University Hospitals of Leicester NHS
NHS Trust

INCIDENT AND ACCIDENT REPORTING UHL POLICY

(INCLUDING THE INVESTIGATION OF SERIOUS, RIDDOR AND SECURITY INCIDENTS AND THE MATERNITY RISK MANAGEMENT POLICY)

Approved By:	**Trust Board**
Date Approved:	**25 July 2002**
Trust Reference:	**B30/2024** **This version replaces the old cat A, Trust Ref: A10/2002. PGC is aware of the Trust Board's decision. Agreed 11th April 2024.**
Version:	**Version 11**
Supersedes:	Version 10 (17 Sept 2021 PGC)
Author / Originator(s):	**Head of Patient Safety**
Name of Responsible Committee/Individual:	**Medical Director** **Executive Quality Board**
Latest Review Date	7 December 2021 – PGC Chair's urgent approvals process
Next Review Date:	**November 2024**

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This version replaces the old cat A, Trust Ref: A10/2002. PGC is aware of the Trust Board's decision. Agreed 11th April 2024.

REVIEW DATES AND DETAILS OF CHANGES MADE DURING THE REVIEW

December 2021 – added appendices 1 and 2 to appendix F

August 2021 – amendment to add in Maternity Risk Management Policy at Appendix F. Change of title from Director of Safety and Risk to Director of Quality Governance. Removal of reference to Incident Decision Tree throughout document which is no longer used. Addition of 'hospital acquired Covid-19' to section 6.9.1. Change of title of Learning from Experience Group to Adverse Events Committee.

March 2020 – minor amendment to Section 7 to reflect a national update in reference to the management of serious incidents in screening programmes.

January 2019 – extension to review date (to September 2019) agreed at PGC

Review date March 2016. Previous version A10/2002. Details of changes made during review:

- Policy wording to reflect change in serious incident guidance from NHS England
- Additional policies added to list of related policies.
- Addition of reference to the management of serious incidents in screening programmes.

KEY WORDS

Incident, accident, RIDDOR, Serious Incident, Datix, Health and Safety, adverse incident, investigation, Never Event, medical device, SI, SIRI, maternity

1 SUMMARY

1.1 This document describes the process for the reporting of all clinical and non-clinical accidents and incidents, reportable both internally and externally, involving patients, staff and others and security.

1.2 The purpose of reporting and investigating any incident is to:-

- Identify the causal factors which may identify underlying failures.
- Learn lessons.
- Implement improvement strategies to help prevent or minimise recurrences, thus reducing future risk of harm.
- Satisfy mandatory reporting requirements.

1.3 If any research activity is associated with an incident, Research and Development must be notified.

1.4 The document also describes the roles and responsibilities of individuals for the reporting and investigating of incidents/accidents, the processes for grading, reporting and investigating patient and staff incidents/accidents.

2 POLICY AIMS

2.1 To ensure timely and appropriate follow up to all accidents, incidents and unintended occurrences these include Patient Safety Incidents (PSI) prevented Patient Safety Incidents (PSI), accidents, security incidents, radiation incidents and near miss (non-clinical) events.

2.2 To identify factors contributing to these events and the root causes of them.

2.3 To identify trends locally (within Clinical Management Groups (CMGs)) and across the Trust.

2.4 To identify preventative measures or procedural changes to reduce or eliminate the risks of recurrence.

2.5 To provide a means for evaluating the effectiveness of control measures designed to improve safety /security for patients, staff and others.

2.6 To help ensure the safety/security of patients, staff and others and to reduce litigation costs.

2.7 To meet national and local and reporting requirements and comply with relevant legislation such as: The Reporting of Injuries, Diseases and Dangerous Occurrence Regulations (RIDDOR), Ionising Radiation Regulations (IRR) and The Ionising Radiations (Medical Exposure) Regulations (IRMER).

2.8 To ensure patients and/or their relatives receive appropriate information about incidents in which they were involved.

2.9 To provide feedback to Clinical Management Groups (CMGs) and other clinical/corporate departments to be used for learning and improving.

2.10 To ensure patients and/or relatives and staff receive a full and honest response following investigation, which provides an account of what happened, why it happened and if appropriate, any actions taken to reduce/avoid recurrence.

3 POLICY SCOPE

3.1 This policy applies to all staff including temporary staff, bank staff and agency staff, those on honorary contracts and contractors working within the Trust. All staff are required to comply

with this policy and have a responsibility to report any PSIs, PPSIs, accidents, non-clinical near misses or security incidents (including violence, threat, abuse, theft, whether resulting in harm/injury or not) to their line manager, supervisor or person in charge.

3.2 This policy does not cover "Whistle Blowing". If as an employee you wish to make a genuine disclosure about an issue that you feel is a wrong doing, you should refer to the Trust's Whistle Blowing Policy.

4 DEFINITIONS

Patient Safety Incident (PSI)	Any incident affecting patients irrespective of the consequences (impact). This is a clinical incident affecting the care or outcome for the patient.
Prevented Patient Safety Incident (PPSI)	An unexpected or unintended event, which had the potential to cause harm but was prevented; resulting in no harm (may be referred to as a "near miss".)
Accident	An incident causing harm to staff, contractors, visitors or others.
Incident	Harm, loss or damage to equipment / property
Near Miss	Non-patient incident which had potential to cause harm, loss or damage to individuals or property at UHL but where no harm occurred. May be referred to as a non-clinical near miss.
Hazard	Something with the potential to cause harm.
StEIS	Strategic Executive Information System is the national system used by CCGs, Trust Development Authority, CQC and NHS England to monitor serious incidents within organisations.
Individuals	This includes all employees including temporary staff, bank and agency staff, volunteers, those on honorary contracts and contractors working within the trust. All healthcare professionals are included within this definition including doctors, nurses, managers and other healthcare professionals. It also includes those working under Honorary research contracts, or those with letters of access including external contractors.
RIDDOR - Reporting of Injuries, Diseases and Dangerous Occurrences Regulations	Regulations made under the Health & Safety at Work etc. Act. A set of reporting requirements applicable to all work activities. Reports generated under RIDDOR notify the enforcing authorities of individual incidents and trends to enable them to target their activities and advice with the aim of preventing injuries, ill health and accidental loss. The health and safety enforcing authority for the Trust is the Health & Safety Executive.
'Out of or in connection with work'	During a work activity, linked to the way work is organised or the condition of the premises.

5 ROLES AND RESPONSIBILITIES

5.1 This section provides an overview of the individual, CMG and committee roles and responsibilities:-

Responsibility	Action
Medical Director	1. Has delegated responsibility for ensuring compliance with this policy as Executive Lead for Patient Safety.

	2. Ensures adequate corporate structures and establishment are in place to fulfil the requirements of this policy. 3. Reviews the final draft Serious Incident reports for all Never Events and provides comment and signs off final Never Event reports. 4. Provides specific support with learning and actions in relation to medical staff.
Chief Nurse	1. Reviews the final draft Serious Incident reports and provides comment for all Never Events and signs off the final report in the absence of the Medical Director or his/her deputy. 2. Provides specific support with learning and action in relation to all other disciplines of staff employed (excepting medical staff).
Executive Quality Board (EQB) (sub-committee of Trust Board)s	1. To receive regular reports on trends and key issues arising from incidents, complaints and claims:- - Monthly Patient Safety Report - Annual Patient Safety Report
Quality Committee (QC) (sub-committee of Trust Board)	1. To receive regular reports on trends and key issues arising from incidents, complaints and claims:- - Monthly Patient Safety Report - Annual Patient Safety Report
Adverse Events Committee (sub-committee of Executive Quality Board)	1. To review all Serious Incidents Requiring Investigation (SIRI), Never Event, Regulation 28 letter and serious complaint action plans to ensure that all actions are appropriate, timely and tracked to implementation. 2. To ensure action plans are SMART and of an acceptable quality. 3. To review SIRI comments received from commissioners upon sign-off of RCA reports. 4. To ensure that all RCA investigations are chaired by the Medical Director, Chief Nurse or their nominated deputy (as allocated by the Director of Safety and Risk's team). 5. To review any complaint letters upheld by the Parliamentary and Health Service Ombudsman and ensure the required action istaken. 6. To review and monitor themes of serious events and ensure there are sufficient corporate actions to reduce future harm. 7. To ensure Directors with safety and quality responsibilities (Chief Nurse, Medical Director and their deputies) are conversant with the most serious events which occur within the Trust. 8. To consider some annual audit of implementation of action plans. 9. To identify key themes from adverse events and feed these back to relevant groups of committees for action. 10. To receive any new national guidance / requirements with respect to SIRI reporting, NHS complaint regulations or Ombudsman compliance.
Director of Quality Governance	1. Provide leadership to the Patient Safety and Staff Health and Safety Teams. 2. Engage with CMG and Corporate Directors to ensure a transparent and open safety culture. 3. Identify an Investigation Chair for each Serious Incident Requiring Investigation (SIRI). 4. Provide patient and staff safety reports to Trust Committees:- ➢ Executive Quality Board ➢ Quality Committee ➢ Health and Safety Committee
Corporate Patient Safety Team e.g. Head of Patient Safety, Patient	1. Provide support and guidance to the CMGs and all other staff in the reporting, investigating and analysis of incidents/accidents. 2. Ensure all SIRI's are reported to the CCG. 3. Ensure that RIDDOR reportable events are notified to the Health &

