

## Serious Incident (SI) Policy

CG 04

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## Essential Contact Numbers – Quick Reference Guide

<b>SERIOUS INCIDENTS (SIs)</b>	
<b>In hours 09.00 – 17.00 Monday to Friday (Except Public Holidays)</b>	<b>Out of Hours 17.01 – 08.59 Evenings, nights, weekends and Public Holidays</b>
Immediately contact a member of the Patient Safety Team (Ext. 1448 / 4632 / 3175) who will ensure onward reporting and will contact the Director of Quality & Safety (Ext. 3858 / 3711) or the Medical Director (Ext. 1262)	Contact the Site Manager who will contact the Executive Director on-call
The Serious Incident Coordinator will immediately complete the serious untoward incident module reporting form on UNIFY (previously referred to as STEIS) on-line system. (Once saved an email alert will automatically be sent to the Strategic Health Authority via a link).	<b><u>Out of Hours Immediate Contact</u></b> Immediately contact NHS West Midlands Director on-call, contact number 01384 215 684 when the following circumstances apply:
<b><u>Reporting Timeframe</u></b> All reports must be completed via the online reporting system by 17:00 within two working days or at the earliest point thereafter with an explanation of the delay.	<ul style="list-style-type: none"> <li>• Unexplained/avoidable death or serious injury of a patient, member of staff or member of the public</li> <li>• A never event</li> <li>• Major Incidents: Incidents which necessitate activation of the Trust Major Incident Plan. <i>(In this instance the SHA Director and ERMA 3 Commander on call would be contacted on 01384 215 684).</i></li> <li>• Media Interest: Incidents which will give rise to significant media interest or will be of interest to other agencies such as Police or other external agencies.</li> <li>• Public Concern: Incidents which will be or significant public concern.</li> </ul>
<b><u>Advice from the SHA</u></b> Should the Trust require advice please contact the Head of Patient Safety, NHS West Midlands on 0121 695 2279 / 0121 695 2591 (within office hours).	
<b><u>Urgent Contact</u></b> When the incident has very significant implications in terms of clinical, managerial or media issues, the Trust is expected to contact the Head of Patient Safety immediately by telephone. The Director of Nursing and Workforce will be alerted and involve SHA CE/Director colleagues as appropriate).	
<b><u>Media Interest</u></b> Where media interest is likely, the Trust Communication Team are expected to make contact with the SHA Communications Team, 0121 695 2252.	<b><u>Decision to Report Out of Hours</u></b> If there is a SI out of hours it must be the Chief Executive of the Trust or the Director on call only who makes the decision to report and also makes the telephone call to First Response Agency 01384 215 684 to contact the SHA Director on-call. The on-line SI form must then be completed on the second working day.
<b><u>Commissioner Involvement</u></b> The Trust must also inform their Co-ordinating Commissioner. This will usually be done by the Director of Quality and Safety or Patient Safety Team Manager.	<b><u>Reporting Timeframe</u></b> For incidents outside the above list, the on-line reporting form must be completed by the Trust reporter as soon as possible, but in any case, by the second working day.

## Executive Summary

Serious incidents in healthcare are relatively uncommon, however when they do occur the National Health Service (NHS) has a responsibility to ensure that there are systemic measures in place for safeguarding of people, property, NHS resources and reputation. This includes the responsibility to learn from these incidents in order to minimise the risk of them happening again.

This policy establishes a clear approach to handling a Serious Incidents (SIs). It is designed to help SaTH staff take appropriate steps in the best interests of patients/clients/service users, staff, and the NHS as a whole. It contains the minimum reporting requirements expected in the West Midlands. Underpinning all of these processes is a system of good governance that promotes a culture of openness and an attitude that facilitates learning from all incidents. This should include prompt reporting, appropriate and robust investigation, action planning, learning and follow-up and where necessary communications management.

The Director of Quality and Safety is the Board lead for Patient Safety and the Head of Nursing is the designated deputy.

The Trust will increasingly liaise with Commissioning organisations. The handover of this responsibility from the SHA will be accompanied by appropriate support for this new function within Commissioning organisations. This policy and procedure contains SI reporting criteria to guide the Trust, but where there are any doubts about thresholds of reporting these should be discussed with the Head of Patient Safety at NHS West Midlands.

Additionally this policy and procedure provides guidance for the Trust when involved in an SI spanning organisational boundaries. In this situation the organisations responsible for the patient's care at the time the incident occurred should co-ordinate and manage the SI investigation and reporting process.

It is important that all organisations work together to manage serious incidents appropriately and sensitively to resolve all incidents. In order to do this a lead organisation must be agreed between all interested parties.

**SI reporting does not mean that organisations need not comply with all other statutory and internal NHS reporting requirements. Specific requirements in the case of particular SIs are discussed within the final section of the document.**

## 1 Introduction

This policy and procedure replaces all previous Trust guidance on serious incidents. In line with the Department of Health (DH) commissioned review of serious incident reporting<sup>1</sup> (*National Framework for Reporting and Learning from Serious Incidents Requiring Investigation* (NPSA, 2010) Serious Untoward Incidents will henceforth be known as Serious Incidents (SIs) and for consistency will be referred to as SIs throughout this document.

The purpose of this policy and procedure is to:

- provide a consistent definition of a serious incident for investigation
- clarify roles and responsibilities
- provide information on notification requirements and timescales
- draw together legal and regulatory requirements associated with the notification and management of serious incidents.

This policy supports openness, trust, continuous learning and service improvement from SIs.

Healthcare is a complex, high risk activity where it is inevitable that occasionally some things will go wrong. SIs in the NHS, and within NHS funded healthcare, are relatively uncommon considering the high number of people receiving care.

When a SI occurs it can have a devastating and far reaching effect. The effect may impact not only on those people directly involved, be they patients, relatives, staff or visitors, but also for the reputation of the health care organisation, the service or the profession within which the incident occurred, and also on the wider NHS.

The National Patient Safety Agency (NPSA) is responsible for the National Reporting and Learning Service (NRLS). The NPSA, through its work, supports a culture that enables staff willingness to report and discuss incidents. The ethos of the NPSA represents an important move away from a culture of blame to one of openness and learning from incidents.

A new Serious Incident Management system (SIM) is under development by the NPSA. Until it is available the UNIFY system will continue to be used for the reporting of SIs. The Commissioners should be notified directly by this system.

Promoting safety by reducing error is a key priority for the NHS, particularly since the publication of *An Organisation with a Memory*<sup>2</sup> (Department of Health, 2000) which emphasises the importance of learning from adverse events. The national framework) describes the implementation of recommendations from the previous report including the National Reporting and Learning System (NRLS). The purpose of the NRLS is to record, analyse and learn from serious incidents, ensuring that lessons learnt in one part of the NHS are properly shared across the whole health community.

The Trust is required by the DH to provide reports on serious incidents to the SHA and Lead Commissioners. Commissioners are required to have systems in place for reporting SIs in accordance with the requirements of the National Framework.

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<sup>1</sup> NPSA, "*National Framework for Reporting and Learning from Serious Incidents Requiring Investigation*", 2010

<sup>2</sup> Department of Health, "*An Organisation with Memory*", 2000

The Trust has legal and mandatory requirements to report serious incidents to external bodies and stakeholders. From 1 April 2010 there is a statutory duty to notify the Care Quality Commission (CQC) of certain events and this policy takes account of CQC guidance.

This policy is not intended to replace the duty to inform, for example, the Police and other authorities, such as Social Services, Counter Fraud and Security Management Services (CF&SMS), Local safeguarding Boards for Children and Adults where appropriate or the Health and Safety Executive (in accordance with RIDDOR 1995).

The SHA will seek assurances from Commissioners that the Trust has a robust system for reporting and monitoring performance of services. There is an expectation that all SIs will be thoroughly investigated and associated action plans implemented.

The Trust will work closely with the Care Quality Commission (CQC) to provide assurance that the Trust is reporting, managing and investigating all serious incidents appropriately.

Please note this policy must be read in conjunction with the Procedure for the Reporting and Investigation of Incidents, Complaints & Claims, which includes the management of serious incidents.

## **2 Purpose and Scope of Policy**

The purpose of this policy is to ensure that a serious incident is managed effectively to minimise any harm / further harm to patients and to minimise the consequences for the Trust.

This policy follows the new NPSA framework "*National Framework for Reporting and Learning from Serious Incidents Requiring Investigation*" (National Patient Safety Agency, 2010) making use of the new definition of a Serious Incident. It supports and encourages an open and honest culture supportive of continual learning

This policy gives an outline of the overall management of a serious incident (SI) within any area of the Trust and all departments and services need to ensure that they have the necessary systems in place to enable these procedures to be followed.

This policy does not interfere with existing lines of accountability and does not replace the duty to inform the police and/or other organisations or agencies where appropriate. Specific national guidance governs certain other types of incidents for example:

- Reporting to the Health & Safety Executive under RIDDOR, homicides and other significant incidents involving mentally ill people (HSG19 94/27)<sup>3</sup> and subsequent updates (Department of Health, 2005),
- Medicines and Healthcare Products Regulatory Agency (MHRA) in the case of equipment failure and medicines related incidents,
- The Counter Fraud and Security Management Service (CFSMS) in the case of fraud

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<sup>3</sup> Department of Health, *HSG19 94/27 :Guidance on the discharge of mentally disordered people and their continuing care in the community*" 1994



- The Health Protection Agency (HPA) in cases involving infectious disease, and for arrangements for dealing with major incidents (HSC 98,1974, Department of Health, 1998).

Because a serious internal incident may take a number of forms, other Trust documents may need to be referred to, for example:

- Procedure for the Reporting And Investigation of Incidents, Complaints & Claims
- Learning from Adverse Events Policy
- Being Open Policy
- Guidelines for Managers and Employees on the management of individuals involved in adverse events
- 10 Steps to Successful Root Cause Analysis Reports
- Guidelines for Supporting Staff involved in Traumatic / Stressful Incidents, Complaints, or Claims
- Information Governance Policies and Procedures
- Risk Management Strategy
- Health and Safety Policies and Procedures
- Infection Control Policies and Procedures
- Fire Policy
- Estates Emergency Policies and Procedures
- Medical Devices Policy
- HR policies including Maintaining High Standards of Performance

These are available on the Trust Intranet.

### 3 Definitions

#### 3.1 Serious Incident (SI)

A serious incident requiring investigation is defined as an incident that occurred in relation to NHS funded services and care resulting in:

- the **unexpected** or **avoidable** death of one or more patients, staff, visitors or members of the public
- **permanent harm** to one or more patients, staff, visitors or members of the public or where the outcome requires life-saving intervention or major surgical/medical intervention or will shorten life expectancy (this includes incidents graded under the NPSA definition of severe harm)
- a scenario that prevents or threatens to prevent a provider organisation's ability to continue to deliver health care services, for example, actual or potential loss or damage to property, reputation or the environment
- a person suffering from **abuse**
- adverse media coverage or public concern for the organisation or the wider NHS

The policy also covers:

- Development of a pressure sore grade 3 or above after admission to hospital and others incidents as required by the CQC (See Appendix D)

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<sup>4</sup> HSC 1998/197: *Planning for major incidents the NHS guidance fully revised and updated guidance*, 1998

- The reporting of **Never Events**. The NPSA has designated a list of events that should never occur in NHS funded care. These are known as “Never Events”. When one of these occurs it should always be reported as an SI. The nationally agreed and most up to date list is at appendix E). This will be updated periodically.
- Significant health care associated infections, as defined by the Health Protection Agency for example an outbreak of infection, failure in decontamination or infected healthcare worker. (see appendix F)
- Significant breach of patient confidentiality or loss of data (see appendix G).
- There are additional categories of incidents for maternity services which should be reported as SIs. (see appendix H)

### 3.2 Incident Grades

Once a reported incident is designated as serious, the Trust in conjunction with the SHA/Commissioner should review grading of seriousness of the incident for the purposes of determining the investigation and monitoring approach. The purpose of Serious Incident grading (*see Appendix A, Table 1*) is to help reduce under reporting of serious incidents by encouraging early reporting of all possible serious incidents. Grading will be agreed between SHA and Commissioner on a case by case basis and with advice from specialist sources where appropriate.

