Incident Reporting Including Investigation and Root Cause Analysis Procedures

Policy & Procedure

Authors Name & Title: Joan Matthews, Risk Manager & Helen Martin, Governance & Safety Lead

Scope: Trust Wide
Classification: Non-Clinical

Replaces: v2.2

To be read in conjunction with the following documents:
- Risk Management Strategy
- Capability and Performance – Dignity at Work
- Being Open Policy
- Supporting Staff Following Traumatic Incident
- Health & Safety Policy
- Consent policy
- SUI Framework March 2013
- Disciplinary – Equality and Diversity
- Grievance – Professional Registration
- Raising Concerns – Stress Prevention
- Supporting Staff – Zero Tolerance
- Revalidation
- Maintaining High Professional Standards
- Learning from Experience Policy
- Safeguarding Children and Vulnerable Adults Policies

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Officer responsible for archive: Document Control Administrator

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Has Endorsement been completed? Yes/No
1. Policy Statement

The Trust Board and the Chief Executive are committed to the establishment of a supportive, open and learning culture that encourages staff to report incidents and near misses through the appropriate channels. The aim is not to apportion blame but rather to learn from incidents and near misses and improve practice accordingly.

2. Roles, Responsibilities and Duties

Chief Executive
- Ensures the Trust has adequate systems for the reporting of all incidents and near misses

Director of Nursing
- Has the Executive Lead for Risk Management
- Ensures organisational learning occurs following the investigation into reported incidents and near misses.
- Implementation of this policy
- Ensure the Trust Board are appraised of all Serious Untoward Incidents by presenting Root Cause Analysis (RCA) reports as necessary

Deputy Director of Nursing
- Will support the Director of Nursing in ensuring the policy is implemented
- Will act in an advisory capacity to the Risk Management Team with regards to the grading of incidents
- Will ensure the Trust Board are appraised of all Serious Untoward Incidents by presenting Root Cause Analysis (RCA) reports as necessary in the absence of the Director of Nursing

Authorised Named Person
- Person responsible for deciding if an incident triggers the SUI procedure (Director of Nursing, Medical Director, Chief Executive)

All Managers
- For ensuring that their staff are fully aware of Trust procedures for the reporting of all incidents and near misses
- Developing mechanisms within their Directorate / Departments for sharing and learning of lessons of reported incidents and near misses
- Present reports and action plans for all adverse events / SUI’s where Root Cause Analysis has been undertaken to the appropriate Directorate Governance Meeting.
- Ensure that recommendations from incident review processes are implemented
- Ensure support is instigated for staff when identified as appropriate following a stressful or traumatic incident
- Where a member of staff is injured, as a result of a work related accident / incident and is absent for seven working days an incident form must be sent to the Risk Management department for RIDDOR reporting. Referral to Occupational Health as necessary will be made by the Ward/Department Manager.
- Consider the utilisation of the Incident Decision Tree before commencing and investigation as a means of ensuring a fair and consistent approach when an incident has occurred

Assigned Manager
- Ensure that all incidents are reviewed according to the grade, which may include some or all the following actions; (for red incidents see page 7)
- Gather information on the circumstances surrounding the incident [who, what, where, why, when]
- Ensure that a risk assessment is carried out within 48 hours of the incident (if appropriate)
- Maintain a contemporaneous record and ensure recorded within PRISM database
- Refer to and act in accordance with other Trust policies as required such as medical equipment
• Develop action plans as required and ensure recorded and updated on PRISM
• Re-grade incident following the investigation and implementation of the action plan
• Ensure timely investigation and closure of incident within 28 working days of the incident occurring (Amber, green/yellow incidents)

All Staff
• To ensure they report any incident or near misses they have been involved in or witnessed
• Instigate support as necessary following a stressful or traumatic incident

Risk Management Team
• To ensure all reported incidents and near misses are recorded, assigned a manager and actioned according to severity.
• Reviewing incidents and trends on an organisation wide basis
• Ensure monthly reports extracted from the PRISM system detailing all reported incidents and near misses within clinical areas or departments are forwarded to General Managers, Associate Medical Directors, Assistant Directors of Nursing and Heads of Departments.
• Maintain a contemporaneous record of all RCA’s performed within the Trust
• Report relevant incidents to monitoring organisations as required (i.e. Monitor, Care Quality Commission)
• Ensure reports to Liverpool Clinical Commissioning Group (LCCG) are presented according to the LCCG Operational Policy for the Performance Management of Serious Untoward Incidents and Never Events

3. Risk Definitions

Risk is the chance or likelihood of harm, loss or damage.

Risk Management is the process by which risks are reduced, managed or controlled to an acceptable level.

Adverse events and near misses are incorporated in the one phrase, ‘adverse incident’. An adverse event is when an unsafe act or omission has occurred in the course of a process. The adverse event may or may not cause actual unintended or unexpected harm, loss or damage. A near miss is where a chain of events/unsafe acts, potential leading to an incident, where in some way detected and thwarted prior to the penultimate harm act, but could have done.

A Serious Untoward Incident (SUI) is a situation in which one or more individuals are involved in an event which is likely to produce significant legal, media or other interest which, if not properly managed, may result in loss of the Trust’s reputation or assets. For a description of possible SUI’s please see appendix 4

Never Events A Never Event is defined as a serious and largely preventable patient safety incident, which should not occur if the available preventative measures have been implemented. A Never Event may or will result in severe harm or death to a patient and/or the public.

A comprehensive list of never events including definitions can be found in appendix 5 of this policy and on the Department of Health website at www.dh.gov.uk

4. Process for the reporting of all Incidents and Near Misses

This Trust welcomes knowledge of adverse events / and raising concerns as an opportunity to learn for the benefit of our patients and staff. Unless there is clear evidence of flagrant malpractice, a complete disregard for the safety of others, malicious intent to harm, theft or fraud, disciplinary policies will not be used for investigatory purposes.
The flowchart provided on (page 6) is designed as a quick reference for reporting all incidents, and should be used in conjunction with the following detailed guidance:

All incidents should be reported to a line manager as soon as they have occurred. Brief details of the incident should be included within the case-notes. The safety of staff and patients will be priority:-

- An incident form must completed at the earliest possible moment
- All sections of the incident form must be completed with particular emphasis on important demographics such as:
- Patient name
- Location
- Date of incidence
- Severity of harm
- Has patient / carer / Consultant been informed of incident
- Has a senior manager been informed
- If a slip/trip/fall has occurred all sections on the incident form must be completed
- If Medicines / Medical Equipment is involved in the incident these sections must be completed
- The form must be dated and signed with any witnesses details included
- If witness statements have been taken attach these to the report.
- All web based reported incidents must have all each section completed before moving on to another section / field.

