level 2 reportable SIRI
INCIDENTS EXTERNALLY AND INVOLVING OTHER STAKEHOLDERS IN INVESTIGATING

Corporate Risk Services will report to the following external stakeholders:

The Commissioners
Serious Incidents as identified in this Policy

The NPSA (National Patient Safety Agency)
All patient safety incidents / near misses inputted each month

The MHRA (Medicines and Healthcare Products Regulatory Agency)
Reports significant events / concerns relating to medical devices

The following designated officers report directly to external agencies ensuring Risk Services and the relevant Executive are aware:

The Health and Safety Executive
RIDDOR (Reporting of Injuries, Diseases and Dangerous Occurrences Regulations) reportable Incidents

Public Health England
Reported by Infection and Prevention Control Lead

Serious Hazards of Transfusions
Reported by the Trust Specialist Practitioner of Transfusions.

Information Commissioner
Reported by Health Records Quality & Risk Manager

IRMER (Ionising Regulations for Medical Exposure to Radiation) Reportable Incidents
Reported by the Trust Radiation Protection Advisor

PARS (Physical Assault Reporting System)
Reported by the Trust Security Advisor

The Human Tissue Authority: Serious Adverse Events / Reactions in relation to the procurement, testing, processing, preservation, storage and distribution of human tissues and cells.
Reported by the Blood Bank Manager / Bone Bank Manager

If more than one organisation is involved in a significant event, the organisation who has discovered the incident will make the initial report. A meeting will then be arranged to include all key stakeholders. A lead professional will be identified to manage, lead and co-ordinate the incident, procedure and investigation. All key stakeholders will contribute and work together with the nominated lead. The Memorandum of Understanding Concordat Agreement outlines the arrangements for investigated involving the NHS, Police and HSE
Consult NCAA or relevant regulatory body.
Adviser individual to consult Trade Union Representative.
Consider:
- Suspension
- Referral to Police and disciplinary body
- Occupational Health Referral.
Highlight any system failures identified.

Consult NCAA or relevant regulatory body.
Adviser individual to consult Trade Union Representative.
Consider:
- Occupational Health Referral.

Consult NCAA or relevant regulatory body.
Adviser individual to consult Trade Union Representative.
Consider:
- Corrective training
- Improved supervision
- Occupational Health Referral.

Consult NCAA or relevant regulatory body.
Adviser individual to consult Trade Union Representative.
Consider:
- Suspension
- Referral to Police and disciplinary body
- Occupational Health Referral.
Highlight any system failures identified.
Appendix 6

Recording Staff Recollection of Events

Interviewing staff is often the best way of getting to the underlying (root) causes as it presents the opportunity to check out understanding and custom and practice that written statements tend to miss.

However gaining statements early in an investigation helps with timeline mapping and identification of where further exploration is required.

Statement writing can be stressful for all individuals concerned and with this in mind, support should be made available to those staff. This support should include the following:

- The staff member(s) should be advised that support is available from Legal Services, the Health and Safety Manager, Risk and clinical Governance Team, Occupational Health, Personnel and Staff Representatives
- A date should be set to review the first draft of the statement
- The staff member(s) should be referred to individuals in the Trust who can provide expert knowledge
- Time and space should be made available to enable staff to review any medical records that may be appropriate.
- For statements about staff / visitor accidents the Health and Safety Manager and Trust Legal Services should have sight of these as appropriate.

For clinical events, staff are required to complete their clinical records, even when statements are required.

Staff should note and be aware that unless witness statements are prepared ‘in contemplation of litigation’ then they will become ‘discloseable’ to the patient and/or his/her representatives in any subsequent legal proceedings which may take place. Statements produced for the purposes of incident investigation will usually be discloseable documents. Further advice on this is available from the Trust Legal Services.
Appendix 7

Template Letter for Staff

Dear

As you may be aware I have been involved in undertaking a root cause analysis investigation into ...........................................

Having had an opportunity to review all the initial information I feel it would be helpful to have an opportunity to talk to you to enable a more indepth understanding of the events.

Please be assured that the purpose of our meeting is not to find fault or blame but to help determine if we can learn from this incident.

However you may bring a colleague for support if you wish.

At the end of our meeting I will summarise the facts discussed, to ensure that you agree with the information ascertained. Following the meeting you will be provided with the notes taken and be given an opportunity to ensure they represent a true reflection of the facts.

My department will be contacting you shortly to arrange a time convenient to both of us to meet. Please contact me if you have any concerns or questions about this

Many thanks
Appendix 8

Root Cause Analysis Incident Investigation Process - higher level internal and Serious Incident

The investigation should address:

- What happened?
- How did it happen?
- Why did it happen?

To establish the above it will be necessary to consider evidence from the following sources:

- Gain information from the people involved, this will initially be through statements/recollection of events) but after further analysis of the incident may require staff interviews to enable more in depth understanding of the events.
- Examine the area (environmental / equipment issues?)
- Consult and copy documentary evidence (equipment instructions, policies / procedures / guidelines, training / maintenance records, health records)

It is often useful to check out the understanding / usual practice of other staff working in the area, especially with regard to implementation of policy / procedure.

Timelines

Understanding the chronology of events (mapping the information) is of utmost importance in visualising the chain of events and identifying where further fact finding is required. The mapped chronology or timeline will clearly identify key problem areas and areas of good practice in the sequence of events.

The timeline chronology will be undertaken by the investigation co-ordinator and one other nominated staff member. It is important that both have a grounding in collating timelines (attendance on half day risk training, modular RCA course or other RCA training) and that one has a working knowledge of the area the incident occurred in. The first draft timeline must be completed within two weeks of the incident.