The incident can be graded as follows:

- Grade 0 – notification only, it is not clear whether a serious incident has occurred
- Grade 1 – Serious incident
- Grade 2 – Very serious incident

See appendix A for further guidance and examples

### 3.3 Supplementary Terms

- **Incident** – an event or circumstance which could have resulted, or did result in unnecessary damage, loss or harm to a patient, visitors or members of the public
- **NHS funded services and care** – healthcare that is partially or fully funded by the NHS, regardless of location
- **Unexpected death** – where natural causes are not suspected. The Trust should investigate these to determine if the incident contributed to the unexpected death
- **Permanent Harm** – permanent lessening of bodily functions; including sensory, motor, physiological or intellectual
- **Major surgery** – a surgical operation within or upon the contents of the abdominal or pelvic, cranial or thoracic cavities or a procedure which, given the locality, condition of patient, level of difficulty, or length of time to perform, constitutes a hazard to life or function of an organ, tissue or tissue (if an extensive orthopaedic procedure is involved, the surgery is considered ‘major’)
- **Abuse** – as defined by *No Secrets for Adults* (DoH 2000)<sup>5</sup> and *Working together to Safeguard Children* (HM Government 2006)<sup>6</sup>

The definition of serious incident extends beyond those which impact directly on patients and includes incidents which may indirectly impact on patient safety or an organisation’s ability to deliver on-going healthcare services. All serious patient safety incidents should be reported to the NPSA and currently also to the Strategic Executive Information

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<sup>5</sup> Department of Health, “*No secrets: guidance on developing and implementing multi-agency policies and procedures to protect vulnerable adults from abuse*”, March 2000

<sup>6</sup> Department for Children, Schools and Families “*Working Together to Safeguard Children*”

System (STEIS) via UNIFY or its replacement. Serious Incidents meeting the above criteria may involve the following:

- NHS patients/clients/service users, relatives or visitors or
- Staff, including students undertaking clinical or work experience and/or their tutors
- Contractors, equipment, building or property

The National Patient Safety Agency (NPSA) has published a series of definitions covering the full range of harms which may result from a patient safety incident. There is an expectation that, as a minimum, patient safety incidents leading to unexpected death or severe harm should be investigated to identify root causes and enable ameliorating action to be taken to prevent reoccurrence.

If there is uncertainty about the status of an incident, the Trust must seek advice from the SHA and/or Commissioners. Advice can be sought from the Commissioner of the service and/or the Head of Patient Safety and Quality, NHS West Midlands. (0121 695 2591).

The Trust is required to notify the CQC about events that indicate or may indicate risks to ongoing compliance with registration requirements. The requirements to report certain categories of serious incidents are defined in the CQC's guidance, *Essential Standards of Quality and Safety*<sup>7</sup>. For Trusts, most of these requirements are met by reporting via the NPSA, with the NPSA forwarding relevant information the CQC.

### **3.4 Safety Advisor**

The Trust has a number of specialist safety advisors whose role is to give advice and support to staff. These include:

- Patient Safety Team
- Health and Safety Team
- Security Manager
- Information Governance Manager
- Legal Services Team
- Complaints Team
- Fire Safety Officer
- Vulnerable Adults Lead
- Child Protection Lead

### **3.5 Serious Incident Coordinator**

The Chief Compliance Officer will be the Serious Incident Coordinator and the Patient Safety Team Manager will be the designated deputy in hours. Out of hours, this will be the Executive Director on call.

SIs will be reported onto the mandated system by the Chief Compliance Officer or their deputy the Patient Safety Team Manager, or a delegated member of their team.

The Serious Incident Coordinator will be the point of contact between the Trust / and the commissioner and / or the SHA. Their contact details should be included in the on line

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<sup>7</sup> Care Quality Commission *Notifications required by the Health and Social Care Act 2008* Guidance for providers 2010

form, in order to provide a point of contact. If the incident meets the criteria for a Grade 2 Incident (*Appendix A, Table 1*) and/or likely to break in the media the following morning, The SHA Director on call should be contacted

### **3.6 Incident Manager**

The manager nominated to oversee the incident investigation (see section 4.6)

### **3.7 Serious Incident Team**

For some very serious incidents, and incidents affecting multiple patients, the Director of Safety and Quality may establish a Serious Incident Team to coordinate and manage the investigation and actions required. (See section 4.13)

## **4 Duties**

### **4.1 Role of affected/involved staff member**

It is the duty of all staff to report all incidents and near misses. Any incidents which may meet the criteria listed in section 3 must be reported as soon as the staff member becomes aware of the incident. The incident should be reported to the immediate line manager in person, or by telephone and followed up with an incident report either electronically, via DATIX web, or completion of a paper form.

### **4.2 Role of line manager**

The line manager must report the incident to their senior manager (Department Head, Lead Nurse or Clinical Site Manager) immediately. They must

- take any immediate action necessary to prevent further harm.
- isolate and save any evidence if applicable. (including any equipment / instruments samples / medicines involved)

### **4.3 Role of senior manager - working hours**

- Determine if the incident falls within the scope of the definition in section 3. If in any doubt contact one of the Trust Safety Advisors for advice.
- Grade the incident using the table in Appendix A (see section 3.2)
- Inform the Divisional Manager (working hours)
- Inform the Patient Safety Advisor (ext 3175 or 4632), Patient Safety Team Manager (ext 1448) or Chief Compliance Officer (ext 1118)
- Start documenting what has happened, who was involved and any immediate or preventative action taken.
- Assist with any incident investigation and root cause analysis in line with the timescales outlined in section 7.1
- Assist with implementing any recommendations in line with agreed timescales

### **4.4 Role of Senior Manager on call – out of hours**

The Senior Manager on-call must be contacted via the Clinical Site Manager

The Senior Manager on-call will:

- Determine if the incident falls within the scope of the definition in section 3.
- Grade the incident using the table in Appendix A (see section 3.2)
- Inform the Executive Director on call who will notify the Chief Executive. In hours this is via the Chief Executives Office, however, out of hours this is via the senior manager on call. If necessary the Executive director on call will notify the Commissioner's on call director immediately.
- The Senior Manager on call (out of hours) must notify all incidents graded 0 and 1 to the Director of Quality and Safety at the start of the next working day. (NB: if the incident relates to a 12 hour trolley wait, this must be escalated in line with the relevant policy)

- If the incident is considered a grade 2 incident (see Appendix A) then the Director of Quality and Safety must be contacted immediately (including out of hours)
- Inform the individuals listed in section 8.5 during office hours. These will be contacted by the Executive Director on-call out of office hours if required. If necessary the MAJAX telephone cascade system should be put into effect.
- Assist with any incident investigation and root cause analysis in line with the timescales outlined in section 7.1
- Assist with implementing any recommendations in line with agreed timescales

**NB When an incident occurs out of hours, the senior manager on-call will usually handover to the appropriate senior manager on their return to duty.**

#### **4.5 Role of Director of Quality and Safety / Chief Nurse**

The Director of Quality and Safety / Chief Nurse

- is accountable to the Chief Executive for the effective management of SIs.
- should agree the wording on the incident report sent via the electronic reporting system prior to an incident being reported externally. In the absence of the Director of Quality and Safety, the Medical Director or other Executive Director should approve the wording to avoid reporting delays.
- will update the Trust Board of progress of SI investigations and with actions arising from incidents.
- will assign an Incident Manager to manage the incident based on the type and grading of the incident.
- will consider whether to assemble a SI Team to respond to the incident. (An SI team will only usually be established for incidents affecting multiple individuals).

#### **4.6 Role of Incident Manager**

For SIs the Director of Safety and Quality will designate an Incident Manager to coordinate and manage the incident.

- For incidents graded 0 and 1 this is likely to be a Lead Nurse/ Midwife , but may be a Consultant or other senior member of staff, as deemed appropriate.
- For incidents graded 2 and inquestable deaths this will be the relevant Safety Advisor with support from a nominated Lead Nurse /Midwife and Clinician

The Incident Manager, with the SI Team if assembled, will decide whether any further preventative action should be taken to prevent any further harm, or potential harm eg suspending treatments or operations, withdrawing facilities, redirecting services, restricting clinical duties if risk of infection

The Incident Manager will:

- Review the grading of the incident as more information becomes available
- Circulate the STEIS notification form for comment to appropriate members of staff. This may include the Clinical Director, Consultant, Line Manager etc
- Ensure that the investigation is carried out in line with the timescales at section
- Ensure that the line manager, safety advisors, Head of Nursing, Head of Midwifery, and senior medical colleagues are involved with the investigation as appropriate
- Manage the incident as described in this policy;
- Ensure that any action to reduce the effect of the incident is taken immediately
- If patients are involved, ensure the Consultant responsible for the care of the patient(s) is informed.
- The Incident Manager is responsible for identifying those involved or potentially affected by the incident with the assistance of department staff, and the SI Team, if established. See Section 8.2.1

- Be responsible for all documentation relating to the incident. It is imperative that an accurate record is kept of all those involved, events, decisions made, and information given to others. See Section 10
- Ensure the relevant individuals and external agencies have been informed. See Section 8.6
- The Incident Manager will ensure all those affected by the incident are informed an incident has occurred. They must decide how those affected will be informed and set timescales for this to happen. It is their responsibility to ensure all persons directly and indirectly affected by an incident are notified before the media if possible. See sections 8.2.2 and 8.2.3.
- Make the decision, in consultation with the Executive Director, whether to set up a hot line for multiple enquiries from the public and media. These would be separate hotlines. Media enquiries should be managed separately from public enquiries. See sections 8.1 and 11
- Liaise with the Director Quality and Safety in the preparation of statements
- For Grade 2 incidents, identify a person to interview each member of staff involved as soon as is reasonably practicable but ideally within 48 hours of the incident
- Ensure signed statements are requested and received from relevant staff and that all statements are legible, signed, dated and timed.
- Lead the investigation if an internal investigation is sufficient, or liaise with external bodies that may wish to carry out an investigation. eg Police, Coroner, MHRA, HSE, Environment Agency.
- Liaise with the relevant Safety Advisor for advice and support as necessary to undertake root cause analysis.
- Make regular reports to the SI Team
- Provide agreed update reports to the Trust Board and Executive Directors.
- Update Commissioners and SHA in line with timescales at section 7.1
- Keep a log of evidence received along with dates and copies of all evidence sent to third parties.
- Ensure that the final report is written up in the approved format as per the NPSA guidance and approved for sign off (section 7.2)
- Monitor any action plan and report to the Director of Quality and Safety as appropriate.
- Use the checklist at appendix L
- Ensure that the learning from the incident is disseminated and discussed at local and Trust wide governance groups.

#### **4.7 Role of Chief Compliance Officer**

- Be the Serious Incident Coordinator for the Trust
- Report the incident to the Commissioners and CQC under the Serious Incident policy if appropriate and maintain regular updates on the progress of the investigation (see Appendix G for details).
- Ensure that the full investigation report is provided to the Commissioners when it is complete.
- Liaise with the Commissioners regarding the sharing of additional information such as witness statements and medical records.

#### **4.8 Role of Patient Safety Team Manager**

- Be the deputy for the Chief Compliance Officer
- Ensure that the incident has been reported to other bodies as appropriate.
- Liaise with the Incident Manager if a hotline is established.
- Ensure that the draft root cause analysis (excluding pressure sores and infection control incidents) is discussed at Incident Review Group

#### **4.9 Role of Safety Advisor**

- Lead investigations for grade 2 incidents and inquestable deaths

- Support the Incident Manager with advice and support for staff
- Assist the Incident manager as required with the investigation and Root Cause Analysis.
- Participate in the SI Team if established
- Liaise with the Legal Services team
- Assist the Incident Manager in identifying recommendations. Advise on the immediate and longer-term actions needed to minimise risk
- Provide feedback to Trust Committees as appropriate

#### **4.10 Role of Head of Midwifery**

- In addition to any other nominated duties the Head of Midwifery will inform the Local Supervisory Authority of all relevant maternity Serious Incidents.

#### **4.11 Role of Chief Executive**

- The Chief Executive is the Accountable Officer for the Trust and has overall accountability and responsibility for ensuring the Trust meets its statutory and legal requirements including patient and staff safety.
- The Chief Executive will promote an open, supportive 'fair blame' culture in line with and support the Trust's 'Being Open' policy
- The Chief Executive will promote the use of incident reporting as an opportunity for learning and improvement. Disciplinary action will only be considered in cases where there is evidence of criminal activity, professional misconduct, or evidence of repeated or malicious events.
- The Chief Executive will nominate an Executive Director to chair the SI team if established (see section 4.13). This may include other Executive Directors, the Incident Manager, the relevant Trust Safety Advisors, Head of Estates and Head of Facilities as appropriate, and other relevant staff. The Director of Communications should also be informed to ensure press enquiries are dealt with appropriately
- If an investigation involving the Police and HSE is required, it is good practice for the Chief Executive to nominate an Executive director to form a Serious Incident Team to provide coordination with the other agencies as described in the memorandum of understanding.<sup>8</sup>
- Receive reports and recommendations from the Incident Manager and the SI Team

#### **4.12 Role of Board**

The Board including the Chairman, will be notified of SIs, usually by email from the Serious Incident Coordinator, on the day the incident is reported. Formal reports and updates will be provided to each formal meeting of the Trust Board.