Once a report form has been completed it must be sent to the Risk Management department. When received these will be input into the incident reporting software system PRISM.

Once this has occurred the incident will be graded and assigned to the relevant manager.
Quick Reference Reporting Flowchart – All Incidents

Was anyone harmed as a result of this event?

Yes

Did the event result in
Death or Permanent
Harm?

No

Could Permanent
Harm or Death have
occurred?

Yes

No

Yes

Telephone Immediately
Out of hours – Hospital
coordinator who will
contact the Senior
Manager on call who will
contact Executive on call
In hours
Risk Management Dept.
Consider SUI

Inform senior member of
staff on duty immediately and
Risk Management within 24hrs

No

Next working day
Risk Management Dept.

Complete an incident report form and;

1. Forward top copy
To: Risk Management Department
2. Forward the second copy to the General Manager for your directorate
3. Retain carbonated copy in book and report to department manager/deputy within 2 working days;

Alternatively you can
1. Complete an e form via the intranet,
2. Report patient incidents via the telephone – which will be entered on to
database on your behalf by Risk Team
Assigning of Incidents

Levels of severity harm

- No Harm / Low
  - prevented
  - not prevented
- Minor / short term
- Moderate / semi permanent harm
- Catastrophic/ Death major permanent harm

Green Incidents and yellow incidents Ward/Department Managers/ Matrons

Amber Incidents including (adverse events) Assistant Directors of Nursing

Red Incidents including (adverse events) General Manager, Medical Director, Associate Medical Director or Executive Director

- Upon being assigned a red incident the assigned manager (usually the General Manager) will call a meeting in the first 48 hours of being notified of the incident with an identified team of investigators, of which there should be three, one of whom will be a Lead Investigator.
- The assigned manager will receive regular updates, on at least, a weekly basis from the Lead Investigator as to the status of the investigation.
- The assigned manager will ensure the investigation timeframe of 28 working days for red incidents is adhered to.
- The assigned manager will escalate concerns of not meeting the investigation timeframe to the Deputy Director of Nursing, who will inform the Director of Nursing/Medical Director
- Not all red incidents will be reported as an SUI, however, it may transpire that once the investigation is carried out, the red incident may have to be reported as an SUI. (see below)

General Managers, Assistant Directors of Nursing and the Medical Director, will receive a monthly report from the Risk Management department with which they will review all incidents occurring within their directorate / department in that month.

Process for identification and reporting of Serious Untoward Incidents

Once an incident is reported by form, web or telephone the content of the incident will be
- Given a category and colour coded according to severity
- If the severity of the incident is red an automatic email will be sent to all Executives and the Deputy Director of Nursing to highlight the possibility of an SUI
- A General Manager /Associate Medical Director/Assistant Director of Nursing/Head of Department will be assigned the incident to manage
- An initial assessment of the incident will be made and reported to the appointed named person (Director of Nursing, Medical Director, Chief Executive)
- Within the 24hr period following preliminary review of the incident a decision would be made by the appointed named person that an SUI had occurred and Liverpool CCG would be informed as per protocol within 2 working days (appendix 5)
- The appointed named person will identify a lead for any investigation
- Some incidents will require direct reporting to the CQC and Monitor. These incidents will also be determined by the appointed named person.
- SUI’s will be reported to the appropriate assurance committee
Out of hours

- The Hospital Coordinator would normally be informed first of an incident occurring in the out of hours period. The Hospital Coordinator would inform the Manager on Call immediately.
- The Manager on call would inform the Executive on call.
- The Executive on call would inform the appointed named person the following day where the process for investigation as in hours would commence.
- The Manager on call will inform the Risk Management Department at the earliest opportunity by the use of the incident reporting process.

Reporting procedure when SUI determined

- Any SUI investigation will be completed within 28 working days from the decision an SUI had occurred.
- The full RCA report will be presented to the Directorate Governance where actions and learning are agreed.
- The RCA report which includes the actions and learning agreed within the Directorate Governance meetings should be presented to the appropriate assurance committee as agreed by the appointed named person and the identified lead for the investigation.
- The agreed RCA report will be forwarded to Liverpool CCG as per the Serious Incident Framework (March 2013) (see appendix 4 for examples of SUI incidents and appendix 5 for flowchart for reporting).

5. Investigation according to Severity of Incident including process for following up relevant action plans

Within the LHCH incidents are categorised in terms of patient harm therefore action plans will be reviewed according to the level of harm.

- Green / no harm / low harm
  Those incidents categorised as green/low harm are assigned to and investigated by the manager of the department were the incident has occurred.
  Relevant mitigated action will be recorded on the PRISM database before the incident is closed.
  Actions arising from these incidents will be reported through the Governance arrangements within the Directorate.

- Yellow minor short term harm
  Those incidents categorised as yellow low harm are assigned to and investigated by the department manager for the Directorate. Mitigation actions are recorded on PRISM and actions discussed and followed up through the Governance arrangements within the Directorate.

- Amber/ moderate semi permanent harm
  Those incidents categorised as amber/ moderate harm are assigned to the Assistant Directors of Nursing. Mitigation actions are recorded on PRISM and their follow up are reported through the Governance arrangements within the Directorate. Depending upon the incident, the Corporate Readiness Committee would be informed of the incident by the presentation of a Root Cause Analysis report and action plan.

- Red/catastrophic / death / major harm
  Those incidents categorised as red/catastrophic / deaths are assigned to General Managers. Mitigation actions are recorded on PRISM and their follow up are reported to the appropriate assurance committee and though the Governance arrangements within the Directorate. Once the appropriate Directorate Governance Committee has determined that the actions are complete, the Lead for the action plan must forward it to the Senior Audit Officer in the audit department in order that the appropriate actions are audited to ensure changes in practice are embedded.
  During an investigation into any categorisation of incident there may be a need to develop an action plan which may mitigate against that incident re-occurring.