Safety Leads, Patient Safety Co-ordinators, Information Analyst, Assistant Information Analyst, Patient Safety and Complaints Officers	Safety Service team. 4. Check and agree SIRI proforma before escalating to the East Leicestershire and Rutland Clinical Commissioning Group (LCR CCG), NHSE/I and internally. 5. The identified Patient Safety Co-ordinator to lead work to identify:- ➢ Investigation Chair (decided by Head of Patient Safety). ➢ Membership of the investigation team. ➢ Terms of reference for investigation. ➢ Agree investigation process/tools. ➢ Writing the report. ➢ Develop action plan. 6. Inform the Head of Legal Services of those PSIs that are inquests. 7. Escalate final reports internally and externally, as appropriate. 8. Receive comments from the CCG following their review of SIRI reports and communicate comments or requests for further information from the relevant CMG. 9. Request and maintain evidence of completion of action plans with main SIRI files. 10. Monitor action plans until completion. 11. Ensure all Patient Safety Incidents (PSI) are reported to the National Reporting and Learning System (NRLS) at NHS England. 12. Provide a corporate patient safety report, monthly. 13. Should a concern/complaint be received or an inquest identifies an issue that should be reported as a SIRI, ensure this is done so retrospectively and appropriately investigated.
Health and Safety Services Team	1. Ensure all relevant incidents are reported to the Health and Safety Executive (HSE) in accordance with RIDDOR. 2. Carry out an independent investigation of RIDDOR reportable incidents and make recommendations to reduce the risk of a recurrence. 3. Investigate any other incident where significant risks are identified. 4. Ensure all physical assaults on staff are reported to NHS Protect and Security Management and Police Liaison Committee. 5. Act as a first point of contact/Trust liaison with HSE or other enforcement agencies where the enforcement body is carrying out investigations in to accidents or incidents within the Trust. 6. Monitor performance for accidents and incidents and carry out trend analysis and provide quarterly reports to Trust Health and Safety Committee.
Corporate Risk Management Team (incorporating the role of Medical Device safety Officer – MDSO)	1. Ensure that appropriate medical device related incidents are reported to the Medicines and Healthcare products Regulatory Agency (MHRA). 2. When required support the development and distribution of internal safety alerts. 3. Monitor actions to reduce risk and provide reports to Trust committees as appropriate
Line Manager e.g. Ward/department sisters, matrons, managers, heads of department	1. If considered to be a Serious Incident Requiring Investigation/Patient Safety Incident, notify the Corporate Patient Safety Team at the earliest opportunity after the event. (Out of hours see section 6.6.2). Refer to SIRI identification section 6.5 if in doubt, or contact the Corporate Patient Safety Team (Seek advice from the Health and Safety Services Team for events/injuries/diseases that may be reportable under RIDDOR. 2. Review all incidents reported on Datix web, confirm detail and grading and approve within ten working days of completion of incident form.

	3. Where you re-grade an incident into a possible RIDDOR reportable category please contact the Health & Safety team by phone to notify them of the Datix incident number and detail. 4. Carry out a local investigation if necessary and review lessons learned with all staff. 5. Identify if an event (such as a near miss or incident) requires risk assessing and entering on the UHL risk register (if required, seek support from the Corporate Risk Management Team regarding the risk assessment process).
Head of Privacy	1. Provide leadership, advice and support to staff in relation to incidents where there has, or it is suspected that there has been a breach of confidential information or data.
Trust Radiation Protection Adviser or Radiation Protection team	1. Provide leadership, advice and support to staff in relation to Datix reported radiation incidents to establish Ionising Radiations (Medical Exposure) Regulations (IRMER) / Ionising Radiation Regulations (IRR) or non-reportable status.
Human Tissue Authority Trust Lead	1. Provide leadership, advice and support to staff in relation to incidents where there has, or it is suspected that there has been a breach of policy regarding compliance with the Human Tissue Act. 2. Further advice from the Corporate Patient Safety Team.
Employee involved in incident and/or person that incident reported to, if circumstances do not allow employee to do so. This relates to all disciplines of staff.	1. Report immediately to line manager/person in charge (duty manager out of hours). 2. Ensure medical attention or treatment is given if required. 3. Take immediate preventative action (if required) to avoid a similar incident or accident. 4. For patient incidents inform them of the occurrence and/or relatives as appropriate and in line with Duty of Candour. 5. Retain and secure any equipment. Label any equipment to prevent use or tampering until it is officially released for use by a senior manager or health and safety manager. This will depend on the nature of the event and any injury sustained. NOTE equipment must be left exactly as it was at the time of the incident. No adjustments or intervention must be made unless needed for safety reasons. (Advice can be sought from the Corporate Patient Safety Team or Health and Safety Services Team or Corporate Risk Management Team in relation to medical equipment). 6. Retain any medication and its packaging involved. 7. Secure all documentation e.g. medical/nursing records, medication charts. 8. Document events and actions taken, including treatment and care given in the patient's records. 9. Complete an incident report on–line using Datix (see section 5.1).

6 POLICY STATEMENTS AND PROCEDURES

6.1 Process for Reporting all Incidents

6.1.1 Reporting of accidents, incidents and near misses will be regarded as a positive action to improve standards and service. Only in exceptional circumstances will action be taken against any individual for reporting such an event, for example malicious motives or knowing disregard of required practice or procedure, or lack of compliance with required standards.

6.1.2 The Trust is committed to having effective systems in place where incidents can be reported, acknowledged and acted upon. Learning from incident events, both major and minor is a vital part of safety and risk management. By actively seeking to identify incident events when they occur, reviewing what went wrong or what went well and to change practices or systems when appropriate, the risk of injury or harm occurring again can be reduced.

6.1.3 All incidents must be reported online using the Datix form as follows and within twenty-four working hours of knowledge of the incident:-

- Access the incident report form through the Trusts “InSite” home page by clicking on the Datix-Web symbol;
- Complete all fields as thoroughly as possible. Those marked with a red are mandatory and must be completed;
- Department/ward managers must review and approve all incidents reported within ten working days from the date of completion on the incident form;
- The research and development office must be notified by email if the incident is related to any research activity.
- The Corporate Risk Management Team must be informed of any incident involving medical equipment in order that a decision can be taken as to whether a report should be made to the MHRA.

6.1.4 Reporting must be initiated either by the member of staff who was involved in/or witnessed the event, or the person to whom the event was reported to, at the earliest opportunity.

6.1.5 The detail reported must be accurate, complete and factual. Do not give opinions, draw conclusions or make subjective statements. Detail must include known factors and circumstances leading up to the event.

6.1.6 Patients and/or relatives should be informed of an incident. Where the incident is graded as a serious PSI; then a “Being Open” leaflet should be given to the patient or relative (refer to UHL Duty of Candour (Being Open) Policy).

6.2 Grading all incidents and Assessing the Level of Harm

6.2.1 All incidents must be graded according to the impact on patient care, risk to patients, staff or others, and the organisation as a whole.

6.2.2 An immediate assessment of the consequence of the incident should be undertaken using the following categories. The correct option should be selected from the drop down 'consequence' categories - The following table provides additional information to enable you to select the correct category for injuries/events. Consequences arising 'out of or in connection' with work may be RIDDOR reportable. Please seek advice from the Health & Safety Services Team if you are unsure if an event is reportable under RIDDOR.