#### **4.13 Role of Quality and Safety Committee**

The Quality and Safety Committee is chaired by a Non-Executive Director and reports to the Trust Board. The Committee is responsible for providing assurance to the Board on Quality & Safety, monitoring clinical governance and providing assurance that clinical governance processes deliver safe high quality and patient centred care. The Committee will receive monthly detailed SI reports and updates on action taken.

The group will discuss SIs which have occurred, analyse any antecedents and identify any trends or other patterns. The aim of the Committee is to suggest remedies and ensure corrective action is implemented and that such action leads to reduced risks. This work will link to education and training. This Committee reports to the Trust Board to ensure the Board is aware of all SIs including trends, management and monitoring of action plans, and

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<sup>8</sup> Memorandum of Understanding – Investigating patient safety incidents involving unexpected death or serious untoward harm: a protocol for liaison and effective communications between the NHS, Association of Chief Police Officers and HSE

evidence of changes brought about to improve patient safety (this may include changes to practice, education and training).

#### **4.14 Role of the SI Team**

Depending upon the nature of the incident, a SI Team may be established. A nominated Executive Director will chair this group. This team will decide on what further actions must be taken. Tasks may include:

- Identify the aims and objectives of the team.
- Establish the basic clinical and other facts
- Delegate responsibilities if appropriate
- Determine frequency of meetings
- Determine action to be undertaken in particular:
- Identifying those affected by the incident
- Agreeing what actions need to be taken to prevent further harm
- Agreeing the objectives and responsibility for communication including liaison with outside agencies
- Identify who will be responsible for informing the patient (s) and or/carers and the manner and timing of the information (see section 11.0)
- Consider the appropriateness of engaging patient support at this early stage. This includes the use of a facilitator, a patient advocate (eg PALS) or a healthcare professional who will be responsible for identifying the patient's needs and communicating them back to the healthcare team.
- Identify immediate support needs for the healthcare staff involved (see section 8.3 )
- Monitor the progress of the incident until completion
- Produce a preliminary report within a week of the incident
- Use the checklist at appendix M for very severe SIs when there is police involvement resulting in a possible criminal investigation

#### **4.15 Role of Shrewsbury and Telford Infection Control Committee**

This Committee, chaired by the Director of Quality and Safety will receive reports, and follow up actions arising from infection related SIs from the Matron for Infection Prevention and Control

#### **4.16 Role of the Incident Review Group**

The Incident Review Group will meet regularly to critically review most RCA reports from SIs; high risk incidents which affect more than one SDU; and high risk complaints; and to consider the recommendations from the reports in order inform the action planning. Relevant staff will be invited to attend as required, however any member of staff is welcome to attend this group NB: Pressure ulcer RCAs will be reviewed by the Pressure Ulcer Group; Infection Control RCAs will be reviewed by STICC; and grade 1 maternity incidents will be reviewed within the Women's and Children's governance structure.

#### **4.17 Role of NHS Direct**

NHS Direct may be contracted to set up and run a hotline in conjunction with the Responsible Manager and Director of Quality and Safety. If this is deemed appropriate the NHS protocol current at the time will be implemented [www.nhsdirect](http://www.nhsdirect). See appendix F.

#### **4.18 Role of Commissioners**

The lead Commissioner is responsible for agreeing the incident grading with the Trust; monitoring progress with investigations and action plans through the contractual clinical quality review meetings. The Commissioners will agree closure of incidents with the Trust.

## **5 Other responsibilities related to reporting serious incidents**



Further guidance can be obtained from the Department of Health publication “*Memorandum of Understanding - Investigating Patient Safety Incidents*”<sup>9</sup> (Department of Health, 2004) and accompanying NHS guidance of December 2006<sup>10</sup>. In such circumstances this SI policy and procedure should be followed as well as the specific national guidance. Reporting an incident to the commissioner or the SHA does not remove any responsibility to comply with statutory responsibilities or national guidance issued by the Department of Health or other organisations such as the National Patient Safety Agency (NPSA) or Local Safeguarding Children Board (LSCB), Local Safeguarding Board for adults in such circumstances

When an incident or incidents are of such a serious nature that an external inquiry is required, it will need to be established in line relevant national guidance for example *HSG 94/27*<sup>11</sup> (Department of Health, 1994) and associated amendment, ‘*Guidance on the discharge of mentally disordered people and their continuing care*’<sup>12</sup> (Department of Health, 2005). The responsibility for commissioning an external inquiry depends on the nature of the incident. Such incidents will be discussed with the Chief Executive, Director of Quality and Safety and the SHA Chief Executive and other appropriate SHA Directors prior to establishing the inquiry.

The SI reporting process should never include any patient or staff identifiable information. Reporting managers must comply with the Caldicott principles of confidentiality when reporting SIs and must not refer to patients by name or by any other identifiable information. The SI report will be given a unique identifier which should be quoted as a reference during telephone queries and/or associated correspondence to the Commissioners and SHA. The Serious Incident Coordinator will maintain an internal incident audit trail for those instances where identifiable information may be required; this is in line with Caldicott requirements.

Managers should be aware of Department of Health guidance that may exempt details of individual serious untoward incident reports being made available to third parties, under either or both Sections 31(2) and Section 40 (2 & 3) of the Freedom of Information Act 2000.

Each SI is allocated a unique number by UNIFY and this is the reference number which should be used by the Commissioner Trust in any communication with the SHA. Trusts may have their own unique incident report reference number and it is important that this is also included, in order to ensure relevant information is not attributed to another incident or investigation.

The Trust is responsible for ensuring the prompt reporting and management of untoward incidents and reactions, and defective products relating to medical and non-medical equipment and supplies, food, buildings and plant to the relevant bodies (HSG 93, 13<sup>13</sup>). Any SI relating to these should additionally be reported in compliance with this policy.

Any SI which may potentially attract media attention, in particular the national media should be highlighted by selecting the Media interest option on the incident form. If the SI has

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<sup>9</sup> Department of Health, “*Memorandum of Understanding - Investigating Patient Safety Incidents*” 2004

<sup>10</sup> NHS Guidance, Dec 2007

<sup>11</sup> Department of Health “*HSG (94) 27*” 1994

<sup>12</sup> Department of Health, “*Guidance on the discharge of mentally disordered people and their continuing care*”, 2005

<sup>13</sup> Department of Health HSG 93, 13

already attracted media attention, this should be clearly identified and details should be included in the commentary.

## 6 Joint Investigations

If more than one organisation is involved in a SI, the organisation that is responsible for the care of the patient at the time of the incident will report the SI. The reporting organisation will arrange a meeting which includes all key stakeholders. This meeting will nominate a lead professional to manage, lead and co-ordinate the management of the investigation. All key stakeholders will contribute and work together with the nominated lead. If the police are involved, the police should guide the lead organisation as to the parameters of the local investigation. The same principle should apply in other categories of SIs where more than one organisation is involved; providers should agree with commissioners the reporting/lead organisation.

## 7 Reporting Processes and Timescales

**See Appendix B Flow-chart “National Framework for Reporting and Learning from Serious Incidents and Appendix C – Local Flow- chart**

Once the Trust has decided that an incident fits the SI reporting criteria, the SI should be reported within 2 working days using UNIFY which should be completed by the Serious Incident Coordinator. The incident should be graded to reflect its level of seriousness. (see Appendix A, Table 1)

In office hours, when the incident meets the criteria for Grade 1 or 2, the Trust may contact the Patient Safety Action Team at the SHA for clarity, guidance and support.

For Out of hours Grade 2 incidents- the on-call SHA Director should be informed by the Trust Chief Executive/Director on-call. They will agree whether the situation requires escalation and if so will agree any action that needs to be taken with the relevant NHS organisation. Where there is a communication component to the incident the SHA Director on call will inform the SHA communications team, this may include confidential briefing to the Department of Health Media Centre.

### 7.1 Minimum reporting standards:

- The incident must be reported within 2 working days or at the earliest point thereafter with an explanation of any delay, once the decision has been made to inform the commissioner and SHA.
- All demographic details must be completed on the SI form to assist monitoring of trends. (Where this is not possible the reason must be entered in the additional information section with an explanation).
- The Trust must provide an update within two weeks, to identify any immediate actions taken as a result of the incident and/or any additional relevant information that may have emerged during the trust’s immediate investigation.
- Root cause analysis should be initiated within 3 days (or a similar process to establish a chronology, identify underlying causes and what further action needs to be taken). Root cause analysis and detailed action planning should be completed within 45 days for level 1 incidents and within 6 months for level 2 incidents, with accompanying action plans (**\*N.B. with the exception of Healthcare Associated Infection, please see Appendix F**). Findings of the RCA must be entered onto the on line system.

- This may be extended on a case-by-case basis by the Commissioner in agreement with the SHA where a delay is necessary for example whilst awaiting the results of criminal investigations or inquests
- In cases of MRSA Bacteraemia and Clostridium Difficile Root Cause Analysis (RCA) must be completed and reported within the guidelines outlined within Appendix F.

## 7.2 Process for internal sign off for Root Cause Analysis and Action Plans

All RCAs and action plans should be signed off by an Executive Director prior to being sent out of the Trust. The table below outlines the suggested routes:

Incident type	Sign off by:	Alternative	Overseeing Committees
Pressure Ulcers	Director of Quality and Safety	Head of Nursing Practice	NMF
Infection Control Incidents	Director of Quality and Safety	Director of Infection Prevention & Control	STICC
12 hour Trolley Waits	Chief Operating Officer	Director of Quality and Safety	ME
Grade 1 Maternity Incidents after review within W&C governance structure	Director of Quality and Safety	Medical Director	Quality & Safety Committee
All other incidents after review at Incident Review Group	Director of Quality and Safety	Medical Director	Quality & Safety Committee

## 8 Communication and Notification

### 8.1 Press Liaison

The Communications Team will be responsible for media relations including setting up press conferences if appropriate.

The Director of Communications in liaison with the nominated Executive will be responsible for the preparation of all press statements and press liaison. They will liaise with the Responsible Manager to ensure they have all the relevant information. They will advise on the script for the telephone helpline to ensure that this is consistent with the public messages being disseminated via the media, and to avoid undue concern or alarm.

The Director of Communications will contact the Communications Department at the Strategic Health Authority

### 8.2 Patient/relative/visitor/contractor communication & support

#### 8.2.1 Identification of those involved

The Incident Manager is responsible for ensuring that all patients, relatives, staff and other members of the public who may have been affected by the incident are identified, in conjunction with the SI Team, if established.

In cases where a number of individuals are thought to have been affected the SI Team will be involved in identification of cases. They will identify all those known to have been affected and any that may possibly have been affected and will make the decision as to when, how and by whom they will be informed. It is also important for the team to consider the

information and advice that needs to be given to staff directly and indirectly involved in the incident.

Where possible, permission should be sought from those affected for information to be given to relatives etc, however this not always practical and it is important records are kept of information given.

The team may need to call on help from other departments or outside agencies, for example, IT, Clinical Audit and Medical Records staff for advice in the identification of patients, local authorities or the Commissioners for the management of large numbers of the public.

### **8.2.2 Informing other affected persons of an incident / accident or dangerous occurrence**

Many of the points listed in dealing with patients also apply to staff or members of the public who are victims of an accident/ incident or dangerous occurrence. It is important to remember that staff who have been harmed by an incident deserve the same treatment as patients or members of the public in terms of consultation and advice.

In a situation where visitors or members of the public have been, or were potentially harmed by an incident, it may not be possible to offer individual notification as they may not be individually identifiable; in which case, the Police, local authorities and /or local media may need to be used as a means of notification. However it is important that the Trust can offer at the point of notification, details of who and how to contact the Trust for further information. The Director of Safety and Quality is responsible for producing the information in liaison with the Incident Manager and other relevant managers.

### **8.2.3 Involving patients and their families in investigations into serious incidents**

Research shows that patients are more likely to forgive medical errors when they are discussed fully in a timely and thoughtful manner and that being open can decrease the trauma felt by patients following a patient safety incident.

The level of patient/family involvement clearly depends on the nature of the incident and the patient or family's wish to be involved. The Trust has a being Open policy in place, which describes the principles of Being Open. This policy is available on the Trust Intranet. Unless there are specific indications to the contrary or the patient/their family requests other arrangements, these issues should be covered in a series of open discussions between staff providing the patient's care and the patient and/or their relatives or carers.

Note: Patients and families have the right to request information held by public authorities (Freedom of Information Act 2000). This includes 'access to medical records and any associated documentation' (Public Sector Information Regulations 2005). This should be considered when writing incident investigation reports and actions.

For incidents involving multiple patients, the Incident Manager will ensure that all affected patients are contacted. The Incident Manager may delegate the task to an appropriate professional but it remains their responsibility to ensure this communication takes place.

It is best practice that all patients are contacted before the media. Where the media becomes aware of an issue before patients have been contacted, the Director of Communications will request that publication is delayed until effective patient notification has taken place. Where the media does not accede to this request, patient notification must be expedited and the establishment of a helpline given full consideration. Media statements and helpline messages should be carefully planned to avoid undue alarm.