Any action plan should contain the following:
- Have a record of the action
- Responsible person for the action
- Timeframe for completion of action
The integrated incident complaints and claims report features those actions arising from the common themes of reported incidents

6. Patient and Family Involvement in investigation process.

The Trust acknowledges that the involvement of patients and their families in the investigation process of a Serious Incident (Moderate/Catastrophic harm) is the right thing. Careful consideration in the management of this process is crucial in ensuring that timely communications are maintained throughout the investigation process.

Communications should be handled in a sensitive manner and commensurate to the needs of the patient and family.

Within the first 24hrs of notification of the incident a meeting with the relevant staff will be called and documented on the 24hr report as per appendix four. The identified communicator for the patient and their family will then be nominated and will agree with the patient/family agreed timescales when they will be updated as to how the investigation is proceeding and when they will receive the final report.

The details of communications with patient/family must be documented with a date and signature within the file for the investigation.

1. Learning the lessons

Process for involving and communicating with internal and external stakeholders to share safety lessons

Adequate and timely feedback is key to ensuring lessons are learned and applied into everyday practice.

The Trust will use the following methods to ensure this:

- Serious incidents graded as red or amber will be investigated, with the lessons learned being discussed via the Directorate Governance Meetings and the appropriate assurance committee.
- The Mortality Review Group will discuss learning from review of mortality cases. Individual feedback is provided to the Consultant whose patient has received the review. Learning points are provided to the Directorate Governance Groups to share safety lessons.
- Medical Audit days will be used as a means of disseminating lessons learnt.
- The Integrated Incident Complaints and Claims report will be produced twice yearly, collating information from the previous 6 months. This will be sent to the Patient and Family Experience Committee and the Directorate Governance Groups.
- High level enquiries received within the organisation reported through Clinical Quality Committee. Action plans and gap analysis will be developed as a consequence of these enquiries.

In order to share safety lessons externally the Trust attends the Critical Care Network.

8. Raising Concerns / Whistleblowing

The Trust will protect individuals as outlined in the disclosure of public information in the public interest Raising Concerns at Work policy. This was previously known as the Whistle Blowing policy.
9. Confidential and Anonymous Reporting

The person reporting the incident may feel vulnerable and apprehensive, and may choose to report anonymously.

The Trust reiterates that the aim of the incident reporting system is to improve safety and quality. Staff participation is vital for a thorough investigation to take place and ensure that appropriate action is taken.

Staff are advised that all documentation relating to an incident or near miss is potentially disclosable to third parties, i.e., a complainant or claimant solicitor. It is therefore vitally important that fact only and not opinion are recorded when reporting an incident. When possible, this information will be anonymised.

10. Process for Reporting to External Agencies

All serious incidents which meet the definition as described above must be reported to the Care Quality Commission (CQC) after consultation with the appointed named person. This will usually be via the NPSA NRLS reporting structure. Some incidents will require direct reporting to the (CQC) and Monitor. A member of the Risk Management Team will be responsible to ensure this occurs.

Safeguarding Incidents

All allegations of abuse must always be referred immediately to the local multi-agency safeguarding arrangements for adults and children and a safeguarding alert raised (See LHCH Safeguarding Children and Vulnerable Adults Policies).

Safeguarding incidents involving children which are reportable to STEIS are:

- Child abuse (family)
- Child Abuse (institutional)
- Child abuse (multiple)
- Child death
- Child Serious injury

The NPSA National Framework states that a STEIS reportable incident should be reported within 48 hours from the time the incident is known and this is an element that PCTs/Trusts are monitored on by the SHA. However, the Safeguarding Incidents are an exception to this and the full extent of the incident is sometimes not clear until after the initial strategy meeting. Therefore, unless there is media attention, the safeguarding incidents should be reported within 48 hours of the strategy meeting taking place.

If it is an unexpected child death where there are clear suspicious circumstances/safeguarding concerns, these should be reported within the 48 hour timeframe from when the death is known. This is usually done initially by the Acute Provider who receives the child’s body.

It is acknowledged that the suspicious circumstances/safeguarding concerns may not always be known at the time of the incident. As not all cases are straightforward, you may wish to discuss it and if this is the case please contact the Patient Safety Child Safeguarding Lead on 0161 625 7265 (always call Safeguarding Leads for LHCH first).

When an acute or mental health provider reports a STEIS incident, they should include in the description the PCT where the child is resident.
Safeguarding Children Incident Reporting Process

1. Incident Reported

2. Incident Flagged as Major (SUI)

3. Executive Aware

4. Senior Manager Aware

5. SUI Identified

6. Lead Investigator Identified

7. Timeframe Agreed

8. Report Issued

9. Reported at Safeguarding Group
NHS Patients from Wales
When serious incidents involve NHS patients from Wales receiving care in English provider organisations, the commissioner of these patients care in Wales must be informed. This will be the local health board, unless it is specialist care being provided in which case Health Commission Wales must be informed.

Specific Managers across the Trust have duties to report to external agencies when required as listed below. When this reporting takes place, an incident reporting form should be completed and forwarded to the Risk Management Department, so the external reporting can be logged.

In the case of a death, resulting from an incident, the coroner must be informed. This is done by a telephone call from the responsible member of medical staff.

Security Incident Reporting System
There is a requirement to report all physical and non-physical assaults on members of staff to the NHS Security Management Service (NHS SMS) via the Security Incident Reporting System (SIRS). The Risk Management Department will manage this reporting. The Local Security Management Specialist will be informed of any report to this system.

Health and Safety Incidents
The Risk Administrator on advice from the Health and Safety Advisor will contact the Health and Safety Executive with regard to Reporting Injuries, Diseases and Dangerous Occurrences (RIDDOR) by completion of the electronic reporting form available on the HSE website.