Description of event : consequence	Grade
Patients / Staff / Others: ▪ Any patient safety incident that directly resulted in the death of one or more persons receiving NHS-funded care. ▪ Death of an employee within 1 year if the death is as a result of an injury or illness sustained at work	**Death**
Patients: ▪ Any patient safety incident that appears to have resulted in permanent harm to one or more persons receiving NHS-funded care. ▪ Chronic pain (continuous, long term pain of more than 12 weeks as a result of the incident) ▪ Psychological harm, impaired or sensory, motor or intellectual function or impairment to normal working or personal life which is not likely to be temporary (i.e. has lasted, or is likely to last for a continuous period of at least 28 days).	**Major**

▪ Multiple permanent injuries OR irreversible health effects ▪ An event which has consequences for a large number of people ▪ Increase of hospital stay by >15 days Staff: ▪ Major injury / occupational disease arising out of or in connection with work ▪ Major injury/disease leading to long-term incapacity/disability ▪ Requiring time off work for > 14 days Others (visitors/contractors) ▪ Major injury	
Patients: ▪ Any patient safety incident that resulted in a moderate increase in treatment and which caused significant but not permanent harm, to one or more persons receiving NHS-funded care. ▪ Increased length of stay by 8-15 days ▪ An event which has consequences for a small number of patients Staff ▪ Moderate injury/occupational disease* requiring professional intervention ▪ Requiring time off work* for 8-14 days ▪ Moderate injury* arising out of or in connection with work Others ▪ Injuries arising out of or in connection with work that result in the individual being transferred/admitted to hospital for treatment*	**Moderate**
Patients: ▪ Any patient safety incident that required extra observation or minor treatment and caused minimal harm, to one or more persons receiving NHS-funded care. ▪ Increase length of staff by 1-7 days ▪ Non-permanent harm Staff: ▪ Minor injury/illness requiring minor intervention i.e. first aid ▪ Non-permanent harm ▪ Requiring time off work for less than 8 days Others: ▪ Minor injury/illness requiring minor intervention i.e. first aid	**Minor**
No harm, injury, loss or damage ▪ Prevented Patient Safety Incident ▪ Near miss ▪ Impact prevented – any patient safety incident that had the potential to cause harm but was prevented, resulting in no harm to people receiving NHS-funded care. ▪ Impact not prevented – any patient safety incident that ran to completion but no harm occurred to people receiving NHS-funded care.	**None**

For patient safety incidents these definitions are in adherence with the National Patient Safety Agency (NPSA) definitions of harm (accessible at http://www.npsa.nhs.uk/corporate/news/npsa-releases-organisation-patient-safety-incident-reporting-data-england/)

6.3 Level of Investigation

6.3.1 The level of investigation for each grade of incident required is as identified in table 1 below:-

Table 1

Grading	Investigation	Report
RIDDOR reportable events	RIDDOR events will be investigated by a Health and Safety/LSMS Manager. Other events may be investigated by the Occupational Health Service or as a joint investigation led by a Health and Safety Manager/LSMS Manager.	Actions and recommendations will be communicated to key stakeholders.
None	Near miss events and prevented patient safety incidents (PSI) should be investigated in order to identify root causes and actions required to reduce the risk of recurrence where harm may occur.	Trends/themes and subsequent actions within CMG board reports. Corporate reports on trends by subject i.e. falls / sharps etc. Within Ward/Dept. only. Subject to periodic review by CMG. No corporate investigation is required. But can be investigated at discretion of management.
Minor	As above	As above
Moderate	As above, however an RCA approach may be appropriate for individual cases - usually led by the CMG. All RIDDOR's are investigated by Health and Safety Services Team.	As above but a concise report on the individual case provided if thought to be appropriate. Some incidents where there are significant lessons to learn will be subject to a comprehensive internal review by the corporate patient safety team. All RIDDOR's will be subject of a full report and recommendations to reduce the risk of a reoccurrence.
Major	A full RCA approach informing the patient/relative that this is being undertaken by the CMG and Corporate Patient Safety Team. See above for RIDDOR incidents. Some serious incidents relating to Health, Safety are HSE reportable immediately. Advice must be sought from the Health and Safety Services Team at the earliest opportunity.	Comprehensive RCA report, to be forwarded to the Clinical Commissioning Group and shared with the patient/relative. See above for RIDDOR incidents.
Extreme	As listed for "Major" incidents. Extreme incidents where there is a foreseeable risk of serious and imminent danger requires immediate action to cease work/prevent others entering the area and possibly contingency planning. This is a legal requirement. Health and Safety advice will be necessary in most instances.	As listed for "Major" incidents

6.4 Duty of Candour

6.4.1 Effective communication with patients begins at the start of their care and should continue throughout their time with the Trust. This should be no different when a patient safety incident

occurs. Openness about what happened and discussing patient safety incidents promptly, fully and compassionately can help patients cope better with the after-effects. Openness when things go wrong is fundamental to the partnership between patients and those who provide their care.

The Being Open/Duty of Candour process begins with the recognition that a patient has suffered moderate harm, major harm, or has died, as a result of a patient safety incident.

For further guidance please see the UHL Being Open (Duty of Candour) Policy (Ref B42/201).

6.5 Management of a Serious Incident Requiring Investigation (SIRI)

6.5.1 Definition

6.5.2 In broad terms, serious incidents are events in health care where the potential for learning is so great, or the consequences to patients, families and carers, staff or organisations are so significant, that they warrant using additional resources to mount a comprehensive response. Serious incidents can extend beyond incidents which affect patients directly and include incidents which may indirectly impact patient safety or an organisation's ability to deliver ongoing healthcare.

The occurrence of a serious incident demonstrates weaknesses in a system or process that need to be addressed to prevent future incidents leading to avoidable death or serious harm to patients or staff, future incidents of abuse to patients or staff, or future significant reputational damage to the organisations involved. Serious incidents therefore require investigation in order to identify the factors that contributed towards the incident occurring and the fundamental issues (or root causes) that underpinned these. Serious incidents can be isolated, single events or multiple linked or unlinked events signalling systemic failures within a commissioning or health system.

There is no definitive list of events/incidents that constitute a serious incident and lists should not be created locally as this can lead to inconsistent or inappropriate management of incidents. Where lists are created there is a tendency to not appropriately investigate things that are not on the list even when they should be investigated, and equally a tendency to undertake full investigations of incidents where that may not be warranted simply because they seem to fit a description of an incident on a list.

The definition below sets out circumstances in which a serious incident must be declared. Every incident must be considered on a case-by-case basis using the description below. Inevitably, there will be borderline cases that rely on the judgement of the people involved.

6.5.3 Serious Incidents Requiring Investigation in the NHS include:

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

- Unexpected or avoidable death of one or more people. This includes:-

  - suicide/self-inflicted death; and
  - homicide by a person in receipt of mental health care within the recent past.

- Unexpected or avoidable injury to one or more people that has resulted in serious harm;

- Unexpected or avoidable injury to one or more people that requires further treatment by a healthcare professional in order to prevent:-

  - the death of the service user; or

- serious harm;

- Actual or alleged abuse; sexual abuse, physical or psychological ill-treatment, or acts of omission which constitute neglect, exploitation, financial or material abuse, discriminative and organisational abuse, self-neglect, domestic abuse, human trafficking and modern day slavery where:

  - healthcare did not take appropriate action/intervention to safeguard against such abuse occurring ; or
  - where abuse occurred during the provision of NHS-funded care.

  This includes abuse that resulted in (or was identified through) a Serious Case Review (SCR), Safeguarding Adult Review (SAR), Safeguarding Adult Enquiry or other externally-led investigation, where delivery of NHS funded care caused/contributed towards the incident.

- A Never Event - all Never Events are defined as serious incidents although not all Never Events necessarily result in serious harm or death. See NHS England Never Events Policy and Framework (March 2015) for the national definition and further information; http://www.england.nhs.uk/ourwork/patientsafety/never-events/

- An incident (or series of incidents) that prevents, or threatens to prevent, an organisation's ability to continue to deliver an acceptable quality of healthcare services, including (but not limited to) the following:
- Failures in the security, integrity, accuracy or availability of information often described as data loss and/or information governance related issues;
- Property damage;
- Security breach/concern;
- Incidents in population-wide healthcare activities like screening and immunisation programmes where the potential for harm may extend to a large population;
- Inappropriate enforcement/care under the Mental Health Act (1983) and the Mental Capacity Act (2005) including Mental Capacity Act, Deprivation of Liberty Safeguards (MCA DOLS);
- Systematic failure to provide an acceptable standard of safe care (this may include incidents, or series of incidents, which necessitate ward/ unit closure or suspension of services); or
- Activation of Major Incident Plan (by provider, commissioner or relevant agency)
- Major loss of confidence in the service, including prolonged adverse media coverage or public concern about the quality of healthcare or an organisation.