The Trust acknowledges that in some instances, particularly when an incident comes to light some months later, it may not be possible to inform the patient prior to the media becoming aware, although every effort to do so must be taken.

All affected patients and their relatives should be informed of the nature of the incident and offered appropriate care, treatment, support And advice as necessary. This may include counselling if appropriate.

Patients should be given a telephone number in order that they can contact an informed member of staff if they have any further queries or concerns.

Depending on the nature of the incident, the numbers and types of patients involved, and patient confidentiality issues, full consideration should be given as to whether it would be helpful for the hospital to inform the patient's relatives at the same time.

GPs must be kept informed and up-to-date of events, as it is often the GP that the patient turns to for advice. The GP should also be advised of any contact with the patient and its outcome.

For incidents affecting a number of patients, all affected patients should be contacted on the same day if at all possible. The Incident Manager (in discussion with the SI Team if appropriate) will consider the most appropriate method. Possibilities include

**A) One to one discussion**

This would be appropriate when the patient is already in hospital.

- It is important to explain honestly to the patient the reason for a consultation without causing undue alarm.
- If the consultation is likely to be traumatic or distressing, it should be arranged for a relative or friend to be with the patient at the time of discussion

**B) Writing offering a consultation**

The Incident Manager together with the SI Team and Director of Quality and Safety must agree:

- The content of the letter
- To whom the letter should be sent (eg patient, relatives, GP)
- The signatory
- The timing of the letter
- The timing of any subsequent press release
- The opening up of a telephone hotline

A contact person may be nominated by the Incident Manager who would be able to reassure the patient until they were able to discuss the incident at a consultation. Switchboard should be informed of the name and bleep number of the contact person.

It is important to explain honestly to the patient the reason for a consultation without causing undue alarm.

If the consultation is likely to be traumatic or distressing, the patient should be advised to bring a relative with them.

Transport arrangements should be offered for patient with transport difficulties.

**C) By visiting the patient at home**

This would be supported by the offer of a consultation as soon as possible and is only suitable when a small number of patients are affected.

#### **D) By telephone/helpline**

The SI Team will consider whether a control room and telephone helpline should be set up to deal with enquiries and the options available are described in section 8

#### **E) IT arrangements**

The Incident Manager may decide to use IT arrangements to inform patients and relatives of the details of the incident. This arrangement would involve using the Trust's own website ([www.sath.nhs.uk](http://www.sath.nhs.uk)).

If a website is used the Incident Manager, together with SI Team and the Head of Communications must agree:

- The content of the website
- How to publicise the website
- The timing of any subsequent press release
- The opening of a telephone hot line.

### **8.3 Supporting Staff**

It should be remembered that staff exposed to an exceptional incident or situation, may find this traumatic and stressful. The impact of such an incident can be significant in human terms.

Support for staff involved in an incident will be coordinated by the Lead Nurse and /or Divisional Director depending on the staff involved. The Incident Manager together with the Lead Nurse / Divisional Director of SI Team will decide what support mechanisms will be activated for staff involved in a serious incident using the Guidelines for Supporting Staff involved in Traumatic / Stressful Incidents, Complaints or Claims

Due consideration needs to be made as to whether staff should be temporarily released from duty, and when fit to return to work, what support, help or advice they will require

The Incident Manager is responsible for communicating with staff both pre and post investigation. Staff personally involved in the incident itself and other staff within the organisation will need to be involved in these discussions. The Incident Manager should ensure that relevant staff are kept up to date with the progress of the investigation. All involved staff should be encouraged to attend the incident review meetings.

The Trust recognises the importance of supporting staff through these events and acknowledges the need to ensure staff have the opportunity to be fully prepared in terms of what to expect in the aftermath of a serious incident. The aims of post-incident support are to assure those involved that their reaction is normal, to anticipate reactions as time goes on, to reduce discomfort and tension and to provide immediate and continuing support. The nature of support required by individuals or teams post incident will vary enormously. Managers need to be aware both of the range of support available to staff, and how stress may affect staff, in order to be most supportive to them.

### **8.4 Raising Concerns**

The Board is committed to an open and honest approach in all matters. The overall approach expected within the organisation is one of help and support rather than blame and recrimination. The Trust's Whistle blowing Policy supports this approach. This allows staff to by-pass line management to raise concerns. The whistle blowing procedure is primarily for concerns where the interests of others or of the organisation itself are at risk.

All staff should be familiar with the Trust's guidance to staff on raising concerns and the requirements of the Public Interest Disclosure Act 1998. The Whistle blowing Policy is available on the Trust Intranet.

## **8.5 Internal Communication**

The incident will be reported by the Incident Reporter externally in accordance with current requirements. Within the Trust the key people who will need to be informed include:

- Service Manager
- Service Director
- Consultant in Charge of the case
- Chief Executive
- Medical Director
- Director of Quality and Safety
- Director of Compliance and Risk Management
- Chief Operating Officer
- Director of Strategy
- Finance Director
- Director of Communications
- Patient Safety Advisor
- Chief Compliance Officer
- Legal Services Manager
- Health and Safety Team Manager
- Staff may also need to be informed
- The Chairman and other members of the Trust Board at an appropriate time.

## **8.6 External stakeholder notification**

In addition to the Commissioner and SHA, the Coroner, CQC, or Health and Safety Executive may need to be notified of an SI. Requirements for reporting SIs to the CQC are outlined in Appendix C.

Deaths and major injuries may also have to be reported to the Health & Safety Executive within 24 hours. It is therefore imperative that Clinical Directors, Senior managers and the Chief Executive are informed within several hours of an incident occurring. Safety Advisors and the Director of Compliance and Risk Management can also be contacted out of hours to advise on which external bodies should be informed of an incident. Details of other parties are listed in appendix I.

If press statements are prepared, a copy should be sent to the Chief Executive at the relevant Commissioner in Shropshire and/or Powys Local Health Board, prior to their release. The Director of Communications will contact the Communications Department at the Strategic Health Authority. The Serious Untoward Incident Protocol for the Health Authority will be activated as appropriate. The team should decide whether other agencies including non-health should be advised or involved in the team. Further information is available in the Incident Reporting Policy.

## **9 Incident investigation**

The incident should be investigated in line with the Trust's Procedure for the Reporting and Investigation of Incidents, Complaints and Claims. (see Patient Safety pages on Intranet). A root cause analysis using the NPSA tools and guidance must be carried out on every SI. SI investigation process must be in line with the DH/ SHA procedures and requirements and meet the additional contractual requirements established by the Commissioners.

The NPSA templates for root cause analysis and other investigative tools are available on the Patient Safety pages on the Trust Intranet.

A comprehensive investigation will be required for SIs reported as grade 1 and 2. However, some grade 2 incidents may require an Independent Investigation. In these cases the extreme SI checklist (appendix M) should be used.

## **10 Record Keeping**

### **10.1 General Record Keeping**

The Incident Manager is responsible for all documentation relating to the incident and its security.

An accurate record must be kept of all events. This will include the patients affected and the action taken. These should form the basis of a progress report for the Director of Quality and Safety. Notes should be made in the patient's medical records, except in exceptional circumstances. If medical records are required for ongoing treatment then copies should be made – clearly marked as 'duplicates' for the incident team. All records will be held by the Incident Manager. See Appendix J for checklist.

- The nature of the incident
- The time it occurred
- Where it occurred
- Any immediate or preventative action taken
- Who was involved – patients, staff, relatives, carers, visitors etc. including contact details where possible
- Names, addresses, unit numbers and GP details of patients
- Details of any staff involved including whether permanent or bank staff and when next on duty.
- Records of the progress of patients, staff, relatives and carers involved in the incident
- Copies of any medical records if the originals are needed for ongoing treatment
- Statements from all those involved which must be legible, dated, timed and signed.
- Update reports to the Director of Quality and Safety
- Minutes of the Serious Incident Team where established
- All information given to persons involved in the incident and statements and information given to other potentially affected parties or outside agencies.
- Any press statement

The Incident Manager must ensure all records relating to the incident are stored securely and a log kept of all evidence received. If any documentation is sent to third parties, copies of correspondence sent must be kept along with details of any evidence included.

Records will be kept, in line with the guidance in the Trusts Records Management Policy

### **10.2 Follow-up Action**

The Responsible Manager and SI Team will establish whether the patients will require follow-up contact and arrange for this to be provided. A full report and analysis of the root causes of the incident will be formulated by the Responsible Manager, with the assistance of the relevant Safety Advisor if required. This, together with the action plan, will be submitted to the Quality and Safety Committee

It is essential that after any SI, a full debriefing takes place to ensure all problems have been identified and lessons learnt for the future. This meeting should take place after the root cause analysis and action plan has been drafted to ensure dissemination of learning to all the team



Recommendations following root cause analysis will be followed up via recommendation tracking.

## **11 Hotline arrangements for multiple enquiries**

In some instances, multiple enquiries could be possible. Examples of such incidents would include:

- Failure of a screening test
- Infection control issue
- Radiation Dose issue
- Infected health care worker
- Other high profile events

### **11.1 Management responsibility**

The Incident Manager will decide whether to activate the 'hotline' for telephone enquiries in liaison with the Head of Facilities. In all cases, the Incident Manager will be responsible for setting up and running the hotline.

### **11.2 Phone lines**

There are three options for this, described below:

#### **11.2.1 The NHS Direct Helpline**

This is a national service via NHS Direct and has been devised to support Trusts who are expecting a large number of calls from the general public relating to a specific health or environmental issue.

NHS Direct can be contacted on 020 7599 4212

Guidelines for using NHS Direct are covered in more detail in appendix J.

Where it is decided to use the NHS Direct Helpline, the arrangement will be agreed with the NHS Direct Manager. The 'Intent to Commission' or 'Service Request Form' from NHS Direct MUST be signed by an executive Director before commissioning the service.

The NHS Direct Manager will set up extra dedicated lines within one hour of the request of the service.

The Hotlines will be manned by NHS Direct Personnel and the NHS Direct Manager will be responsible for organising staff rotas and ensuring that sufficient staff are on duty to cope with the volume of calls.

The NHS Direct Personnel will log details of all calls received and advice given.

#### **11.2.2 Princess Royal Hospital**

The strategy for dealing with multiple enquiries will be to set up a 'hotline' in Room K of the Management Centre. Staff will be recruited by the SI Team to deal with multiple enquiries. A dedicated phone number will be issued to the media by the Head of Communications avoiding the PRH switchboard.

The Incident Manager will ensure that the personnel have had the necessary training and ensure that up to date information is available.

The necessary phones are housed in switchboard.

### **11.2.3 Royal Shrewsbury Hospital**

The control centre would be in the fracture clinic, adjacent to the A&E department, or in room 229. A dedicated phone number will be issued to the media by the Head of Communications avoiding the RSH switchboard.

If either of the above options is chosen:

The Incident Manager will be responsible for liaising with the Head of Facilities to ensure that extra phone lines are available.

The Telecommunications Manager will set up extra dedicated lines within one hour of the request of the service

The Hotlines will be manned by Hospital staff and the Incident Manager will organise staff rotas and ensure that sufficient staff are on duty to cope with the volume of calls, redeploying staff if necessary.

The Incident Manager will ensure that the personnel have had the necessary training and ensure that up to date information is available.

### **11.3 Documentation**

The help lines will log calls and details of advice given – see appendix K for specimen log

## **12 Further Guidance on Categories for Reporting**

The criteria for reporting Serious Incidents are available via the on-line system. This is not an exhaustive or static list and is intended only as a guide. It is not anticipated that every incident falling within the categories given should be reported as a matter of course. Serious Incidents would normally be expected to be graded by the Trust, using the grading matrix (Appendix A table 1). Apparently trivial events which may form clusters and could lead to something more significant, including those which could attract media attention, should be reported.

### **12.1 Information Governance**

Information governance incidents must fulfil the criteria of being a SI before being reported; other data loss instances must be reported to the SHA Chief Information Officer. External information governance incidents identified as “confidential information leaks” on the online reporting System must be handled in accordance with the DH document “Checklist for Reporting Managing and Investigating Information Governance Serious Untoward Incidents”<sup>14</sup> Gateway Reference 13177. Further guidance is contained at Appendix G

### **12.2 Communicable Disease Outbreaks**

For communicable disease outbreaks, the Regional Director of Public Health or a Consultant from her team will have responsibility for the reporting and follow-up process, in liaison with the Commissioner. The HPA must be informed of these SIs and the online reporting system should be used when completing the incident form. (*See Appendix F – Serious Incident Reporting Requirements for Reporting Clostridium difficile, MRSA bacteraemia and other HCAI Outbreaks or Incidents*)

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<sup>14</sup> NHS Connecting for Health, “Checklist for Reporting Managing and Investigating Information Governance Serious Untoward Incidents”, Gateway Reference 13177, January 2009

### **12.3 Serious Incidents Involving Medicines**

All Serious Incidents involving medicines should be notified to the Head of Medicines Management or Chief Pharmacist and must be reported through the online reporting system.