Incidents involving Fire
The Estates Manager will report under the requirements of the Firecode HTM 05-01. All outbreaks of fire in the NHS (to which the fire and rescue service has been called) must be reported within 48 hours to the Department of Health, using the on-line efm-information system (www.efm.nhsestates.gov.uk).

The Estates Manager will report more serious outbreaks such as fires involving death, injury, large-scale evacuation or damage on a large scale immediately by e-mail to fire@dh.gsi.gov.uk, by telephone (0113 254 6881) or by fax (0113 254 5793) (with an assessment of the cost involved, if possible). An analysis of fire reports can be obtained via the efm-information system.

Fires involving death or injury must also be reported to the Health and Safety Executive under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR).

Estates Incidents
The Estates Manager will report more serious incidents involving death, injury, large-scale evacuation or damage on a large scale relating to buildings and plant immediately to the Department of Health, Estates and Facilities Management Directorate, using the on-line efm-information system (www.efm.ic.nhs.uk).

Infection Control Incidents
The Trust Catering Manager will report incidents involving food to the Food Standards Agency by telephone. Additionally, any incidents of food poisoning or suspected food poisoning will be reported to the Environmental Health Service by telephone.

The Trusts Consultant Microbiologist will report incidents involving Salmonella and Legionnaires to Environmental Health

Medical Device Incidents
The Manager of the Trusts Medical Engineering Department will report incidents relating to medical devices to the Medical and Healthcare Products Regulatory Agency (MHRA) on-line.
Clinical Negligence
For Clinical Negligence or other incidents resulting in a claim, the Trust Litigation Department will inform NHSILA & CNST by a letter from the Legal Services Manager.

Reportable Drug Incidents
The Trust's Chief Pharmacist will report Incidents involving faulty drug products to the Medical and Healthcare Products Regulatory Agency (MHRA) Defective Medicines Report Centre by telephone or e-mail using the regional quality control cascade system.

The Trust's Chief Pharmacist will report incidents involving adverse reaction to drugs via the yellow card scheme: Medicines Control Agency – Committee for Safety of Medicines. This will be done by completing and posting a yellow card to the MHRA.

Radiotherapy Incidents
The Trust's Clinical Lead for Nuclear Medicine, Radiotherapy or Radiology will ensure that radiation incidents which are required to be reported under the Ionising Radiation (Medical Exposure) Regulations 2000 are reported by the Radiation Protection Supervisor to the Department of Health. This is done by letter.

The Trust's Infection Control Team will report infectious disease outbreaks to Merseyside and Cheshire Health Protection Unit by phone.

Blood Transfusion
The Trust's Blood Transfusion Team will report all Serious Hazards of Transfusion (SHOT) via the Serious Adverse Blood Reactions and Events (S.A.B.R.E.) on-line system.

11. Helpline to Deal with Multiple Enquiries

Setting up a helpline/hotline to deal with multiple enquiries following a local or national incident

The Trust has set up several helplines in the past, the venue and structure of which have varied according to the circumstances and nature of the incident.

The following will assist in setting out a proposed Help line facility to deal with multiple enquiries, a decision will be taken as to the most appropriate facilities, dependent on the circumstances of the incident.

The Chief Executive or Executive Lead will nominate an individual to manage the setting up of a helpline. That person will be responsible for assessing the requirements, setup and management.

Helplines may be set up in the medical secretariat where there are a number of telephone lines and computers available.

- The Help line Manager will:
- Work with key staff to identify staff to man the helpline, taking into consideration the level of knowledge, experience & communication skills required
- Discuss the advertising of the helpline with the person responsible for media relations, and produce guidelines for the staff manning the helpline.
- Consideration will be given to expected level of calls and the timeframe it may need to be manned.
- If staff from clinical areas are diverted for the help line, consideration will need to be given regarding the arranging of agency or locum cover if required. If other staff are used the impact of them not being able to carry out their usual roles will need to be considered.
- The Helpline staff will use documentation as in communications and media and helpline packs for the recording of calls taken and advice given.
- Consideration needs to be given to provision of support & counselling to Helpline staff.
- Production of guidance / advice to switchboard staff should be considered.
• It may also be necessary to setup a hotline reserved for high level calls in and out of the Trust – for example for NHS Northwest

12. **Policy Implementation Plan**

The Director of Nursing will be responsible for ensuring the implementation of this policy. It will be ratified by the Corporate Readiness Committee

Staff will be made aware of this policy by the Governance structures within the Directorates.

**Training**

In order to ensure that staff have sufficient awareness of risk management incident reporting, training will be made available to staff on Corporate induction and thereafter as part of their mandatory training as detailed in the Induction and Mandatory Policy and Procedure Learning Needs Analysis (LNA) appendix 4. Following up non attendance at face to face corporate induction and mandatory training will be performed by the Learning and Development department by monthly exception reporting to department managers.

Training will be delivered at Corporate Induction and thereafter annual mandatory training sessions. For specific staff groups refer to the Trust Learning Needs Analysis.

Training sessions will cover
• Risk Management
• Health & Safety
• Incident reporting
• Root Cause Analysis

13. **Monitoring and Compliance**

Compliance with the requirements of this policy will be monitored against NHS Litigation Authority (NHSLA) minimum requirements as set out below. A monitoring report will be produced by the Patient Safety Lead / Clinical Risk Manager. Where the report identifies deficiencies, the Patient Safety Lead/ Clinical Risk Manager will produce an action plan to address these. The monitoring report and the action plan will be presented to Corporate Readiness Committee which will be responsible for reviewing the action plan on at least a quarterly basis until the actions are complete.