6.5.4 <u>Assessing whether an incident is a serious incident requiring investigation</u>

In many cases it will be immediately clear that a serious incident has occurred and further investigation will be required to discover what exactly went wrong, how it went wrong (from a human factors and systems-based approach) and what may be done to address the weakness to prevent the incident from happening again.

Whilst a serious outcome (such as the death of a patient who was not expected to die or where someone requires on going/long term treatment due to unforeseen and unexpected consequences of health intervention) can provide a trigger for identifying serious incidents, outcome alone is not always enough to delineate what counts as a serious incident. The NHS strives to achieve the very best outcomes but this may not always be achievable. Upsetting outcomes are not always the result of error/ acts and/ or omissions in care. Equally some incidents, such as those which require activation of a major incident plan for example, may not reveal omissions in care or service delivery and may not have been preventable in the given circumstances. However, this should be established through thorough investigation and action to mitigate future risks should be determined.

Where it is not clear whether an incident fulfils the definition of a SIRI, providers should engage in open and honest discussions with the LLR CCG and relevant parties to agree the appropriate and proportionate response.

6.5.5 Can a 'near miss' be a serious incident requiring investigation?

It may be appropriate for a 'near miss' to be a classed as a serious incident because the outcome of an incident does not always reflect the potential severity of harm that could be caused should the incident (or a similar incident) occur again. Deciding whether or not a 'near miss' should be classified as a serious incident should therefore be based on an assessment of risk that considers:

- The likelihood of the incident occurring again if current systems/process remain unchanged; and
- The potential for harm to staff, patients, and the organisation should the incident occur again.

This does not mean that every 'near miss' should be reported as a serious incident but, where there is a significant existing risk of system failure and serious harm, the serious incident process should be used to understand and mitigate that risk.

6.5.6 For frequently recurring incidents that do not meet the SIRI criteria a multi-incident root cause analysis for or equivalent investigation process to help identify common themes and problems which leads to the development of one organisational action plan should be in place. This places emphasis on learning and improvement rather than conducting repetitive investigations.

6.6 Serious Incident Reporting Process

6.6.1 Incident reported within normal office hours report immediately to:-

- Line manager and Corporate Patient Safety Lead or Patient Safety Co-ordinator (extension 18530, 18539,18538, 17987, 15999, 14757, 14472, and 14927).
- The Corporate Patient Safety Team will report verbally to the East Leicestershire and Rutland Clinical Commissioning Group (LLR CCG).
- Health and Safety Services Team will need informing for certain incident/accident categories.

Contact Details

Title	Extension
Director of Quality Governance	13117
Head of Patient Safety	18901
Patient Safety Leads	13502/18386/18558
Health and Safety Services Manager	18031
Health and Safety Managers / LSMS	13269/13392
Manual Handling Advisors	18308/18146
Corporate Risk Management Team	13479/ 13441
Research and Development Office	18351

6.6.2 Incident occurring outside office hours, report immediately to the duty manager to escalate to the on-call director who will assess whether reporting to the LLR CCG and can wait until normal office hours.

6.6.3 In those circumstances where the incident has very significant implications for the NHS in term of clinical, managerial or media issues the on-call director at UHL, will contact the on call director for the LLR CCG.

6.6.4 All incidents must be reported onto the Datix system as point 6.1.3 as soon as it is practicable to do so, and within 24 working hours of knowledge of the incident.

6.6.5 An SIRI proforma (**Appendix A**) must be completed by the allocated Patient Safety Co-ordinator within 48 working hours of knowledge of the incident who will circulate as below:-

- Chief Executive
- Chief Nurse
- Chief Operating Officer
- Chief People Officer
- Medical Director
- Deputy Medical Director/s
- Deputy Chief Nurses
- Assistant Chief Nurses
- Director of Corporate and Legal Affairs
- Director of Quality Governance
- Director of Strategy and Communications
- Head of Legal Services
- The CMG Senior Management Team/s (Appropriate to the incident)
- Head of Risk and Assurance (if medical equipment involved)
- The Non-Executive Directors
- Research and Development Office (if research related)

Note: this list is not exhaustive and may be added to dependent on the nature of the incident.

6.6.6 A patient and/or their relative/carer should be informed at the earliest opportunity that an incident has occurred, graded as major that a full investigation will be undertaken, and the final report shared with them to comply with Duty of Candour.

6.6.7 Reporting to external agencies should be made as appropriate. (See **Appendix B** for SIRI flowchart)

6.6.8 When the involvement of external agencies is required i.e. H.M. Coroner, Police, MHRA etc. The Director of Quality Governance or their nominated point of contact will share all relevant information as required.

6.7 Investigation

6.7.1 The investigation and final sign off of a report must be concluded within 60 working days. For guidance please refer to: NHS England Serious Incident Framework (March 2015)

6.7.2 There may be occasions when NHS England and the CCG require additional information. NHS England and Improvement will contact the relevant Commissioner for additional information (72 hour reports) from providers as required. This report should, as a minimum, contain an overview of events (as understood at the time of reporting), any key critical questions which the investigation will be seeking to examine and actions taken to mitigate any identified risks and to minimise the risk of recurrence. Providers should ensure that reports are submitted promptly and within three working days of the request.

6.7.3 An investigation lead will be identified by the Patient Safety Leads.

6.7.4 An Investigation Chair will be identified by the Director of Quality Governance or Head of Patient Safety

6.7.5 Following a review of the immediate information available it may be concluded that an incident review meeting should be established, bringing together the investigation team members and those involved in the incident.

6.7.6 The investigation team lead will be the Corporate Patient Safety Co-ordinator, Health and Safety Manager or Manual Handling Advisor.

6.7.7 The investigation team will identify clear terms of reference and agree individual roles and responsibilities, and methodology for the investigation. The patient and/or family will be offered the opportunity to be involved in agreeing the terms of reference if they wish.

6.7.8 The Investigation Team will identify the relevant people to be interviewed.

6.7.9 Written statements must be obtained and where necessary interviews will be conducted at the earliest opportunity and must be provided by individuals whether or not they have discussed the incident with the investigating team or attended an investigation team/review meeting. (See point 10 below).

6.7.10 Interviews will be conducted in a private environment, in a sensitive manner and will be undertaken by a member of the investigation team. Debriefing and support will be offered i.e. line managers, counselling (AMICA).

6.7.11 The Trust template (**Appendix C**) should be used for the provision of a statement and further guidance can be found in the information leaflet “Stating the Facts” (**Appendix D**). Support can be provided by the Corporate Patient Safety, Health and Safety or Legal Teams.

6.7.12 A full Root Cause Analysis (RCA) investigation will be undertaken using the most appropriate tools.

6.8 Serious Incident Report (Patient)

6.8.1 At the conclusion of the investigation a report that identifies clearly, as a minimum, the following, must be written. **(Appendix E)**

- Executive Summary
- Purpose of the Investigation
- Being Open and Duty of Candour – involvement of patient/relative
- Involvement and support provided for staff
- Summary Incident description and consequences

- Terms of reference
- Investigation Team
- Information and evidence gathered
- Root cause analysis tools used
- Background and context of incident
- Chronology of events
- Detection of Incident
- Care delivery/service delivery problems
- Notable practice points
- Root causes
- Contributory Factors
- Lessons learned
- Recommendations
- Implementation, Monitoring and Evaluation Arrangements
- Arrangements for Sharing and Learning
- Action plan
- Appendices
- References
- Glossary

6.8.2 An incident time line or chronology of events will be produced and included in the investigation report.

6.8.3 An analysis of the information and evidence will be undertaken to determine the underlying causes and lessons to be learned. There are a number of analysis tools which can be used including:-

- Fishbone and spider diagrams
- Five whys
- Brainstorming
- Nominal group technique
- Barrier analysis
- Change analysis

6.8.4 The report will be reviewed at approximately 35 working days at the UHL Serious Incident Review Group meeting (Fresh Eyes).

6.8.5 The final draft report will be circulated at approximately 50 working days to the following for review and comment before final sign off:-

- CMG Management Team
- Investigation Chair

Note: the above list is not exhaustive and will be dependent on the individual incident.