Any medicines related incident which involves harm to the patient must be reported as a Serious Incident. This includes all aspects of the medicines pathway: i.e. prescription, dispensing, handling, administration and storage.

All serious incidents involving medicines reported through the reporting system **must** contain the following basic information the correct name of the medicine(s) involved and the age of the patient, this is particularly important for children and older people.

For serious incidents involving medicines, in addition to reporting through the online reporting system, it is the responsibility of the Trust to ensure that:

- action is taken to minimise any recurrence of these incidents; a full report of this action to be forwarded to the NHS West Midlands Patient Safety Action Team
- those incidents that involve a breach of medicines legislation are reported to the relevant legal authorities.
- those incidents that involve a suspected defect in the medicine (e.g. contamination, incorrect labelling by the manufacturer, unexpected odour, evidence of tampering with manufacturer's packaging, etc), are notified to the Medicines and Healthcare Products Regulatory Agency (MHRA) and a sample of the suspect medicine retained
- those incidents resulting from an adverse reaction (side effect) to a medicine are reported through the MHRA suspected adverse drug reaction ("Yellow Card") scheme
- where a serious medication incident occurs outside of normal working hours that consideration is given to the need to initiate the regional out-of-hours medicine recall procedure

### **12.4 Maternity/Newborn/Children And Young People**

There are a number of categories of incidents relating to maternity and children which, must be reported including maternal, intrauterine and intrapartum deaths. For the most up to date requirements see **Appendix H**

Suspension of maternity services are currently monitored and audited by the Local Supervisory Authority (LSA) and therefore are not required to be reported as an SI.

A homicide, serious injury or abuse of a child or young person will be subject to Local Safeguarding Children Boards (LSCBs) Reviews, it will be the designated Lead Nurse and/or Officer for Child safeguarding who has the responsibility for the reporting and follow-up process, in liaison with the Trust Risk Management lead. All Children and Young People SIs should be reported to the SHA however a homicide inquiry is not commissioned if the child is under 18. The care is reviewed by the Child Death Overview Panel (CDOP) as set out in the statutory guidance.

### **12.5 Vulnerable Adults**

There are occasions where SIs also represents an adult safeguarding concern. Forthcoming legislation will enshrine in law the need for every local area to have in place a Safeguarding Adults Board (SAB) – a body made up of the local social services authority, the police, the NHS and working with all other groups involved in protecting vulnerable. The Board will ensure that vulnerable adults who suffer abuse will have quick and easy access to the people who can help them best. See Appendix I for the local process

## **12.6 Cervical Screening Programme Incidents**

The Cervical Screening Programme within the Trust has been issued guidance on the recognition and management of Incidents<sup>15</sup>. This document provides guidance for managers on the identification and investigation of suspected problems in the cervical screening programme, and the steps to be taken if a serious incident in the cervical screening programme is confirmed.

## **13 Learning from experience**

Where serious failures in care occur they can have devastating consequences for individual patients and their families, as well as health care staff involved. Disappointingly, such failures often have a familiar ring, displaying strong similarities to incidents which have occurred before and in some cases almost exactly replicating them. Many could be avoided if only the lessons of experience were properly learned.

The Trust recognises that we may not always get things right. When this happens, the response should not be one of blame, but of learning in order to improve the service for future patients, visitors and staff.

This requires a collaborative approach to the analysis of incidents, complaints and claims (adverse events), and that the lessons learnt from this analysis are shared across the organisation as well as outside the organisation when appropriate. The policy on Learning from Adverse Events describes this in more detail.

## **14 Process for monitoring the serious incident policy**

The Chief Compliance Officer will be responsible for monitoring the effectiveness of this policy which will be overseen by the Quality and Safety Committee

### **14.1 Standards/key performance indicators and process for monitoring effectiveness**

The following key performance indicators will be monitored quarterly by the Chief Compliance Officer:

- Number of SIs reported within 2 working days of the decision to report
- Completeness of demographic details on on-line reports (excluding incidents which affect more than one individual)
- Number of MRSA bacteraemia root cause analysis completed within 10 days
- Number of pressure sore root cause analysis completed within 10 days
- Number of incidents in which update is provided within 2 weeks of report
- Number of root cause analysis reports completed within 6 months (excluding cases HCAI; pressure ulcers and cases with police involvement and / or inquests)
- Number of SIs reported to external agencies (excluding SHA and Commissioners)

Incidents will be notified to Executives within 24 hours of decision to report.

A paper will be provided for relevant committees and meetings detailing any new incidents and updating on previous incidents.

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<sup>15</sup> NHSCSP Publication 11 *Guidelines for managing incidents in the cervical screening programme* November 1999

The number of completed recommendations will be monitored at least six monthly via recommendation tracking by the Chief Compliance Officer.

For further information on monitoring of the policy please refer to the table at appendix O

## **15 Dissemination and Implementation**

Staff will be made aware of the introduction of this guideline via their Manager or Head of Department. New staff will be made aware of the existence of this guideline local induction.

Training in Root Cause Analysis and incident reporting will be offered by the Safety Advisors. The following training sessions will be offered each year:

- Incident reporting - general course, suitable for all staff
- Incident reporting – taking action – as part of team leaders/supervisors development programme
- Root Cause Analysis (RCA) – Band 7 development programme
- SI and RCA - as part of management development programme
- SI – reporting – taking action – For Clinical Site Managers

## **16 Review, Updating and Archiving of this Document**

Please note that the Intranet version of this document is the only version that is maintained. Staff, at their managers discretion may print copies of Trust documents but these paper copies should be viewed as 'uncontrolled' and as such, may not necessarily contain the latest updates and amendments.

All previous versions of the document will be archived by the governance on the Trust intranet using Document Library. Archived documents will be stored electronically in line with the Trust Organisation / Business Records Management Policy. This is done automatically when a revised document is placed in the document library. The database will be backed up according to the Trust Information Technology security policy

Retrieval of archived documents can be arranged through the governance department. (Contact the Clinical Audit Department at PRH)

This policy will be reviewed in April 2011, or before if circumstances dictate.

Comments on the content or implementation of the document should be directed to the Patient Safety Team Manager.

In order that this policy remains current, any of the appendices to the strategy can be amended and approved during the lifetime of the policy without the entire policy having to return to the Quality and Safety Committee

## **17 Equality Impact Assessment (EQIA)**

This document has been subject to an Equality Impact Assessment and is not anticipated to have an adverse impact on any group.

## 17 References

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- 9 National Patient Safety Agency – *Root Cause analysis toolkit*  
<http://www.npsa.nhs.uk/patientsafety/improvingpatientsafety/patient-safety-tools-and-guidance/rootcauseanalysis/>
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## 18 Glossary

<b>CFSMS</b>	<b>Counter-fraud and Security Management Services</b>
<b>CNST</b>	<b>Clinical Negligence Scheme for Trusts</b>
<b>CQC</b>	<b>Care Quality Commission</b>
<b>DH</b>	<b>Dept of Health</b>
<b>IG</b>	<b>Information Governance</b>
<b>HPA</b>	<b>Health Protection Agency</b>
<b>LSCB</b>	<b>Local Safeguarding Children Board</b>
<b>MHRA</b>	<b>Medicines and Healthcare Products Regulatory Agency</b>
<b>NPSA</b>	<b>National Patient Safety Agency</b>
<b>NRLS</b>	<b>National Reporting and Learning System</b>
<b>PCT</b>	<b>NHS Primary Care Trust</b>
<b>PSOG</b>	<b>Patient Safety Overview Group</b>
<b>RIDDOR</b>	<b>Reporting of Injuries, Diseases, and Dangerous Occurrences Regulations 1995</b>
<b>SHA</b>	<b>Strategic Health authority</b>
<b>SI</b>	<b>Serious Incident</b>
<b>SIMS</b>	<b>Serious Incident Management System</b>
<b>STEIS</b>	<b>Strategic Executive Information System</b>
<b>SUI</b>	<b>Serious Untoward Incident</b>
<b>UNIFY</b>	<b>Department of Health Information Gathering System that includes STEIS</b>
<b>UI</b>	<b>Untoward Incident</b>



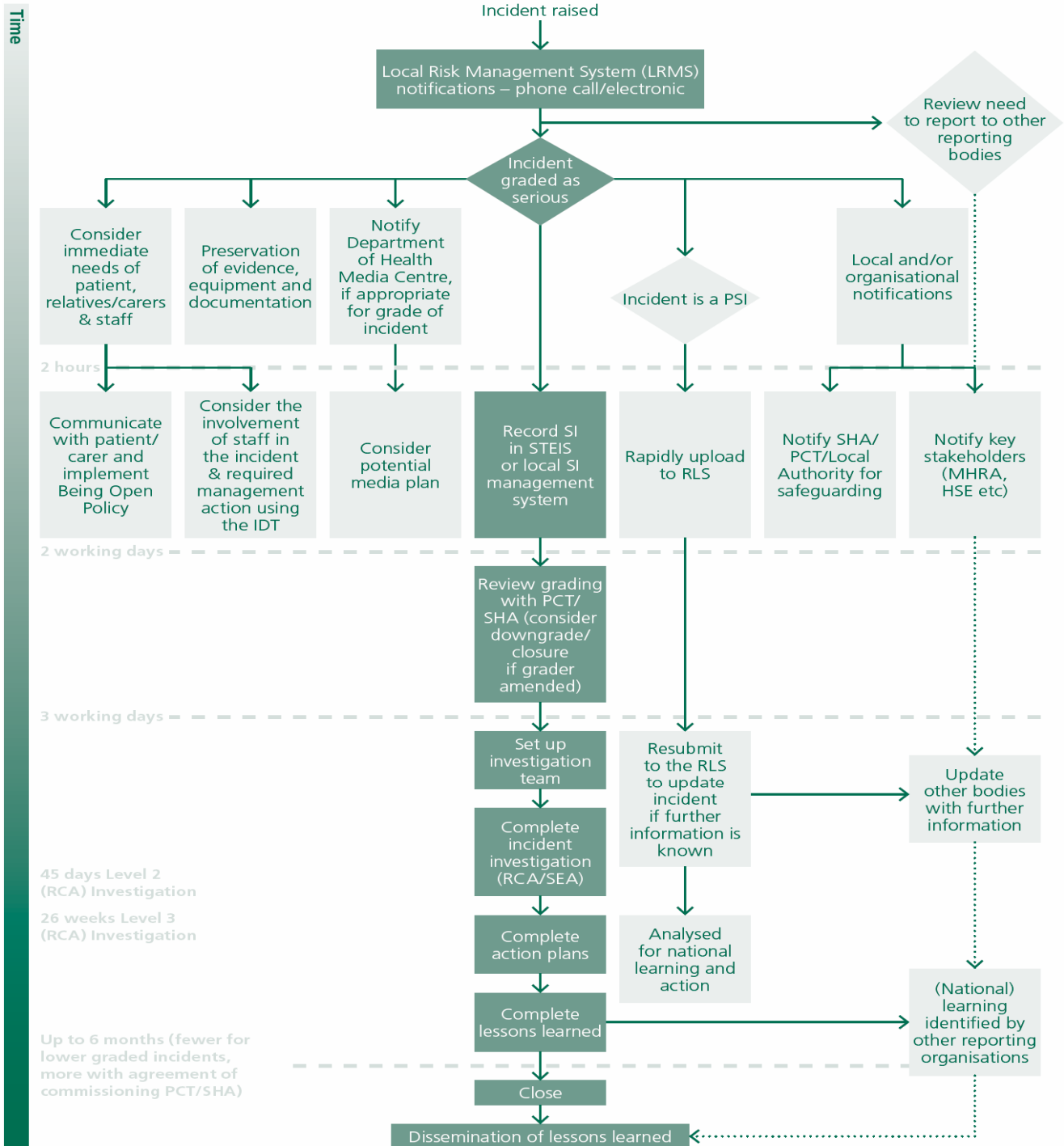
## Appendix A Grading of Serious Incidents

Table 1 is a guide to the incident grades developed by the NPSA, timescales and monitoring requirements. Grading should be agreed on an individual case by case basis, with advice from specialist safety advisors if necessary.