14. **References**


“Being Open” National Patient Safety Agency 2005
Further information and e –Learning module can be found at [www.npsa.uk](http://www.npsa.uk)

Serious Incident Framework March 2013 NHS Commissioning Board
# APPENDIX 1

## Key Stakeholders / Contacts

<table>
<thead>
<tr>
<th>Organisation/Contact</th>
<th>Contact details</th>
<th>Reporting requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chief Executive</td>
<td>Internal-1366</td>
<td></td>
</tr>
<tr>
<td>Medical Director</td>
<td>Internal-1706</td>
<td></td>
</tr>
<tr>
<td>Director of Nursing</td>
<td>Internal-1631</td>
<td></td>
</tr>
<tr>
<td>Head of Governance</td>
<td>Internal-1653</td>
<td></td>
</tr>
<tr>
<td>Governance &amp; Safety Lead</td>
<td>Internal-1051</td>
<td></td>
</tr>
<tr>
<td>Liverpool CCG</td>
<td>In office hours switchboard 0151 296 7476</td>
<td>To report adverse incidents via STEIS as in guidelines.</td>
</tr>
<tr>
<td>Health and Safety Executive</td>
<td><a href="http://www.hse.gov.uk">www.hse.gov.uk</a></td>
<td>Report as under RIDDOR</td>
</tr>
<tr>
<td>Hill Dickinson – Trust Solicitors</td>
<td>0151 600 8000</td>
<td>For advice on any legal issues</td>
</tr>
<tr>
<td>Medicines and Healthcare products Regulatory agency (MHRA)</td>
<td>020 7210 3000 <a href="http://www.mhra.gov.uk">www.mhra.gov.uk</a></td>
<td>Voluntary user reporting of Incidents involving medical devices</td>
</tr>
<tr>
<td>Needle stick injury</td>
<td>Contact via LHCH switch to Aintree Occupational Health</td>
<td>Following a sharps injury</td>
</tr>
<tr>
<td>NHS Litigation Authority</td>
<td>020 7430 8700</td>
<td>Any claim or incident/complaint that may result in a claim</td>
</tr>
<tr>
<td>Clinical – team leader</td>
<td></td>
<td></td>
</tr>
<tr>
<td>RIDDOR</td>
<td>0845 300 9923 <a href="mailto:riddor@nabrit.com">riddor@nabrit.com</a></td>
<td>Refer to RIDDOR Guide in resource folders</td>
</tr>
<tr>
<td>Serious Hazards of Transfusion</td>
<td>Manchester Blood Service Plymouth Grove Manchester M13 9LL email: <a href="mailto:shot@nbs.nhs.uk">shot@nbs.nhs.uk</a> tel: 0161 251 4208</td>
<td>Voluntary user reporting of Incidents involving blood transfusion</td>
</tr>
<tr>
<td>Neighbouring Trusts</td>
<td>Listed in the stakeholder data source on the intranet miscellaneous section and available at switchboard</td>
<td>If the incident crosses the boundaries of care or ongoing support of patients or high media interest expected</td>
</tr>
<tr>
<td>Local GP’s</td>
<td>Listed in the stakeholder data source on the intranet miscellaneous section</td>
<td>If the incident crosses the boundaries of care or ongoing support of patients or high media interest expected</td>
</tr>
<tr>
<td>Liverpool City Council</td>
<td>0151 233 3000/1300 362170</td>
<td>If the incident crosses the boundaries of care or high media interest expected</td>
</tr>
<tr>
<td>Merseyside Police</td>
<td>0151 709 6010</td>
<td>Incidents where criminal activity suspected</td>
</tr>
<tr>
<td>Coroner</td>
<td>Mon-Fri 08:00 to 17:30 0151 233 4701 Out of hours Pager 07669178252 0151 709 6010 [via police]</td>
<td></td>
</tr>
<tr>
<td>Mersey Regional Ambulance Service NHS Trust</td>
<td>0151 260 5220</td>
<td>If the incident crosses the boundaries of care or ongoing support of patients or high media interest expected</td>
</tr>
<tr>
<td>NHS Direct</td>
<td>020 7599 4200</td>
<td>In the case of high media interest</td>
</tr>
<tr>
<td>Department of health</td>
<td>0207 210 4850</td>
<td></td>
</tr>
<tr>
<td>Health Care Commission</td>
<td>020 7448 9200 helpline 0845 601 3012</td>
<td>The Healthcare Commission is an independent body, set up to promote and drive improvement in the quality of healthcare and public health</td>
</tr>
<tr>
<td>Environmental health</td>
<td>Refer to Infection Prevention Team</td>
<td>Incidents relating to environment for example food hygiene or Legionella.</td>
</tr>
<tr>
<td>Social Services</td>
<td>Via LHCH switchboard</td>
<td>If the incident crosses the boundaries of care or ongoing support of patients</td>
</tr>
</tbody>
</table>
**APPENDIX 2**

**INCIDENT DECISION TREE**

*Work through the tree separately for each individual involved*

**Start Here**

<table>
<thead>
<tr>
<th>Deliberate Harm Test</th>
<th>Incapacity Test</th>
<th>Foresight Test</th>
<th>Substitution Test</th>
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<tbody>
<tr>
<td>Were the actions as intended?</td>
<td>Does there appear to be evidence of ill health or substance abuse?</td>
<td>Did the individual depart from agreed protocols or safe procedures?</td>
<td>Would another individual coming from the same professional group, possessing comparable qualifications and experience, behave in the same way in similar circumstances?</td>
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Consult NCAA or relevant regulatory body
Adviser individual to consult Trade Union Representative
Consider:
• Suspension
• Referral to police and disciplinary/regulatory body
• Occupational Health referral

Consult NCAA or relevant regulatory body
Adviser individual to consult Trade Union Representative
Consider:
• Occupational Health referral
• Reasonable adjustment to duties
• Sick leave

Adviser individual to consult Trade Union Representative
Consider:
• Corrective training
• Improved supervision
• Occupational Health referral
• Reasonable adjustment to duties

Consult NCAA or relevant regulatory body
Adviser individual to consult Trade Union Representative
Consider:
• Referral to disciplinary/regulatory body
• Reasonable adjustment to duties
• Occupational Health referral
• Suspension

Highlight any System Failures identified

Highlight any System Failures identified

Highlight any System Failures identified

Highlight any System Failures identified

* Based on James Reason's Culpability Model

**System Failure**

Review system
APPENDIX 3

Root Cause Analysis (RCA) Procedure
This is a structured investigation that aims to identify the true cause of a problem and the actions that are necessary to eliminate or significantly reduce the risk.

The beginning of the RCA process should commence with the completion of the NPSA Incident Decision Tree (accessed via the NPSA website).

This is followed by the completion of a tabular timeline. This information informs the chronological episodes of the incident.