Comments must be returned to the Corporate Patient Safety Team within three working days.

6.8.6 The final report must be signed off formally by the CMG Management Team, either Clinical Director, CMG Manager or CMG Head of Nursing and the Investigation Chair.

6.8.7 All investigation reports relating to Never Events (NE) must be signed off by the Medical Director, his /her Deputy, or the Chief Nurse.

6.8.8 Following sign off the report will be circulated internally and externally by the Corporate Patient Safety Team.

6.8.9 The Corporate Patient Safety Investigation Lead will forward to all staff members involved in the incident.

6.8.10 The Corporate Patient Safety Investigation Lead will agree with the CMG the arrangements for communicating with and sharing the report with the patient and/or the family. Additionally the patient and/or family are to be encouraged to be involved in making recommendations and developing actions.

6.8.11 The outcome of how this is done and any communication with/from the patient/family will be documented and kept with the original file by the Corporate Patient Safety Investigation Lead.

6.8.12 Interested parties will receive feedback from the Investigation Team or senior CMG staff in line with compliance reporting requirements.

6.8.13 Following completion of the investigation, the Director of Quality Governance will consider the appropriateness of sharing the report as necessary with agencies, such as:-

- Police
- H.M. Coroner
- MHRA
- General Medical Council
- Nursing and Midwifery Council

6.8.14 Actions are monitored by the corporate patient safety team via the action plan tracker and signed off by the Adverse Events Committee, where any overdue actions are escalated.

6.8.15 For assurance the Clinical Commissioning Groups (CCGs) monitor any overdue actions from the action plan tracker.

6.9 Infection Control Incidents

6.9.1 Condition related infection control incidents include:-

- All MRSA bacteraemias
- Death of a patient due to Clostridium Difficile
- Colectomy due to Clostridium Difficile
- Hospital acquired COVID-19 infection

6.9.2 All incidents must be reported on line using Datix Web.

6.9.3 The Infection Prevention Team must notify the appropriate CMG Management Team and where known, the Consultant Lead, of any incidents relating to Clostridium Difficile or MRSA.

6.9.4 The CMG Management Team must ensure there is an internal process for commencing a root cause analysis investigation for condition related infection control incidents.

6.9.5 Information and documentation has been developed to support CMGs in completing the root cause analysis process to ensure all possible learning is achieved through the investigation of the incident. This is available to all staff through the Infection Control Website:-

http://insite.xuhl-tr.nhs.uk/homepage/clinical/infection-prevention/root-cause-analysis

6.9.6 Pressure Ulcer Incidents

6.9.7 All grade 2, 3 and 4 pressure ulcers (PU) must be reported on line using Datix Web, irrespective of whether they are hospital or community acquired.

6.9.8 All grade 2, 3 and 4 pressure ulcers (PU) must be graded as no harm until validation.

6.9.9 Post validation, all grade 2 pressure ulcers that have been identified as hospital acquired must be consequence graded as minor harm.

6.9.10 Post validation, all grade 3 pressure ulcers that have been identified as hospital acquired must will be consequence graded as moderate harm.

Post validation, all grade 4 pressure ulcers that have been identified as hospital acquired must be consequence graded as major harm.

Post validation, all pressure ulcers that have been identified as hospital acquired must be consequence graded as no harm.

6.9.11 Following the monthly RCA validation process, grade 4 pressure ulcers that have been validated as hospital acquired pressure ulcers where there has been act and/or omission occurring in avoidable harm will be discussed and agreed with the Corporate Patient Safety team and will be reviewed against the NHS England Serious Incident framework (March 2015).

6.9.12 An RCA validation checklist must be used to facilitate the RCA process for grade 2, 3 and 4 Hospital Acquired Pressure Ulcers and to ensure learning from each incident is shared and appropriate actions are taken.

6.9.13 The pathway and Checklist documents are available to all staff via the tissue viability website

http://insite.xuhl-tr.nhs.uk/homepage/clinical/tissue-viability/pressure-ulcer-prevention

7 Screening Programme Serious Incidents

7.1.1 These are managed with specialised input from Public Health England's Screening Quality Assurance Service and guidance should be followed in accordance with "Managing Safety Incidents in NHS Screening Programmes (2017).

https://www.gov.uk/government/publications/managing-safety-incidents-in-nhs-screening-programmes

7.1.2 This document details the accountability for reporting, investigating and managing NHS screening programme safety incidents.

7.2 Human Tissue Authority Reportable Incidents

7.2.1 The HTA must be notified of all reportable incidents (HTARIs) that have occurred at licensed establishments in the post mortem sector since 1 May 2010.

7.2.2 From 1 April 2013, notifications must be made using the HTARI form on the HTA web Portal. Notification of HTARIs must be submitted to the HTA within five working days of the incident occurring or being discovered. Establishments must not wait until any internal review or investigation is complete before notifying the HTA of a HTARI.
For further guidance see;
https://www.hta.gov.uk/guidance-professionals/regulated-sectors/post-mortem/post-mortem-hta-reportable-incidents-htaris

7.3 Incidents Involving a Medical Device

7.3.1 The MHRA helps safeguard public health by working with users, manufacturers and lawmakers to ensure that medical devices meet appropriate standards of safety, quality and performance and that they comply with the relevant directives of the European Union.

7.3.2 The MHRA operates a national voluntary system for reporting adverse incidents involving medical devices. An adverse incident involving a medical device is defined as "an event which causes, or has the potential to cause, unexpected or unwanted effects involving the safety of device users (including patients) or other persons. Any adverse incident involving a medical device should be reported to the MHRA".

7.3.3 Advice on the handling of devices involved in incidents is provided on the Government website at:

https://www.gov.uk/report-problem-medicine-medical-device

7.3.4 The Corporate Risk Team can support the manager reporting the patient safety incident or accident by notifying the MHRA about the case on their behalf. Alternatively, if the manager reporting the patient safety incident or accident notifies the MHRA directly they should also inform the Corporate Risk Team by email (UHLMedicalDeviceSafetyOfficer@uhl-tr.nhs.uk) about the case including the MHRA reference number for information. The manager reporting the patient safety incident or accident must inform the Research and Development Office by e-mail for any incident related to research activity.

7.3.5 Any medical device suspected of being implicated in an adverse incident must be quarantined and labelled accordingly until inspection by the MHRA or manufacturer can take place. Where the medical device is a non-consumable item any control settings **must not** be altered following the incident No equipment to be released to the manufacturer for investigation until permission has been received from the MHRA the MHRA.

7.3.6 If the medical device involved is anaesthetic, electro medical or related to respirable gases, then it should also be reported to the appropriate person within the Medical Physics Department on the relevant hospital site.

7.3.7 Health and Safety related medical device incidents may be reportable to the HSE and require Health and Safety investigation.

7.3.8 Further guidance can be obtained by reference to the UHL Medical Devices Policy (Ref B26/2005)

7.4 Statement Writing

7.4.1 The investigation of an incident is a fact-finding exercise, which will be conducted in a timely, impartial and sensitive manner.

7.4.2 Statements must be written as soon as possible after the incident, whilst memories are still fresh and to ensure accurate information is recorded.

7.4.3 Statements may be requested by the line manager, Corporate Patient Safety Teams, Health and Safety Teams or Inquest and Claims Teams.

7.4.4 Support and guidance may be provided by the patient safety team and you should follow the guidance set out in "Stating the Facts" leaflet - **Appendix D**".

7.5 Procedures for Dealing with Staff and Other Persons Accidents/Security Incidents

Responsibilities of staff.

7.5.1 In addition to the responsibilities of staff as detailed in section 5, the following applies specifically for staff accidents or security incidents. The CMG Management Teams are responsible for ensuring that:-

7.5.2 Where appropriate, an investigation is carried out into all staff accidents and security incidents such as assaults, theft, criminal damage, with recommendations and appropriate actions co-ordinated and fully documented.

7.5.3 Occupational Health must be informed in the event of needlestick/blood exposure incidents. Please see UHL's policy on the Management of Occupational Exposure Incidents to blood borne viruses (B42/2007).

7.5.4 Notification of a serious staff accident/incident is made to those people identified in point 9.2.5 so that the necessary investigation can be undertaken.

7.5.5 The accident/incident analysis reports are brought to the attention of their staff at regular intervals.

The Health and Safety/LSMS Manager will be responsible for:-

7.5.6 Acting as the responsible person under RIDDOR, and ensuring the completion and forwarding of report forms (F2508 and F2508A) to the Health and Safety Executive.