<b>Grade 0</b>	<p><b>Action required</b> Notification only – it is unclear if a serious incident has occurred. The provider organisation must update the Commissioner / SHA with further information within three working days of a grade 0 incident being notified. If within three working days it is found not to be a serious incident, it can be downgraded with the agreement of the accountable SHA /PCT. If a serious incident has occurred it will be regarded as a grade 1 or grade 2</p>		
<b>Grade 1</b>	<p><b>Action required</b> Commissioners will monitor the case and report findings, recommendations and associated action plans to the SHA.  SHA will monitor progress on a quarterly basis with PCT unless earlier discussion is required or the serious incident is regarded</p> <p><b>Comprehensive Investigation Root Cause Analysis (RCA) required (level 2 investigation.)</b></p>	<p><b>Monitoring required Local monitoring</b> The PCT and/or SHA will close the incident when it is satisfied the investigation, recommendations and action plan are satisfactory, and local monitoring arrangements are in place and working efficiently.  Publish incident details within Annual Reports</p> <p><b>Timescales: Up to 45 working days / 9 weeks</b> from the date the incident is notified to the PCT/SHA.</p>	<p><b>Examples of cases</b> Mental health – deaths in the Community HCAI outbreaks Avoidable/unexplained death Mental health – attempted suicides as inpatients Ambulance services missing target for arrival resulting in death/severe harm to patient Data loss and information security (DH Criteria level 2, see Information Resource) Grade 3 pressure ulcer develops Poor discharge planning causes harm to patient</p> <p><b>See Information Resource Tool</b></p>
<b>Grade 2</b>	<p><b>Action required</b> Case will be monitored by the SHA/PCT/LA in conjunction with the provider organisation  The SHA will review findings, recommendations and associated action plans  For Never Events, the commissioning PCT will be obliged to monitor overall numbers and actions and report these in its annual reporting arrangements</p> <p><b>Comprehensive Investigation (RCA level 2 investigation) (as above) or Independent Investigation (RCA level 3 Investigation)</b></p>	<p><b>Monitoring required SHA/PCT monitoring</b> Incidents leading to an independent investigation or inquiry or those considered high risk will continue to be monitored by the SHA/PCT or Local Authority until evidence is provided that each action point has been implemented. Incidents involving adult or child abuse are referred to local safeguarding arrangements  Publish quarterly reports</p> <p><b>Timescales: For Independent Investigations allow up to 26 weeks / 6 months</b> for completion of investigation. Extensions can be granted on an individual case-by-case basis by the SHA/PCT.</p>	<p><b>Examples of cases</b> Maternal deaths Inpatient suicides (including following absconsion) Child protection Data loss and information security (DH Criteria level 3-5) Never Events Accusation of physical misconduct or harm is made Homicides following receipt contact with mental health services</p> <p><b>See Information Resource Tool</b></p>

# Appendix B Flow-Chart: National Framework for Reporting & Learning from SIs

## Serious Incident Reporting Process



**Abbreviations:**

**IDT:** Incident Decision Tree  
**PSI:** Patient Safety Incident

**RLS:** Reporting & Learning System  
**SEA:** Significant Event Audit

**RCA:** Root Cause Analysis  
**SI:** Serious Incident

**Abbreviations:**

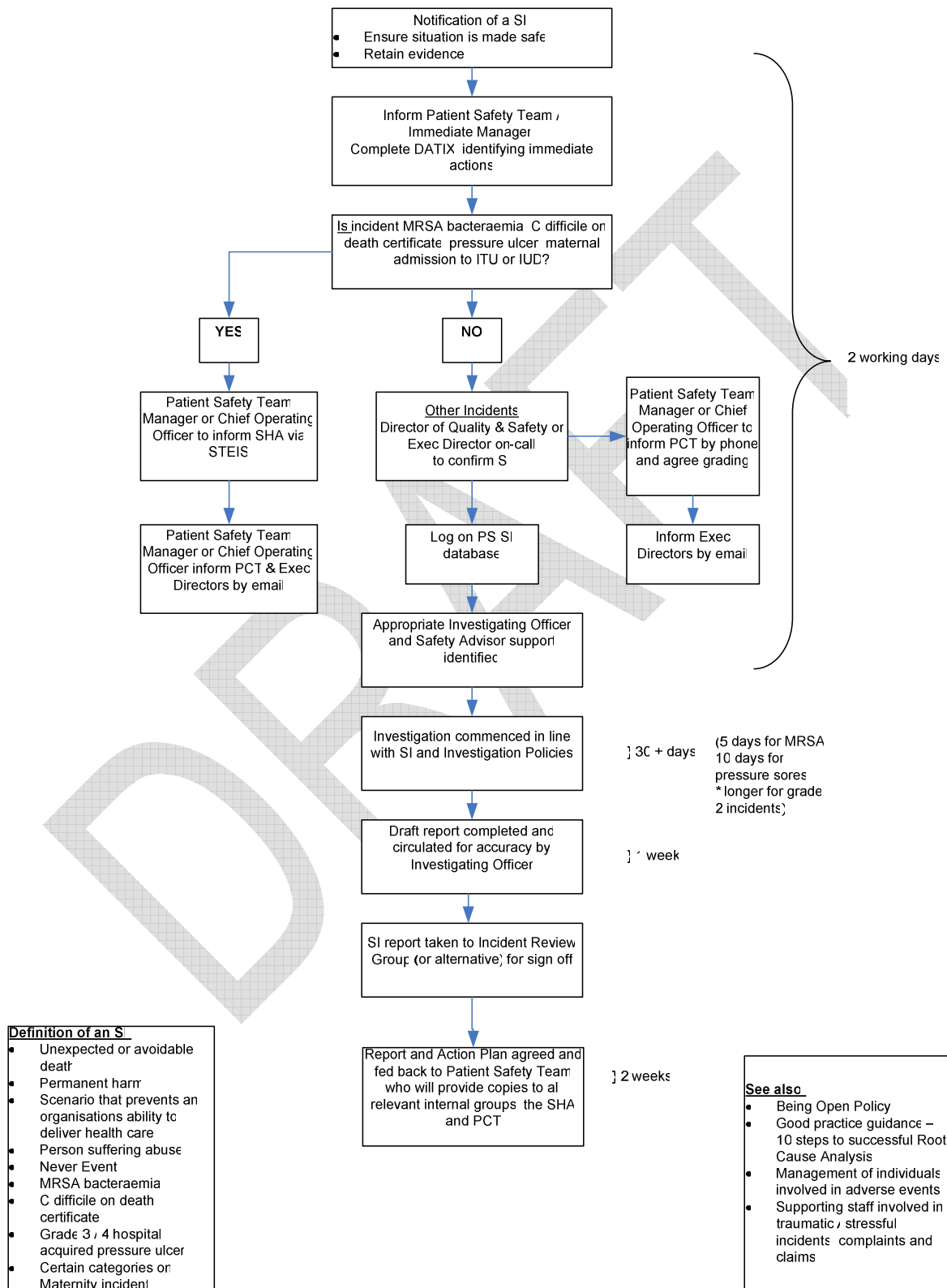
**IDT:** Incident Decision Tree  
**PSI:** Patient Safety Incident

**RLS:** Reporting & Learning System  
**SEA:** Significant Event Audit

**RCA:** Root Cause Analysis  
**SI:** Serious Incident

## Appendix C Local Flowchart: Reporting and Learning from SIs

### SATH Serious Incident (SI) Responsibilities



## Appendix D CQC Reporting Requirements

There is a statutory requirement to report the following incident types to the CQC via the National Reporting and Learning System run by the NPSA:

### Unexpected death

Deaths should be reported where this cannot reasonably be attributed to the course which the patient's illness or medical condition would naturally have taken. The death must have occurred:

- While the service was being provided
- As a consequence of the service being provided and
- Was not caused by an illness or condition that was being appropriately treated

### Serious injuries

Serious injury to any person using the service or an injury requiring treatment by a healthcare professional to prevent death or serious injury. This category includes the following:

- Injuries that lead to or are likely to lead to permanent damage (or damage that lasts or is likely to last more than 28 days) to:
  - a person's sight, hearing, touch, smell or taste
  - any major organ of the body (including the brain and skin), or bones, muscles, tendons, joints or vessels
  - intellectual functions, or Injuries or events leading to psychological harm,
- the development **after admission of a pressure sore of grade 3 or above that develops** after the person has started to use the service (**European Pressure Ulcer Advisory Panel Grading**)
- any injury or other event that causes a person pain lasting or likely to last for more than 28 days

### Events that stop or may stop the service running safely and properly

- A level of staff absence or vacancy, or damage to the service's premises that mean that people's assessed needs cannot be met.
- The failure of a utility for more than 24 hours.
- The failure of fire alarms, call systems or other safety-related equipment for more than 24 hours.
- Any other circumstances or events that mean the service cannot – or may not be able to – meet people's assessed needs safely

### Allegations of abuse

Any suspicion, concern or allegation from any source that a person using the service has been or is being abused, or is abusing another person (of any age) and where:

- The alleged abuser is a member of staff or volunteer working for the provider or
- The alleged abuser is another person who uses the service or
- The abuse is alleged to have occurred on the premises of the provider.

NB: English NHS trusts notify allegations of abuse of children to local multiagency child protection arrangements.

The following incident types incident must be reported direct to CQC via an eform on CQC website

- **Notification of death or unauthorised absence of a person who is detained or liable to be detained under the Mental Health Act.**
- **Any application by the service to a Supervisory Body to deprive an adult of their liberty or any application by the service to the Court of Protection to deprive an adult of their liberty.**

Appendix E 'Never events' 2010/2011

Type of Incident	Description	Main care setting
<b>Wrong site surgery</b>	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.	Organisations that provide major, minor and/or day case surgery
<b>Retained instrument</b>	One or more instruments or swabs, or a throat pack, are unintentionally retained following an operative procedure, and an operation or other invasive procedure is needed to remove this, and/or there are complications to the patient arising from its continued presence. This Never Event does not include interventional radiology or cardiology procedures, and the definition of instrument does not include guidewires, screws, or other similar material. It does not include retained swabs after <b>non-operative</b> vaginal delivery.	Organisations that provide major, minor and/or day case surgery
<b>Wrong route administration of chemotherapy</b>	Intravenous or other chemotherapy (for example, vincristine) that is correctly prescribed but administered via the wrong route (usually into the Intrathecal space).	Acute care
<b>Misplaced naso or orogastric tube not detected prior to use</b>	Naso or orogastric tube placed in the respiratory tract rather than the gastrointestinal tract and not detected prior to commencing feeding or other use	All care settings
<b>Inpatient suicide using non-collapsible rails</b>	Suicide using curtain or shower rails by an inpatient in an acute mental health setting	Mental health
<b>Escape from within the secure perimeter of medium or high secure mental health services by patients who are transferred prisoners</b>	A patient who is a transferred prisoner escaping from medium or high secure mental health services where they have been placed for treatment on a Home Office restriction order	Mental health
<b>In hospital maternal death from post-partum haemorrhage after elective caesarean section</b>	In-hospital death of a mother as a result of a haemorrhage following elective caesarean section, excluding cases where imaging has identified placenta accrete	Acute care maternity services
<b>Intravenous administration of mid-selected concentrated potassium chloride</b>	Intravenous administration of mis-selected concentrated potassium chloride	All care settings

## Appendix F Healthcare Associated Infection Reporting

There is a requirement for all cases of MRSA Bacteraemias to be reported as a SI and RCA completed and in the incidence of C difficile cases that are identified first and secondary cause of death (1a, 1b, 1c and 2 on the death certificate)

Other incidents of C difficile that would require escalation of investigation and SI reporting are:

- C difficile outbreak- background levels should be taken into account and variations from that threshold should be judged when establishing an outbreak control group
- Clusters – where there is an increased number of cases within an area without them necessarily having a direct time link
- Consistently high levels of cases or an increasing base line
- High rates of recurrences
- Increasing proportion of patients developing complications

In situations where MRSA cases are passed to PCTs in cases known as 'Pre-48 hours', (patients who are clinically symptomatic within the first 48 hours of admission) SIs must be reported and managed by the reporting Trust (i.e. the Trust identifying the positive specimen). RCA should be completed by the appropriate PCT. A SI cannot be generated in one organisation and passed to another. In some cases joint working will be required to monitor the RCA is completed within timescales and the findings loaded to the SI system and SI closed accordingly.