Flowchart

Collect the facts
- What happened?
- Witnesses
- Physical evidence
- Sketches or photographs
- Records and Documentation
- Medical Evidence Etc.

Analyse the facts
- How did it happen?
- Causal factors
- What happened throughout the chain of events?
- Focus on problem-solving not on blame.
- System and process based – don’t concentrate on the individual.

Integrate evidence and establish causes.
- Why did it happen?
- Findings
- Probable causes
- Judgements of need.

Make recommendations

Principles
- Utilise other individual’s skills and knowledge i.e. use multidisciplinary teams
- Concentrate on the facts only and avoid subjectivity
- Avoid early judgements, blame or assumption

Methodology
May need to include a variety of approaches such as:
- Interviews
- Statement writing
- Review of documentation
- Direct observation

Process
- Outline the sequence of pertinent events in chronological order
- State the immediate action taken; including when the event took place, where it occurred and who was involved.
- Identify the causal factors leading up to each pertinent event.
- Analyse the causal factors for example; Equipment failure, Team performance, Training
- Produce a report using the Root cause analysis form on the intranet
- Provide recommendations which may prevent reoccurrence in the form of an action plan with named leads and agreed timescales.

It is essential that at the conclusion of a root cause analysis lessons have been learnt and that changes are recommended which will ultimately enable the Trust to improve patient care, to be a safe place of work for its staff, and to be a safe environment for its patients, visitors and contractors.
### APPENDIX 4

**A guide to serious incident grading (Serious Incident Framework March 2013)**

<table>
<thead>
<tr>
<th>Incident Grade</th>
<th>Example Incidents (these are suggestions, not definitive)</th>
<th>Investigation Grade and action</th>
<th>Timeframe</th>
</tr>
</thead>
</table>
| **1**          | **Grade 1 incident examples:**  
  - Apparent suicide of people currently under the care of community mental health services.  
  - Mental health inpatient attempted suicides.  
  - Avoidable or unexplained death.  
  - Failure to meet standards for ambulance service response times, resulting in patient death/severe harm  
  - HCAI outbreaks.  
  - Grade 3 and 4 pressure ulcers.  
  - Data loss & information security (DH Criteria level 2)<sup>iv</sup>.  
  - Adult safeguarding incident.  
  - Never events  
  - Accusation of physical misconduct or harm  
  - Data loss and information security (DH Criteria level 3-5)<sup>xv</sup>. | **Investigation Level 1**  
  - Concise root cause analysis (RCA) for incidents involving No Harm and Low Harm and/or where the circumstances are very similar to other previous incidents. In these cases it is more proportionate to use a concise RCA to ensure there are no unique factors and then focus resources on implementing improvement than conducting comprehensive investigations that will not produce new learning. These will be a small minority of cases. | **Following initial reporting within 2 working days**, the provider organisation must submit a completed investigation **within 45 working days** |

| **2** | **Grade 2 incident examples:**  
  - Inpatient suicides (including following absconsion)  
  - Maternal deaths  
  - Child protection incidents  
  - Never events  
  - Accusation of physical misconduct or harm  
  - Data loss and information security (DH Criteria level 3-5)<sup>xv</sup> | **Investigation Level 2**  
  - Comprehensive RCA for incidents involving moderate and severe harm or death. This should be the default level for most incidents. | **Following initial reporting within 2 working days**, the provider organisation must submit a completed investigation **within 60 working days** |
**Selected Grade 2 incidents:**
The need for independent investigations is identified and arranged by the commissioner or NHS CB, for example a major system failure with multiple stakeholders. Homicides following recent contact with mental health services require an independent investigation. These will be commissioned by the relevant NHS CB area team.

**Investigation Level 3**
Independent RCA (note NHS trusts should directly notify the NTDA of Grade 2 serious incidents)

Following initial reporting within 2 working days independent investigators should be commissioned to complete an investigation within 6 months.
APPENDIX 5

Taken from Serious Incident Framework (March 2013)

Steps to be taken when a serious incident occurs – simplified flowchart

Incident occurs → Report to local reporting systems → Inform patient → Report to commissioner, and other relevant organisations if not already aware (eg TDA for Grade 2 SIs in NHS Trusts) within two working days of incident being identified → Grade incident

Ensure recorded on STEIS (administered by Area Teams) → Review grading with commissioner (and Area team if necessary) → Undertake investigation, keeping patient / their family and relevant organisations → Establish appropriate investigation → Develop action plan → Submit incident investigation report and action plan to commissioner (as appropriate) within 45 days for Grade 1, 60 days for Grade 2 incidents or six months for Grade 2 incidents involving independent investigation → Depending on incident grade*

Commissioner signs off incident as closed → Implement Action Plan → Share learning if appropriate → Review implementation of actions

*Incident grade dictates whether an action plan must only be submitted or must actually be implemented before incident closure.
APPENDIX 6

Never Event List 2012

The expanded “never event” list is, in the view of the Department of Health, a reasonable list of events that are unacceptable and eminently preventable in the NHS. It is the list that all organisations providing NHS care should work from.

SURGICAL

1. Wrong site surgery

A surgical intervention performed on the wrong site (for example wrong knee, wrong eye, wrong patient, wrong limb, or wrong organ); the incident is detected at any time after the start of the operation and the patient requires further surgery, on the correct site, and/or may have complications following the wrong surgery.

- Includes biopsy, radiological procedures and drain insertion, where the intervention is considered surgical.
- Excludes wrong site anaesthetic block.
- Excludes interventions where the wrong site is selected because of unknown/unexpected abnormalities in the patient’s anatomy. This should be documented in the patient’s notes.

Setting: All healthcare premises.

Guidance:

2. Wrong implant/prosthesis

Surgical placement of the wrong implant or prosthesis where the implant/prosthesis placed in the patient is other than that specified in the operating plan either prior to or during the procedure. The incident is detected at any time after the implant/prosthesis is placed in the patient and the patient requires further surgery to replace the incorrect implant/prosthesis.

- Excludes where the implant/prosthesis placed in the patient is intentionally different from the operating plan, where this is based on clinical judgement at the time of the operation.
- Excludes where the implant/prosthesis placed in the patient is intentionally planned and placed but later found to be suboptimal.