7.5.7 Acting as the responsible person for reporting relevant security incidents to NHS Protect on the SIRS reporting system.

The Health and Safety Services Manager or Manual Handling Advisors will be responsible for:-

7.5.8 Investigating all clinical and non-clinical accidents that are notified to the Health and Safety Executive, which involve a possible breech of Manual Handling practice.

7.5.9 Compilation of reports including remedial actions as necessary.

7.5.10 Lead or participate in investigations for patient related RIDDOR reportable incidents.

7.5.11 Investigate non-reportable clinical and non-clinical accidents/incidents as necessary.

7.6 Reporting Non Clinical Adverse Incidents

7.6.1 Staff who are involved in, witnessed or discover a staff accident, or non-clinical near miss, should immediately report it to their Line Manager, Supervisor or senior person in charge. For all near misses and incidents, it is important to identify if there remains a risk or there is a risk of recurrence. Where necessary, a risk assessment should be carried out and the risk entered on the risk register in line with the requirements set out in the UHL Risk Management Policy. (A12/2002).

7.6.2 As soon as possible afterwards, the person who was involved in witnessed or discovered the accident, or near miss, should initiate and fill in the electronic report form (Datix-Web) at the earliest opportunity.

7.6.3 If a member of staff suffers from an injury such that they are unable to complete a report form, the Line Manager must ensure that the form is either completed themselves, by a witness or anyone else who is able to enter an account of the adverse incident. The injured persons

account of the accident must be documented (separately if necessary) as soon as reasonably practicable after the event.

7.6.4 Staff injuries may be dealt with by a suitably trained first aider, or an incident situation taken under control by an appropriate person. If the need arises, staff or visitors should be referred to their GP, Urgent Care Centre or Emergency Department at the LRI.

7.6.5 No member of staff will be disciplined or harassed for the completion of a Datix-web report form. Completion of the form will NOT lead to disciplinary action, EXCEPT where actions/omissions are intentional, criminal, an assault or in the case of malicious reporting of any kind by any person.

7.6.6 In the event of damage to equipment and/or buildings, such equipment and/or buildings shall not be interfered with or moved until such time as they have been fully inspected by, amongst others, relevant Trust staff and loss adjusters acting on behalf of the Trust's appointed insurers.

7.7 RIDDOR Reportable Accidents / Incidents

7.7.1 Certain accidents and incidents must be reported to the Health and Safety Executive under The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) 2013, and these categories are as follows:-

- Fatal accidents.
- Specified injury/accidents.
- Dangerous occurrences.
- Accidents causing more than seven days incapacity for work.
- Certain work related diseases.

7.7.2 Lost time events - This particular category applies to all accidents, which result in the injured person being **incapacitated for work or are unable to carry out their normal work duties for more than seven consecutive days, not counting the day of injury**. This includes any days which are not normally working days for example, weekends, bank holidays, days when they are not rostered to work.

7.7.3 RIDDOR requires the reporting of events within strict timescales:

Event	Reporting deadline	Report to HSE by
Death	Notify by the quickest practicable means without delay and send a report within 10 days of the incident.	Health & Safety Manager / LSMS Out of hours: TBA
Specified injuries to workers/injuries to non-workers	Notify by the quickest practicable means without delay and send a report within 10 days of the accident.	Health & Safety Manager / LSMS
Dangerous Occurrences	Notify by the quickest practicable means without delay and send a report within 10 days of the accident, unless reported under another category. This is to avoid duplication	Health & Safety Manager / LSMS
Over 7 day injuries	As soon as practicable and in any event within 15 days of the accident	Health & Safety Manager / LSMS
Occupational Diseases	Upon receipt of a written statement prepared by a registered medical practitioner	Health & Safety Manager / LSMS

Note: injuries to Non-workers. Where any person not at work, as a result of a work-related accident, suffers (a). an injury, and that person is taken from the site of the accident to a hospital for treatment in respect of that injury; or (b) a specified injury on hospital premises.

7.7.4 Notification of the following non-clinical adverse incident outcomes must be made immediately to the following respective persons by telephone or e-mail. Please include in the title of the e-mail, the incident grading.

	Chief Executive	CMG Manager	Patient Safety Team	Health and Safety Services Team
Death	✓	✓	✓	✓
Dangerous Occurrences	X	✓	✓	✓
Major Injury	X	✓	✓	✓
Over 7 day Injury	X	X	✓	✓
Condition / disease	X	✓	✓	✓

Accident and Incident Investigation

7.7.5 Prompt action is needed to ensure that a recurrence of the staff accident/incident does not take place. This can be actioned by undertaking a critical investigation of the circumstances surrounding the incident, and to identify both the direct and indirect causes. The depth of investigation will depend on the seriousness of the staff accident/incident and this in turn will indicate the type of approach to be taken (i.e. formal/informal).

Methods of Investigation

7.7.6 **An informal investigation** will occur where adverse incidents of minor nature have happened. This will be carried out by the local manager. The results of the investigation and any follow up actions taken must be attached to the DATIX incident report and retained within the Ward/Department.

7.7.7 **In the case of a RIDDOR reportable incident**, the incident will be investigated by the Health and Safety Services Team and the Senior Manager responsible for the area where the event occurred. The following may also be involved in the investigation as required:

- Fire Safety Adviser,
- Human Resources Manager,
- Occupational Health,
- Other specialist advisors.

7.7.8 The purpose of the investigation is to:-

- Ascertain the facts of the event by interviewing and taking statements from witness(es) as soon as possible after the event.
- Determine the causes of the event and consider any relevant factors raised by the incident.
- Recommend steps to be taken to prevent, so far as is reasonably practicable, a recurrence of the event in a written report.

NOTE

- Staff will be advised of his/her right to representation by either an accredited Trade Union/Professional Organisation representatives or a friend not acting in a legal capacity.
- All investigations are strictly confidential.

7.7.9 All documented reports must contain the following information:-

- Details of staff involved in the investigation.
- History of events leading up to the adverse incident, including reference number of report form.
- Description of the adverse incident, including causes and consequences.
- Conclusion.
- Recommendations – including the identification of an individual(s) responsible for progressing recommendation, actions and an agreed completion date.

7.8 Learning Lessons from Non-Clinical Incident Investigations

7.8.1 The University Hospitals of Leicester NHS Trust endeavour to ensure that lessons are learnt and changes are made as a result of incident investigations made; through the following processes:-

Local Level

7.8.2 Final reports will have an action plan that identifies the recommendation/s, the person(s) / group responsible and the date of completion of the actions.

7.8.3 Locally, the Patient Safety Lead will be responsible for monitoring plans produced in order to ensure their completion.

7.8.4 Those changes that present the opportunity for organisational learning will be presented to the Health and Safety Team for further dissemination through the “Safety Matters” bulletin and on the safety portal.

Organisational

7.8.5 The Health and Safety Services team discuss all serious RIDDOR reportable incidents and any non-clinical Employee and Public liability claims against the Trust.

7.8.6 The Health and Safety Services Team investigate all such incidents as soon as practicable and produce a report on each one that details the causes of the incident and any lessons learnt along with an action plan that includes who will take what action to prevent a reoccurrence.

7.8.7 A quarterly report is produced by the Health and Safety Services Team and this is presented to the local Health and Safety Committee and the UHL Health and Safety Committee. The report includes details of all RIDDOR reportable incidents for the previous quarter by CMG/Corporate Directorate, site and type of incident so that trends and patterns can be monitored.

7.8.8 This report also details all the Public and Employee (non-clinical) claims that have been opened and all those that have been closed whether they have been settled, withdrawn or successfully defended. As well as listing these by type to show any trends, they are also presented by CMG to show any patterns. Each and every claim on the quarterly report has a note of the action taken to reduce the risk of a reoccurrence and any further action that is being taken.

7.8.9 A similar quarterly report is produced for the Quality Committee.

7.8.10 A quarterly security report is produced by the HS/LSMS and is presented to the Security Management and Police Liaison Committee.

7.9 Analysis of Incidents and Complaints

7.9.1 The Datix online reporting system will allow the information relating to incidents to be collated, co-ordinated and presented as part of the Corporate Safety and Risk Reports. These reports will be presented to the Quality Committee; Executive Quality Board; the UHL Health and Safety Committee and other committees as required.