**These incidents should not be reported to the CQC under the notification system but should continue to be reported to the HPA**

Incident	Specific guidance	Comments	Minimal grading of Incident
MRSA bacteraemia	All cases	<ul style="list-style-type: none"> <li>• Regardless of where acquired or the source of infection.</li> <li>• Includes contaminated specimens</li> <li>• PCT commissioners should make clear the process by which the incident is reported dependant on pre/post 48 hour cases and contaminants.</li> </ul>	Grade 1 (serious incidents: PCT responsible for monitoring the case; SHA will monitor on a monthly basis unless earlier discussion is required or incident is re-graded).
<i>Clostridium difficile</i> related deaths	Deaths where <i>Clostridium difficile</i> is recoded in <b>part 1 (a, b, or c)</b> of the death certificate only	<ul style="list-style-type: none"> <li>• PCT commissioners must ensure that there is robust reporting in place and all cases are captured. This includes deaths in the community were <i>C. diff</i> is on part 1 of the death certificate.</li> </ul>	Grade 1 (serious incidents: PCT responsible for monitoring the case; SHA will monitor on a monthly basis unless earlier discussion is required or incident is re-graded).
<i>Clostridium difficile</i> Periods of increased incidence (PII)	All incidents regardless of bed closures	<ul style="list-style-type: none"> <li>• Period of increased incidence is defined as 2 or more new cases (occurring more than 48 hours after admission, not</li> </ul>	Grade 0 (Notification only: the provider organisation must update to the PCT within 3 days of the

		<p>relapses) in a 28 day period on a ward.</p> <ul style="list-style-type: none"> <li>• PII may occur in the community linked to prescriber's practices or in a care situation. Again more than 2 cases in a 28 day period linked by time, place or person must be reported.</li> </ul>	<p>incident; it can be closed with the agreement of the PCT).</p>
Outbreaks of infection	All outbreaks regardless of bed closures	<p>An outbreak is an incident which meets any of the following criteria:</p> <ul style="list-style-type: none"> <li>• An incident in which two or more people experiencing a similar infectious illness are linked in time/place;</li> <li>• A greater than expected rate of infection compared with the usual background rate for the place and time where the outbreak has occurred;</li> <li>• A single case for certain rare diseases such as diphtheria, botulism, rabies, viral haemorrhagic fever, legionnaire's disease or polio (NB: this list is not exhaustive).</li> </ul>	<p>Grade 1 (serious incidents: PCT responsible for monitoring the case; SHA will monitor on a monthly basis unless earlier discussion is required or incident is re-graded).</p>
Deaths attributed to a healthcare associated infection (HCAI)	Any death where a HCAI is listed on <b>Part 1a</b> of the death certificate only.	<ul style="list-style-type: none"> <li>• Trusts will need to identify methods of consistently collating this data.</li> <li>• Through this process avoidable deaths should be identified and the risk of repetition of the incident reduced.</li> </ul> <p><b>NB:</b> Deaths due to <i>Clostridium difficile</i> infection should be reported as specified.</p>	<p>Grade 1 (serious incidents: PCT responsible for monitoring the case; SHA will monitor on a monthly basis unless earlier discussion is required or incident is re-graded).</p>

## Appendix G Guidance from Department of Health – Data Loss

### Reporting Serious Untoward Incidents (SIs) Relating to Actual or Potential Breaches of Confidentiality involving Person Identifiable Data (PID), including Data Loss.

It is essential that all serious untoward incidents that occur in the Trust are reported appropriately and handled effectively. This document covers the reporting arrangements and describes the actions that need to be taken in terms of communication and follow up when a serious untoward incident occurs. Trusts should ensure that any existing policies for dealing with Serious Untoward Incidents are updated to reflect these arrangements.

#### Definition of a Serious Untoward Incident in relation to Personal Identifiable Data.

There is no simple definition of a serious incident. What may at first appear to be a minor importance may, on further investigation, be found to be serious and vice versa. As a guide, any incident involving the actual or potential loss of personal information that could lead to identity fraud or have other significant impact on individuals should be considered as serious.

#### Immediate response to Serious Untoward Incident

The Trust should have robust policies in place to ensure that appropriate senior staff are notified immediately of all incidents involving data loss or breaches of confidentiality. Where incidents occur out of hours, the Trust should have arrangements in place to ensure on-call Directors or other nominated individuals are informed of the incident and take action to inform the appropriate contacts.

#### Assessing the Severity of the Incident

The immediate response to the incident and the escalation process for reporting and investigating this will vary according to the severity of the incident.

Risk assessment methods commonly categorise incidents according to the likely consequences, with the most serious being categorised as a 5, e.g. an incident should be categorised at the highest level that applies when considering the characteristics and risks of the incident.

0	1	2	3	4	5
No significant reflection on any individual or body Media interest very unlikely	Damage to an individual's reputation. Possible media interest e.g. celebrity involved	Damage to a team's reputation. Some local media interest that may not go public	Damage to a services reputation/low key local media coverage	Damage to an organisation's reputation/local media coverage	Damage to NHS reputation/national media coverage
Minor breach of confidentiality. Only a single individual affected	Potentially serious breach. Less than 5 people affected or risk assessed as low, e.g. files were encrypted	Serious potential breach & risk assessed high, e.g. unencrypted clinical records lost. Up to 20 people affected	Serious breach of confidentiality, e.g. up to 100 people affected	Serious breach with either particular sensitivity, e.g. sexual health details or up to 1000 people affected	Serious breach with potential for ID theft or over 1000 people affected

#### Reporting to PCT

The Trust should report the SI, i.e. all incidents rated as 1 – 5 to the PCT as described in appendix F. The following information should be provided in each case:

A short description of what happened, including the actions taken and whether the incident has been resolved

- Details of how the information was held: paper, memory stick, disc, laptop, etc



- Details of any safeguards such as encryption that would mitigate risk
- Details of the number of individuals whose information is at risk
- Details of the type of information: demographic, clinical, bank details, etc
- Whether a) the individuals concerned have been informed, b) a decision has been taken not to inform or c) this has not yet been decided
- Whether a) the Information Commissioner has been informed, b) a decision has been taken not to inform or c) this has not yet been decided
- Whether the SI is in the public domain and the extent of any media interest and/or publication

Reporting to the PCT should be undertaken as soon as practically possible (and no later than 24 hours of the incident during the working week). If there is any doubt as to whether or not an incident meets the SI reporting criteria, the Trust's Risk Manager or the PCT should be contacted by telephone for advice. Early information, no matter how brief, is better than full information that is too late.

The Trust should keep the PCT informed of any significant developments in internal/external investigations, as appropriate. The PCT should continue to keep a watching brief on developments including following up further details/outcomes of the incident.

The Trust's communications team should contact the PCT's communications team immediately if there is the possibility of adverse media coverage in order to agree a media handling strategy. Where necessary, the PCT communications team will brief the Department of Health Media Centre.

#### **Reporting to the Department of Health (DH)**

The PCT will be responsible for notifying the DH of any category 3 – 5 incident reported by forwarding details to the appropriate dedicated mailbox established within the DH. Incidents should be notified to **DH comms only** if the lighter shaded risk areas in the top two rows in the table apply, and to both **DH comms and the Ministerial Briefing Unit** if the significant risks in the darker shaded area at the bottom right of the table apply. This latter, most serious category is the one that should be referenced as a nationally reported SI. Those reported to DH Comms alone should be referred to as a comms alert derived from a local SI. Once an incident has been reported to DH, any subsequent details that emerge relating to the investigation and resolution of the incident should also be supplied. The DH will review the incident and determine the need to brief Ministers and/or take other action at a national level.

#### **Reporting to the Information Commissioner or other Bodies**

The Information Commissioner should be informed of all category 3 – 5 incidents. The decision to inform any other bodies will also be taken, dependent upon the circumstances of the incident, e.g. where this involves risks to the personal safety of patients, the National Patient Safety Agency (NPSA) may also need to be informed.

#### **Informing Patients**

Consideration should always be given to informing patients when person identifiable information about them has been lost or inappropriately placed in the public domain. Where there is any risk of identity theft it is strongly recommended that this is done.

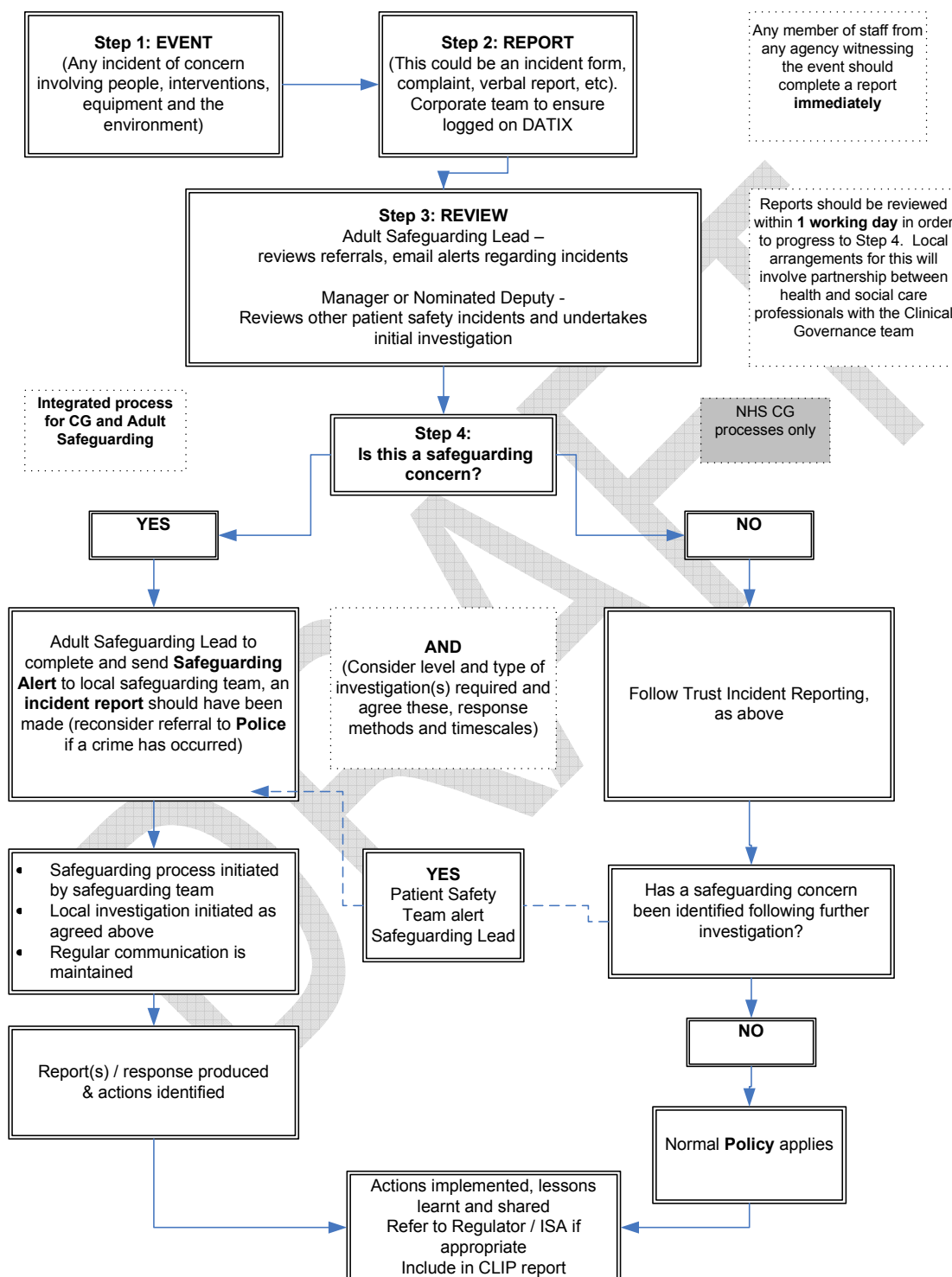
## Appendix H Maternity Categories on UNIFY

Category	Further explanation
Maternal Deaths	Specifically; those that occur whilst under booked care and should follow from antenatal care through to post natal care.
Intra-uterine deaths	Which occur over 37 weeks gestation <b>and during an inpatient admission</b>
Intra-partum deaths	Those that die during labour or during an inpatient admission.
Unexpected neonatal death	From 37 weeks gestation to 28 days post delivery
Non-elective (emergency) maternal admissions to ITU	<b>This is for Critical Care Level 3 (ventilated) patients only:</b> These are patients requiring advanced respiratory support alone or basic respiratory support together with support of at least two organ systems. This level includes all complex patients requiring support for multi-organ failure.
Unexpected admissions to Neonatal Intensive Care	i.e. Where the Apgar remains below 4 at 10 minutes or baby has already required intubation
Serious Drug administration errors	As per Medicines Management and SHA SI Reporting Policy
Surgical Operative Obstetric errors as per Never Events Framework or surgical error	All surgical errors and please note that NPSA have added retained vaginal swabs <b>during an operative delivery</b> as an additional category to the Never Events Framework
Lost cytology/histopathology tissue or errors	As per the Human Tissue Authority and Humans Tissue Act 2004

# Appendix I Safeguarding and SI processes

## Clinical Governance and Adult Safeguarding – An Integrated Process

### Flow Chart



## Appendix J NHS Direct Helpline Protocols

### Introduction

As a national service NHS Direct can be a useful tool for NHS Trusts and Primary Care Trusts (PCTs) who are expecting a large number of calls from the general public relating to a specific health or environmental issue.

The 0845 4647 number can be used, for instance, in the case of a major area health alert (e.g. chemical spillage, gas leak) or an individual health issue affecting a significant number of patients (e.g. TB look back exercise).

However, this must **ONLY** ever be done following agreement between the relevant lead NHS organisation and the local NHS Direct site.