Setting: All healthcare premises.

Guidance:

3. Retained foreign object post-operation

Unintended retention of a foreign object in a patient after surgical intervention, including interventional radiology, cardiology and vaginal birth.
• Includes swabs, needles, implants, fragments of screws, instruments and guidewires.
• Excludes where any relevant objects are found to be missing prior to the completion of the surgical intervention and may be within the patient, but where further action to locate and/or retrieve would be more damaging than retention, or impossible. This must be documented in the patient's notes and the patient informed.

Settings: All healthcare premises.

Guidance:

**MEDICATION EVENTS**

### 4. Wrongly prepared high-risk injectable medication

Death or severe harm as a result of a wrongly prepared high-risk injectable medication.

- High-risk injectable medicines are identified using the NPSA’s risk assessment tool†. A list of high-risk medicines has been prepared by the NHS Aseptic Pharmacy Services Group using this tool†. Organisations should have their own list of high-risk medications for the purposes of the “never event” policy, which may vary from the NHS Aseptic Pharmacy Services Group list, depending on local circumstances.
- A high risk injectable medicine is considered wrongly prepared if it was not;
  - prepared in accordance with the manufacturer's Specification of Product Characteristics;
  - prepared in accordance with a protocol formally agreed by the local organisation (for example for off-label or unlicensed product use);
  - prepared in accordance with patient specific directions of a prescriber in an urgent or emergency situation and supported by evidence or expert advice.
- This event excludes any incidents that are covered by other “never events”.
- Where death or severe harm cannot be attributed to incorrect preparation, treat as a Serious Untoward Incident.

Setting: All healthcare settings.

Guidance:

### 5. Maladministration of potassium-containing solutions

Death or severe harm as a result of maladministration of a potassium-containing solution. Maladministration refers to;

- selection of strong‡ potassium solution instead of intended other medication,
- wrong route administration, for example a solution intended for central venous catheter administration given peripherally,
- infusion at a rate greater than intended.

Setting: All healthcare settings.

Guidance:
- Standard Operating Protocol fact sheet; Managing Concentrated Injectable Medicines, part of the WHO High 5’s project, available at https://www.high5s.org/bin/view/Main/WebHome
6. Wrong route administration of chemotherapy

Intravenous or other chemotherapy (for example, vincristine) that is correctly prescribed but administered via the wrong route (usually into the intrathecal space).

Setting: All healthcare premises.

Guidance:

7. Wrong route administration of oral/enteral treatment

Death or severe harm as a result of oral/enteral medication, feed or flush administered by

≥10% potassium w/v (eg ≥ 0.1mg/ml potassium chloride, 1.3mmol/ml potassium chloride) any parenteral route.

Setting: All healthcare settings.

Guidance:

8. Intravenous administration of epidural medication

Death or severe harm as a result of intravenous administration of epidural medication.

• A broader “never event” covering intravenous administration of intrathecal medication or intrathecal administration of intravenous medication is intended once the deadlines for Patient Safety Alert 004A and B actions have passed.

Setting: All healthcare premises.

Guidance:
- Safer spinal (intrathecal), epidural and regional devices - Parts A and B, available at http://www.nrls.npsa.nhs.uk/resources/?EntryId45=94529

9. Maladministration of Insulin

Death or severe harm as a result of maladministration of insulin by a health professional.

Maladministration in this instance refers to when a health professional

• uses any abbreviation for the words ‘unit’ or ‘units’ when prescribing insulin in writing,
• issues an unclear or misinterpreted verbal instruction to a colleague,
• fails to use a specific insulin administration device e.g. an insulin syringe or insulin pen to draw up or administer insulin, or
• fails to give insulin when correctly prescribed. Setting: All healthcare settings.
Guidance:

10. Overdose of midazolam during conscious sedation

Death or severe harm as a result of overdose of midazolam injection following use of high strength midazolam (5mg/ml or 2mg/ml) for conscious sedation.

• Excludes areas where use of high strength midazolam is appropriate. These are specifically only in general anaesthesia, intensive care, palliative care, or where its use has been formally risk assessed.
• Excludes paediatric care.

Setting: All healthcare premises.

Guidance:

11. Opioid overdose of an opioid-naïve patient

Death or severe harm as a result of an overdose of an opioid given to a patient who was opioid naïve. Specifically this means:

Where a dose is used that is not consistent with the dosing protocol agreed by the healthcare organisation, or the manufacturer’s recommended dosage for opioid-naïve patients*.  
• Where the prescriber fails to ensure they were familiar with the therapeutic characteristics of the opioid prescribed.
• Excluded are cases where the patient was already receiving opioid medication.

Setting: All healthcare settings.

Guidance:
- *Specific Product Characteristics available at www.medicines.org.uk

12. Inappropriate administration of daily oral methotrexate

Prescription, supply or administration of daily oral methotrexate to a patient for non-cancer treatment including supply to the patient with the instruction to take daily.

• Excludes cancer treatment with daily oral methotrexate
• Excludes where the error is intercepted before the patient is supplied with the medication.

Setting: All healthcare settings.

Guidance:
### MENTAL HEALTH

#### 13. Suicide using non-collapsible rails N/A

Death or severe harm to a mental health inpatient as a result of a suicide attempt using non-collapsible curtain or shower rails.

**Setting:** All mental health inpatient premises.

**Guidance:**

#### 14. Escape of a transferred prisoner

A patient who is a transferred prisoner escaping from medium or high secure mental health services where they have been placed for treatment subject to Ministry of Justice restriction directions.

**Setting:** All medium and high secure mental health inpatient premises.

**Guidance:**

### GENERAL HEALTHCARE

#### 15. Falls from unrestricted windows

Death or severe harm as a result of a patient falling from an unrestricted window.

- Applies to windows “within reach” of patients. This means windows (including the window sill) that are within reach of someone standing at floor level and that can be exited/fallen from without needing to move furniture or use tools to assist in climbing out of the window.

- Includes windows located in facilities/areas where healthcare is provided and where patients can and do access.

- Includes where patients deliberately or accidentally fall from a window where a restrictor has been fitted but previously damaged or disabled, but does not include events where a patient deliberately disables a restrictor or breaks the window immediately before the fall.