7.9.2 The Corporate Patient Safety Team and Health and Safety Services Team will collate these reports and will include a qualitative and quantitative summary of incidents and identify trends where possible and as a minimum as follows:-

Incidents

- All reported patient incidents for each CMG, by month.
- All reported patient incidents by type for each CMG, by month.
- All reported patient incidents by severity for each CMG, by month.
- All reported patient incidents by type, by month.
- All reported Serious Patient Incidents by month for each CMG.
- Number of RIDDOR Incidents by type for each, by quarter.

7.9.3 Qualitative Analysis

If specific trends are identified then the contributors, where possible, will provide a qualitative analysis of the trend. This may require making reference to external data sets and/or a comparison to previous quarterly figures.

7.9.4 The Director of Quality Governance will be responsible for presenting the report to the appropriate committees internally and externally.

7.10 Process for Communicating, Learning and Promoting Improvements from Incidents

7.10.1 The organisation shares learning from its analysis of incidents, complaints and claims in a variety of ways including:-

- Dissemination of the quarterly Health and Safety report and monthly Patient Safety report internally to the Quality Committee, Executive Quality Board, CMG Management Boards.
- Dissemination of the monthly Patient Safety Reports externally to the Clinical Quality Review Group.
- Dissemination of quarterly security reports internally to the Security Management and Police Liaison Committee.
- Dissemination of quarterly Health and Safety reports internally to local H&S Committee.
- The distribution of internal/security safety alerts as required.
- The distribution of external safety/security alerts and other external guidance.
- Discussion of all serious incidents at Adverse Event Committee.
- Safety portal.
- Education and simulation training session.

7.10.2 Learning and promoting practice may be advertised in a variety of media formats including:-

- The Trust's "Blue Screen" shots.
- "Safety Matters" newsletter.
- Patient Safety Week
- Safety portal.

- Twitter and news feed.

7.10.3 Changes in organisational culture and practice leading from incidents, complaints and claims investigations will be monitored by the review of data and themes presented in the monthly Patient Safety report by the Quality Committee.

8 Process for Communicating Reports/Learning to Relevant Individuals or Groups

REPORT	COMMITTEE/GROUP/INDIVIDUAL
Individual SI reports and action plan	Adverse Events Committee, Investigation Lead
Serious complaint and action plan (PHSO upheld cases)	As above
CMG Board Reports	CMG Management Boards, Patient Safety Leads
Corporate monthly patient safety reports	Quality Committee (internal) Executive Quality Board (internal) Director of Quality Governance
Quarterly Health and Safety report	Local Health and Safety Committee (internal) Quality Assurance Committee (internal) Director of Quality Governance
Quarterly Security Report	Security Management and Police Liaison Committee Director of Quality Governance
Specific safety messages as required	Blue screen shot (computer) Safety portal All staff
Safety Matters bulletin	All CMGs/Departments via e-mail

8.1 Sharing the Learning from Incidents

8.1.1 Any lessons learnt from individual incident investigations or through the monitoring of trends and patterns are cascaded to CMGs through the use of the safety portal accessed via INsite, “Safety Matters” bulletin, CMG Quality and Safety Boards , CMG Boards, Adverse Events Committee.

8.1.2 The Safety teams regularly update the various training sessions that they deliver to include any issues that are identified from individual incidents or from monitoring incident statistics.

Themes from incidents are used to inform safety improvement work; this in particular is reflected in the annual safety improvement programme within the UHL Becoming the Best priorities.

8.2 Process for Implementing Risk Reduction Measures

8.2.1 All risks identified from the aggregation of data from accidents, incidents, complaints and claims must be graded in accordance with the Trust’s Risk Management Policy. Processes for the implementation of risk reduction measures will be in line with those processes identified within the Trust’s Risk Management Policy (e.g. entered on to the Risk Register and actions to mitigate risks reviewed at a frequency dependent upon the severity of the risk).

8.2.2 Actions identified must be SMART (Specific, Measurable, Achievable, Realistic, Time bound).

The Trust will identify risk reduction measures which are:-

- Realistic.
- Sustainable.
- Cost effective.

8.2.3 Risks and actions must be entered on to the organisational risk register as described in the Trust's Risk Management Policy.

8.2.4 If the equipment involved is anaesthetic, electro medical or related to respirable gases, then it must also be reported to the appropriate person within the Medical Physics Department on the relevant hospital site.

8.3 Patient Safety Incidents (PSI) that are Multi-Organisational

8.3.1 Occasionally incidents may identify issues that go across one or more organisations.

8.3.2 The organisation that identifies the incident will usually assume the role of lead investigator, unless otherwise instructed by the CCG.

8.3.3 For those incidents within UHL that identify cross organisational issues, the identified Corporate Patient Safety or Health and Safety Service Lead will liaise with his/her counterpart in the other organisation/s to agree the management of the incident investigation reporting and sign off.

9. MATERNITY RISK MANAGEMENT POLICY

9.1 Maternity specific patient safety internal processes and external referral requirements can be found in the Maternity Risk Management Policy at **Appendix F**..

10. EDUCATION AND TRAINING

10.1 Basic training on the importance of reporting accidents and incidents and how to report using DATIX is provided at UHL Trust induction.

10.2 Further training needs should be assessed within CMGs to identify skills and knowledge required for staff groups in relation to the reporting and investigation of incidents and complaints.

10.3 The Corporate Patient Safety and Health and Safety Service Teams will, on request, provide customised training to meet the particular needs of staff groups.

11. PROCESS FOR MONITORING COMPLIANCE

11.1 The audit criteria for this policy and the process to be used for monitoring compliance are given in the table above.

Element to be monitored	Lead	Tool	Frequency	Reporting arrangements	Acting on recommendations and Lead(s)	Change in practice and lessons to be shared
Process for reviewing duties of staff	Head of Patient Safety	Appraisal	Annual	Appraisal documentation	Senior Patient Safety Manager	Required changes will be discussed and agreed with the Senior Patient Safety Team and CMG Management Boards

Process for reporting incidents	Health and Safety Team Corporate Patient Safety Team	Datix	Annual	Monthly reports through Executive Quality Board	Health and Safety Services Manager Information Analyst	Required changes will be discussed and agreed with the Senior Patient Safety Team and CMG Management Boards
Process for reporting to external agencies	Corporate Patient Safety Team Health and Safety Services Team	Datix	Annual	Quarterly and annual reports	Corporate Patient Safety Team	Required changes will be discussed and agreed with the Senior Patient Safety Team and CMG Management Boards

12 EQUALITY IMPACT ASSESSMENT

12.1 The Trust recognises the diversity of the local community it serves. Our aim therefore is to provide a safe environment free from discrimination and treat all individuals fairly with dignity and appropriately according to their needs.

12.2 As part of its development, this policy and its impact on equality have been reviewed and no detriment was identified.

13 SUPPORTING REFERENCES, EVIDENCE BASE AND RELATED POLICIES

13.1 The following policies may be helpful throughout the reporting and investigating of incidents.

Risk Management Policy (A12/2002)
Health and Safety Policy (A17/2002)
Medical Devices Policy (B26/2005)
Policy for the Management of Complaints (A11/2002)
Claims Handling Policy and Procedures (B24/2008)
Whistleblowing Policy (A15/2001)
Duty of Candour (Being Open) Policy (B42/2010)
Supporting Staff Involved in Incidents, Inquests, Complaints and Claims (B28/2007)
Clinical Negligence, Personal Injury and Property Claims Handling Policy (B24/2008)
Statutory and Mandatory Training Policy (B21/2008)
Information Governance Policy (B4/2004)
Protecting Patients Policy when a Safeguarding Allegation is made against an Employee (B13/2003)
Policy for the Management of Medication Errors (B45/2008)
NHS England Serious Incident Framework (March 2015)
NHS England Never Events framework (January 2018)

14. PROCESS FOR VERSION CONTROL, DOCUMENT ARCHIVING AND REVIEW

- The availability of an updated policy will be communicated by the Trust's Senior Patient Safety Manager to clinical CMGs and corporate directorates via email to Directors and managers.
- An electronic version will be stored on the *'UHL Insite Documents'* to allow ease of access. Wards and departments are encouraged to print out a paper copy for reference in those areas where a PC is not always available.
- The policy will be reviewed every three years unless there is reason for earlier review. Document review will be the responsibility of the document author.
- Previous electronic versions held on the UHL 'InSite Documents' will be archived automatically. Paper copies of previous versions will be destroyed by departments in which they are held.