It is important to note that NHS Direct is **NOT** a casualty bureau but can provide a vital resource in providing correct, up-to-date and timely health advice and information to the general public and the 'worried well'.

The idea of this document is to provide advice to NHS Trusts and Primary Care Trusts on how to work with NHS Direct to maximise its usefulness in such situations.

### NHS Direct

Contacts:  
NHS Direct  
7<sup>th</sup> Floor  
207 Old Street  
London  
EC1V 9NR

Telephone: 020 7599 4212  
email: stakeholders@nshdirect.nhs.uk

### Crisis/Helpline Guidelines

These guidelines relate to major area-wide environmental and health incidents. They also cover any instances where a helpline could be used to support both planned and unplanned situations which might generate a number of calls from the general public, i.e. those who might have been exposed as a result of an incident and/or the worried well.

- 1 Contact the NHS Direct site as soon as possible with the basic details of the incident by ringing 020 7599 4212. Helplines can take some time to establish so it is essential that early warning is given.

**An 'Intent to Commission' document or 'Service Request' Form must be completed and signed by an Executive Director before this service is commissioned.**

On contacting NHS Direct the manager will ensure the senior management team are briefed with the General Manager assigning internal clinical, operational, communications and training leads.

Specific operational requirements will be decided between the General Manager and the NHS Trust/PCT. Operational options fall into three categories depending on the incident/issue and the level of NHS Direct's involvement

- i. Calls are directed to the **0845 4647** and integrated into core business with call volumes monitored.
- ii. Interactive Voice Response (IVR) – a front ended message prior to verbal interaction i.e. *'If you are calling in connection with the recent chemical spillage in (area). Please press #1'*. This operational model can be initiated at short notice, is cost effective and provides detailed monitoring of call volumes.
- iii. Activate separate telephone number – used ideally for planned activity i.e. look back exercises. The cost implication for activating the telephone line and resourcing would be the responsibility of the NHS Trust/PCT.

It is vital that NHS Direct is made aware of any incident at the earliest opportunity – even if the incident is later found to be less serious than first thought and it proves unnecessary to direct people to the help line.

- 2 Should the lead NHS Trust or PCT decide NHS Direct could play a vital role in reassuring/informing the general public, the NHS Direct site should be provided with a general briefing of the incident (see attached briefing/information form). A question and answer sheet will also be required about the incident along with the core script for NHS Direct call handlers. ***This must be done before any publicity is carried out.***

If the help line is fielding calls from at-risk individuals, potentially at-risk individuals and the worried well, a core script is particularly important if the Site is to act as a screening service for calls from the public. It is important to note that it remains the responsibility of the relevant NHS Trust or PCT to deal with any such identified callers.

The above information should be signed off at Director level by a representative of the lead NHS organisation.

- 3 Alternatively, calls from the public to NHS Direct might prompt the NHS Direct Site to contact the lead NHS organisation proactively to request the above information.
- 4 The relevant NHS Direct site will coordinate dissemination of this information via NHS Direct's national network, for instance if the incident crosses site boundaries or in the event of a workload being distributed across the virtual call centre network.
- 5 Publicity of the NHS Direct number should be in the form of a press release agreed between the lead NHS organisation and either the General Manager or Communications Manager at the NHS Direct site.

## **Appendix K External bodies to whom an incident may need to be reported**

**POLICE** if a criminal act or activity or suicide/accidental/suspicious death is suspected.

SHREWSBURY Speed call 896

TELFORD (MALINSGATE) Speed call 8132 or 290888

**CORONER** if an accidental/suspicious death is suspected

SHREWSBURY AND SHROPSHIRE COUNTY Mr Ellery (01743) 237445

TELFORD AND WREKIN Mr Ellery (01952) 641651

**HEALTH and SAFETY EXECUTIVE** if an accident occurs resulting in major injury or death.

**01782 602300 or 0845 300 9924 (Incident Contact centre)**

Reporting under RIDDOR will be done by Health and Safety team

**ENVIRONMENT AGENCY** Any environmental incidents which may cause water contamination or pollution **0800 80 70 60**

**COMMISSIONERS** for any SI. Normally done by Patient Safety Team Manager via the on line reporting system. For urgent advice telephone SHA Head of patient safety 0121 695 2302 (in hours) or First Response Agency 01384 215 684 (out of hours)

**MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AUTHORITY** Any incident in which a medical device was involved which caused death, life threatening injury, or extra medical/surgical intervention. Also now includes severe adverse drug reactions.

**020 7972 8080**

Incidents involving medical devices are usually reported by Head of MES based at RSH (extension 1149)

Incidents involving medicines by Head of Pharmacy at RSH (extension 3800)

Incidents which did not cause major permanent harm will be reported via the Internet.

**SERIOUS HAZARDS OF TRANSFUSIONS (SHOT)** Any incident involving blood transfusions. Normally done by Blood Transfusion Practitioner

**DoH: The Ionising Radiation (Medical Exposure) Regulations 2000, (IR(ME)R 2000)** Certain radiology incidents. Normally done by Radiology manager

**LOCAL SAFEGUARDING CHILDREN BOARD (LSCB)** Any serious incident involving a child already considered 'at risk' or likely to become so as a result of the incident please discuss with the named child protection team:-

Named Midwife: Extension 3104 at RSH

Named Nurse: Extension 4195 at PRH

Paediatric Lead Nurse: Extension 4195 at PRH

Action will be taken in accordance with LSCB procedures.

**LOCAL AUTHORITY** Any incident which may impact on the public at large or surrounding areas

TELFORD AND WREKIN COUNCIL 01952 619251

SHREWSBURY & ATCHAM BOROUGH COUNCIL 01743 281500

The list is not exhaustive and may also include:

- Chief Pharmacist
- General Practitioners, particularly where a large number of patients are involved
- Other NHS organisations
- PALS
- Director of Infection Control

- Public Health
- Trust Legal Advisors
- Local Supervising Authorities in case of Serious Obstetric Incidents
- National Confidential Enquiries (Suicides, Homicides, Maternal and Child Deaths)
- NHS Litigation Authority
- National Patient Safety Agency
- Social Services
- Local Safeguarding Board
- Child Death review panel
- Mental Health Commission
- Home Office
- The public at large, or in the neighbouring areas if an environmental hazard has occurred.
- NHS Directorate of Health and Social care
- Area Child Protection Committee
- Health Protection Agencies
- Environmental Health
- Legal Advisors
- Local Representative Committees
- Medical Defence Organisations

DRAFT

**Appendix L SI response checklist – for use by Incident Manager**

**Preliminary Action**

Establish if any action needs to be taken immediately to prevent further harm.

**Identification**

Obtain a full list of all known/possible patient(s) affected.

**Informing GPs**

Fully inform GP's before the patient(s), to ensure patients still alive & at same address.

**Informing Patient(s) and relatives**

IT IS ESSENTIAL TO INFORM PATIENT (S) BEFORE THE MEDIA.

Decide whether to inform relatives at same time as patient(s).

Decide on most appropriate method of communication.

Give name of individual for further information.

**Practical Considerations**

Communicate honestly without causing alarm.

Transport.

Escort/Relative invited.

**Record Keeping**

Record details of patient(s) involved & actions taken. Record actions & conversations.

Enter details in medical records; if appropriate.

**Inform Commissioners**

Ensure all patient(s) have been notified.

Copy press statements to Chief Executive, Chief Executive of PCT

Inform Communications Department at Strategic Health Authority.

**Media Relations**

Director of Communications to organise production of press statements in conjunction with Responsible Manager.

Director of Communications to ensure contact maintained with SHA



**Appendix M Checklist to follow in the case of an extreme SI**

**(based on Leeds Teaching Hospital NHS Trust checklist)**

<b>Internal</b>	<b>Action</b>	<b>Purpose</b>	<b>Responsibility</b>	<b>Incident</b>	<b>Inquiry</b>	<b>Court Proceedings</b>
<b>Staff affected</b>	1. Keep staff informed re investigation and time it may take	Honesty re timeframes	Patient Safety Team Manager	✓		
	2. Appoint named support person	Active support of staff through process of investigation/trial Help with personal arrangements through trial (travel, child care, work commitments)	Patient Safety Team Manager		✓	
	3. Agree plans for covering clinical work where individual staff are required to take time off to assist with an investigation	Ensure patient care is maintained	Divisional Management Team		✓	✓
	4. Ensure easy and timely access to Occupational Health support	To reduce the personal impact of their contribution to the inquiry	Line Manager		✓	✓
<b>Trust Board</b>	5. Keep updated with timeframes for report; agree briefing process for the Board	Achieve and maintain effective engagement with Trust Board, ensure the Board is advised on risks associated with the incident and actions taken (and required) to mitigate against these risks	Director of Quality and Safety		✓	✓
<b>Internal Communications</b>	6. Agree who needs cascade of information and when; agree communication plan and identify named communication leads within the organisation	Need for clarity of messages to staff and ensure consistency	Director of Communications		✓	✓
<b>External</b>	7. Designate an individual to liaise with commissioners on progress and with SHA where appropriate	Ensure all parties are updated on progress and timescales for completion	Serious Incident Coordinator	✓	✓	✓
	Keep stakeholders informed, e.g.		Director of	✓	✓	✓

Internal	Action	Purpose	Responsibility	Incident	Inquiry	Court Proceedings
	Scrutiny Board, local MPs and Council leaders, patient representative organisations		Communications			
<b>Media</b>	8. Agree media handling plan with communications teams, working in conjunction with commissioners and SHA	Ensure all parties are communicating with media in line with plan and agreed content to ensure consistency of messages	Director of Communications	✓	✓	✓
<b>Relatives</b>	9. Agree communications with relatives and lead individuals for doing this, taking account of specific advice from police	See below - contact from Trust essential but will need to be in line with agreement at initial meeting with police	Patient Safety Team Manager		✓	
	10. Contact relatives at the beginning of the investigation	Relatives need to know when and how much communication they will receive from the Trust and why this will be limited	Divisional Management Team		✓	
	11. Appoint an individual to act as liaison with relatives should they need to use the hospital's services	To ensure that relatives who use our services on an ongoing basis have the support to do so - they will be accessing services in an organisation that has harmed a family member	Patient Safety Team Manager		✓	
<b>Police</b>	12. Arrange initial meeting with Police and other key stakeholders within 24 - 48 hours of reporting incident	Agree process for investigation	Director of Quality and Safety	✓		
	13. Agree single named contact for Trust and the Police	Who will be key contacts for families and staff	Director of Quality and Safety	✓		
	14. Agree what needs to be done immediately to make an area safe	Ensure safe environment for staff and patients	Divisional Management Team	✓		

**Appendix N     Hotline forms**

***DETAILS TO BE LOGGED WHEN HOTLINE STAFF MAKE CONTACT***

Patient's name & address	Patient's unit no.	Patient's telephone no.	Patient's GP	Check patient's: Address Alive	Date & time GP informed	Date & time and method of contact	Contacted by	Response to contact	Noted in record	GP informed of contact	Follow up action

***DETAILS TO BE LOGGED WHEN PATIENTS/ RELATIVES / PUBLIC /GPS CONTACT HOTLINE***

Callers name & address	Callers unit no. (if applicable)	Callers telephone no.	Callers GP (if applicable)	Date & time and method of contact	Spoke to:	Response to contact	Noted in record	GP informed of contact ( if applicable)	Follow up action

## Appendix O Monitoring effectiveness of policy

Element to be monitored	Lead	Tool	Frequency	Reporting arrangements	Acting on recommendations and Lead(s)	Change in practice and lessons to be shared
Number of SIs reported within 2 working days of the date of knowledge of incident	Chief Compliance Officer	Incident date; Date of incident notification; Reported date on online system	Quarterly report monitoring these elements	The Safety and Quality Committee is expected to read and interrogate the report to identify deficiencies in the system and act upon them	Incident Review Group will identify required actions monitor completion in a specified timeframe.	Required changes to practice will be identified and actioned within a specific time frame. A lead member of the team will be identified to take each change forward where appropriate. Lessons will be shared with all the relevant stakeholders.
Completeness of demographic details on on-line reports (excluding incidents which affect more than one individual)	Chief Compliance Officer	Date of birth; sex and ethnic group reported on online system				
Number of MRSA bacteraemia root cause analysis completed within 5 working days	Chief Compliance Officer	Date incident reported and date of RCA completion				
Number of pressure sore root cause analysis completed within 10 days	Head of nursing practice	Date incident reported and date of RCA completion				
Number of incidents in which update is provided within 2 weeks of report	Chief Compliance Officer	Date incident reported and date of update				
Number of root cause analysis reports completed within 6 months (excluding cases HCAI; pressure ulcers and cases with police involvement and / or inquests)	Chief Compliance Officer	Date incident reported of closure				
Number of SIs reported to external agencies (excluding SHA and Commissioners)	Chief Compliance Officer	Cross tab of Incidents and external reporting				