**Setting:** All healthcare premises.

**Guidance:**
<table>
<thead>
<tr>
<th>16. Entrapment in bedrails</th>
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<tbody>
<tr>
<td>Death or severe harm as a result of entrapment of an adult in bedrails that do not comply with Medicines and Healthcare products Regulatory Agency (MHRA) dimensional guidance.</td>
</tr>
<tr>
<td>Setting: All adult inpatient care premises.</td>
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<td>Guidance:</td>
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<tr>
<th>17. Transfusion of ABO-incompatible blood components</th>
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<tbody>
<tr>
<td>Death or severe harm as a result of the inadvertent transfusion of ABO-incompatible blood components.</td>
</tr>
<tr>
<td>• Excludes where ABO-incompatible blood components are deliberately transfused with appropriate management.</td>
</tr>
<tr>
<td>Setting: All healthcare premises.</td>
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<td>Guidance:</td>
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<table>
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<tr>
<th>18. Transplantation of ABO or HLA-incompatible organs</th>
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<tr>
<td>Death or severe harm as a result of inadvertent HLA (Human Leukocyte Antigen) or ABO antibody-incompatible solid organ transplantation, where the antibodies are of clinical significance.</td>
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<tr>
<td>• Excluded are scenarios in which clinically appropriate ABO and/or HLA incompatible solid organs are transplanted deliberately.</td>
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<tr>
<td>• In this context, ‘incompatible’ antibodies must be clinically significant. If the recipient has donor-specific anti-ABO and/or anti-HLA antibodies and is therefore likely to have an immune reaction to a specific ABO and/or HLA incompatible organ, then it would be a “never event” to transplant that organ inadvertently and without appropriate management.</td>
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<td>Setting: All healthcare premises.</td>
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<td>Guidance:</td>
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19. Misplaced naso- or oro-gastric tubes

Death or severe harm as a result of a naso- or oro-gastric tube being misplaced in the respiratory tract.

Setting: All healthcare premises.

Guidance:
- Patient safety alert – Reducing harm caused by misplaced naso and orogastric feeding tubes in babies under the care of neonatal units, 2005, available at http://www.nrfs.npsa.nhs.uk/resources/?entryid45=59798&q=0%c2%acnasogastric%c2%ac

20. Wrong gas administered

Death or severe harm as a result of the administration of the wrong gas, or failure to administer any gas, through a line designated for Medical Gas Pipeline Systems (MGPS) or through a line connected directly to a portable gas cylinder.

Setting: All healthcare premises.

Guidance:

21. Failure to monitor and respond to oxygen saturation

Death or severe harm as a result of failure to monitor or respond to oxygen saturation levels in a patient undergoing general or regional anaesthesia, or conscious sedation for a healthcare procedure (e.g. endoscopy).

• Includes failure to physically have monitoring in place, and failure to act on relevant information from monitoring oxygen saturation.

Excludes where action is taken in response to recorded adverse oxygen saturation levels, but this fails to prevent death or severe harm for other reasons (e.g. pre-existing problems with oxygenation that cannot be resolved).

• Excludes where the accepted limitations of monitoring equipment mean that adverse readings may be artefactual (e.g. shock/vasoconstriction).

Setting: All healthcare premises.

Guidance:
22. Air embolism

Death or severe harm as a result of intravascular air embolism introduced during intravascular infusion/bolus administration or through a haemodialysis circuit.

- Excludes the introduction of air emboli through other routes. This therefore excludes introduction via surgical intervention (particularly Ear, Nose and Throat surgery and neurosurgery), during foam sclerotherapy and during the insertion of a central venous catheter.
- Introduction of an air embolism after the insertion of a central venous catheter, through the line, and during its removal, is included.
- Excludes where the introduction of the air embolism was caused by the actions of the patient.

Settings: All healthcare premises.
Guidance:
Avoidance of air embolism is part of basic training of clinicians, hence a lack of additional alerts to date. However, this is to be the subject of a forthcoming evidence based guideline from the Society of Acute Medicine. More information and basic instruction is available from the following medical texts;
- pp 366-372, Lippincott’s Nursing Procedures, Lippincott, Williams and Wilkins
- pp254-256, Clinical Dialysis, Nissenson AR and Fine RN

23. Misidentification of patients

Death or severe harm as a result of administration of the wrong treatment following inpatient misidentification due to a failure to use standard wristband (or identity band) identification processes.

Failure to use standard wristband identification processes means;
- failure to use patient wristbands that meet the NPSA’s design requirements,
- failure to include the four core patient identifiers on wristbands – last name, first name, date of birth and NHS number,
- failure to follow clear and consistent processes for producing, applying and checking patient wristbands,
- printing several labels with patient details at one time.

This event excludes where the patient refuses to wear a wristband despite a clear explanation of the risks of not doing so, or where it has been documented that the patient cannot wear a wristband due to their clinical condition or treatment, or in emergency care environments where high patient turnover, insufficient patient identity information, or the need for rapid treatment can delay wristband use.

Setting: All healthcare premises.
Guidance:
24. Severe scalding of patients

Death or severe harm as a result of a patient being scalded by water used for washing/bathing.

- Excludes scalds from water being used for purposes other than washing/bathing (eg from kettles)

Settings: All healthcare premises.

Guidance:
- Hospital Technical Memorandum HTM64 (Sanitary assemblies), 2006, available from http://www.spaceforhealth.nhs.uk/

MATERNITY

25. Maternal death due to post partum haemorrhage after elective caesarean section

In-hospital death of a mother as a result of haemorrhage following elective caesarean section.

- Excludes cases where placenta accreta is found, or where there is a pre-existing bleeding disorder, or the mother refuses blood components for any reason.
- Excludes emergency caesarean section and where a scheduled elective caesarean section is brought forward.

Setting: All healthcare premises.

Guidance
- Saving mothers’ lives: Reviewing maternal deaths to make motherhood safer – 2003-2005,
<table>
<thead>
<tr>
<th>Name of Lead Clinician/Manager or Committee Chair</th>
<th>Position of Endorser or Name of Endorsing Committee</th>
<th>Date</th>
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