Further questions identified from the timeline usually require a more in depth understanding of thought processes and underlying working conditions and as such interviewing staff will often provide the richest source of information.

Investigative Interviewing

It is important to be clear in communications with staff that the intention of the investigation and subsequent interviews are to learn lessons rather than apportion blame. If at any time during the interview or investigation, facts are revealed which could potentially lead to disciplinary action the interview will be suspended and the staff members union representation contacted before further interviews are undertaken.

One of the issues that often make successful interviewing difficult is that interviewers have to listen and take notes at the same time. It is in the interests of both the interviewer and interviewee that either someone sits in to take notes (but is not involved in asking questions) or a full tape recording be made for later transcription (with prior agreement of all parties). The interviewee will be asked to check the notes and date, sign and return a copy indicating it as a true representation of the interview.

A good interview will include the following:

- Introductions and welcome
- Explain the purpose of the interview i.e. to find out as much as possible and understand how the event occurred
- Ask the interviewee to describe the events, it is essential that this is uninterrupted
o When the interviewee has completed their story questions may be asked for clarification purposes or to draw more information
o Once the interviewer has finished asking questions it is important that a summary of information is repeated back to the interviewee. This enable the interviewee to identify any inaccuracies in interpretation by the interviewer and gives a final opportunity for new information
o Close the interview by thanking the interviewee, answering any questions, provide a contact for further support if necessary and return to neutral topics of conversation.

Local Investigation Review Meeting
When all additional information gained by further fact finding has been included within the timeline, a meeting will be called with the key stakeholders to explore problems and identify safety quality improvements.
This will include the incident co-ordinator, and others as appropriate to the incident which may include, Executive Director, Risk Services Representative, Member(s) of the Division Management Team, Ward / Department Manager where incident occurred and individuals involved within the Incident.
Serious Incidents will be chaired by the Division Nurse/Divisional Director/Divisional Medical Director.
Internal Higher Lever Incidents will be chaired by the Clinical Governance Facilitators The timeline will be discussed with problems being explored using further root cause analysis tools as necessary i.e. 5 whys, fishbone diagrams, cause and effect diagrams and barrier analysis. This further problem exploration will contribute to the formulation of any action plan / remedial actions that might be required to reduce the risk of a reoccurrence.

Generating the Root Cause Analysis Report:
A report detailing the investigation and subsequent actions will be generated which includes the following (contact the Risk and Clinical Governance office for the current report template):
o the incident, chain of events
o Identify areas of good practice
o the investigation, (who compiled the timeline, other tools used, who was involved in further problem exploration and solution identification and further facts discovered)
o Key actions that need to occur as a result of the event
o Identify contributing factors, care & service deliver problems and system failures
o Person(s) responsible for taking actions forward
o Communication strategy for wider circulation i.e. other professional groups, Trust groups and areas who might benefit including outside agencies
o Dates for review
A copy of the completed report with copies of any timelines, interview notes/ witness statements, relevant documents, photographs and / or sketches attached must be forwarded to Risk Services for review by the Trust Incident Quality Assurance Group. The completion of the incident review and report must be within 40-45 days. For Incidents reported as Serious Incidents more detailed report will be generated (Available on Flo, contact the Risk Office or Divisional Clinical Governance Team for the current template)
Appendix 9

**Investigation and Reporting of a Trust Apportioned MRSA Bacteraemia**

1. **Infection Prevention and Control (IPC) informed of positive result**
2. Inform Lead Nurse IPC, or deputy, of result.
3. **Inform DIPaC and MD**
4. **Inform IPC Lead at the CCG**
5. **Inform Risk Department**
6. **Report on Datix**
7. **Record on Public Health England data capture system**
8. **Inform Lead Nurse IPC (or deputy) to upload findings of the meeting to DH. (Login details will be emailed when reported on Data Capture System) within 14 working days**
9. **Lead Nurse IPC (or deputy) to upload findings of the meeting to DH.**
10. **Report via STEIS**
11. **Submit final report to CCG**
12. **Division to present final SI report and action plan to Infection Control Committee and HCAI review group for learning**
13. **Division to forward agreed report and action plan to dhft.incidentinvestigations@nhs.net**
14. **Instigate RCA review. Meeting to include**
   - DMD
   - DND
   - Matron
   - Senior Sister
   - Lead Consultant
   - Clinical Governance Facilitator
   - Infection Prevention and Control
   - Additional attendees as required e.g. pharmacist
15. **Division to set up RCA meeting within 10 working days of being informed of the bacteraemia.**
16. **Prepare timeline & distribute to attendees prior to the meeting**
17. **RCA report and action plan presented to IQAG by the Division as per SI timeframe. Amend report as necessary following review by IQAG**

**Risk Management Team responsibility**

**Divisional responsibility**

**Infection Prevention and Control Team responsibility**
Appendix 10

Mental Health/Learning Disability Patient 12 hour Trolley Breach

1) Any 12 hour breach for an adult/child in MH/LD is reported on Datix by A&E and reported on STEIS (by Risk team).

2) The incident is jointly investigated by Royal Derby Hospital and Derbyshire Healthcare FT as per the SI Framework focusing on pre A&E care and reasons for delays whilst in A&E.

3) The lead provider will provide an initial review report (contact Risk office for template) within 5 working days, and submit to the CCG quality team as per normal SI process.

4) The completed SI investigation report, recommendations and action plan is to be signed off by both providers prior to submission within the 60 working day timeframe.

5) The SI investigation report will be reviewed by Southern Derbyshire CCG/Hardwick CCG as per normal process. Any actions/recommendations will be monitored in the usual way.

6) Commissioners and Providers will continue to hold the monthly breach review meetings to support the investigation process, monitor progress and ensure learning is disseminated appropriately.