Appendix A

University Hospitals of Leicester NHS Trust (UHL) Serious Incident Management Report		
Reporting Organisation: University Hospitals of Leicester NHS Trust (UHL) **CCG Area:** East Leicester, Leicestershire and Rutland		
Reporter Details		
Name:	**Title:**	
Email:	**Telephone Number:**	
Incident date:	**Incident time:**	**Date incident identified:**
Incident Site:	**Incident Location:**	**CMG:**
Trust internal incident number:	**STEIS reference number: (to be completed once uploaded)**	**Specialised Commissioning: (Yes/No)**
Who was involved		
Care Sector:	**Type of patient:**	**Clinical Area:**
Patient's Initials:	**Patient's Gender:**	**Patient's Ethnic Group:**
Patient's DOB:	**Patient's GP:**	**Patient's Legal Status (at time of incident):**
What Happened		
Reason for reporting:	**Type of incident:**	**Where patient is at time of reporting:**
Never Event?: (Y/N)	**Expected level of investigation:**	**Independent review required?: (Y/N)**
Non health led review required?: (Y/N)	**Safeguarding Information:**	
Description of Incident		
[delete/amend as appropriate] **(date)** • Confirmation that the incident meets Criteria (Number of NE), the Never Events list 2015/16, NHS England **(date)** • Incident escalated internally within the Trust and externally to the Commissioners		
Immediate Actions Taken		

(Include equipment quarantine/medical records secured)
Duty of Candour Information
(include steps taken to support those affected)

Persons notified:	**Patient:**	**Family:**	**Carer:**
Media interest?: (Y/N)	**Communications informed?: (Y/N)**	**Externally reportable?: (Y/N)**	**If so, to whom?:**

Any Other Comments
Suggested Terms of Reference

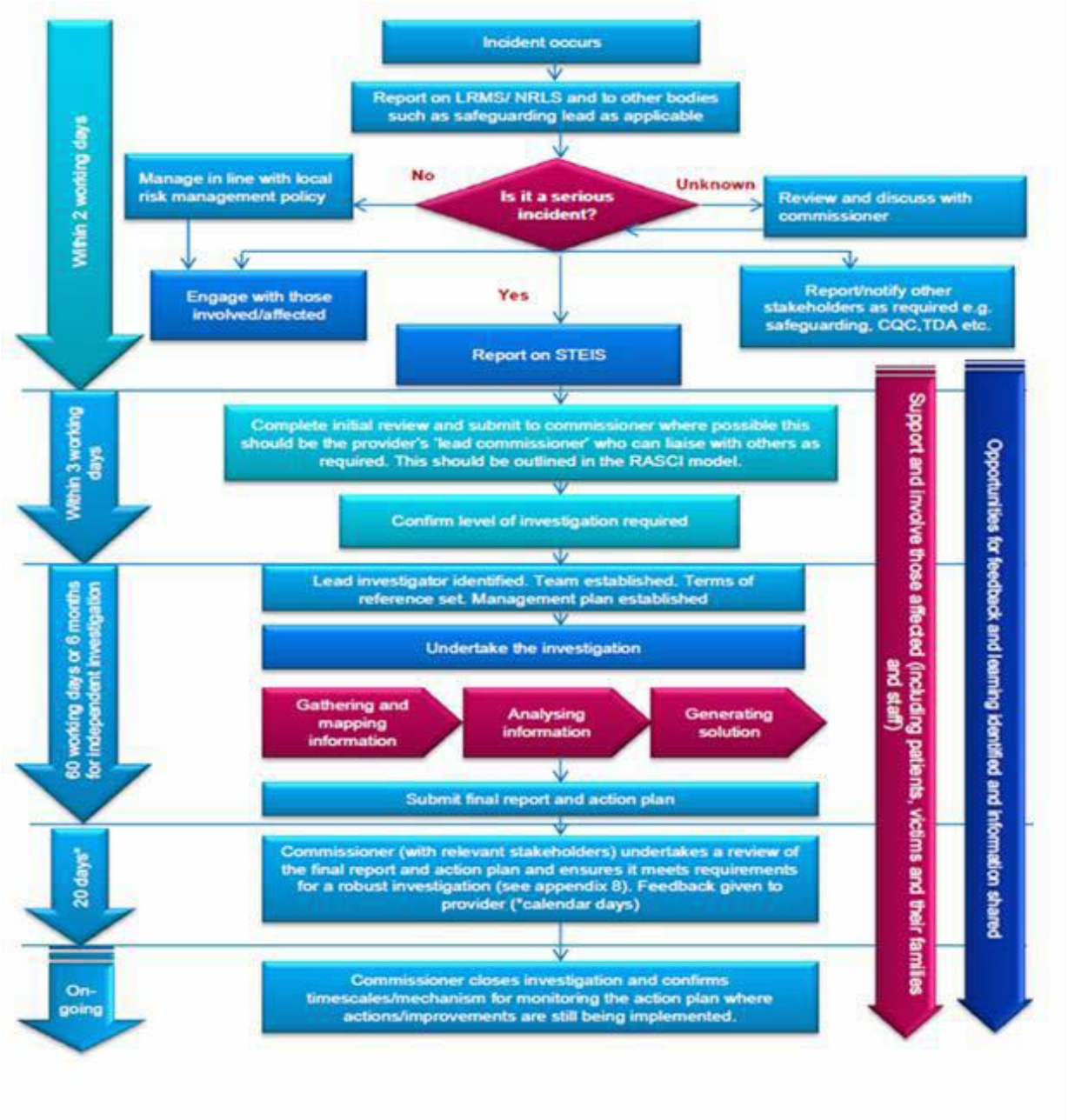
- To establish the facts
- To identify system and/or individual failures
- To establish how reoccurrence may be reduced or eliminated
- To review current barriers preventing (****)
- To formulate recommendations and an action plan
- To provide a means of sharing the learning from the incident

Person completing report (name and job title)

Appendix B

SERIOUS INCIDENT REQUIRING INVESTIGATION MANAGEMENT PROCESS

The following process must be complied with in accordance with the NHSE SI Framework 2015.



Appendix C

UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST
CORPORATE STATEMENT TEMPLATE

STAFF DETAILS

NAME:	
ROLE:	
PROFESSIONAL QUALIFICATIONS:	
PROFESSIONAL REGISTRATION NO. :	
PROFESSIONAL ADDRESS:	
PROFESSIONAL CONTACT NO:	

DETAILS OF PATIENT STATEMENT RELATES TO

NAME:	
DATE OF BIRTH:	
DATE OF DEATH:	
DATE OF INCIDENT:	

INCIDENT ☐ **COMPLAINT** ☐ **INQUEST** ☐

Please provide your response/account of what happened on the back of this form and use additional sheets if required. (Please see appendix D for further information).

The statement should be factual, not opinion. The statement may be shared with other parties e.g. Police, Coroner, Solicitors, patient/family. Please be aware that you may seek advice and support in its completion via your Lead Nurse, Consultant lead, Matron, Corporate Patient Safety team, Corporate Health and Safety Team, Corporate Claims and Litigation Team, Research & Development, or professional body or union.

PLEASE DATE, SIGN AND PRINT YOUR NAME AT THE BOTTOM OF EACH SHEET OF PAPER USED

UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST
CORPORATE STATEMENT TEMPLATE

DATE: ……

SIGNATURE ……

PRINT YOUR NAME……...

Do Not:-

- Make reference to statements by other witnesses
- Go beyond your recollection of events and never base the statement on hearsay
- Seek to blame others
- Report facts of which you do not have direct knowledge
- Use abbreviations
- Include your home address

Tips

- It is helpful to recall others who were working at the time of the incident/accident/adverse event/near miss
- Try to have your statement typed
- Always keep a copy of the statement for your own records
- Seek advice from a more experienced person if you wish

Advice and Support

- Line Manager
- Corporate Patient Safety Team
- Corporate Health and Safety Team
- Corporate Legal Team
- Trade/Professional Union

And Finally

Your statement may be disclosed to the patient or their next of kin (if the patient is deceased), their legal representative or H.M. Coroner. It is not normally necessary to seek the advice of your professional union before submitting your statement, but if you wish to do so, you must ensure that you comply with the appropriate deadlines. If, however, your statement has been prepared for the Trust's solicitor, in anticipation of legal proceedings against you or the Trust, your statement will be "legally privileged", which means it will be treated as confidential and will not be disclosed to a third party without your prior notification.

Appendix D

University Hospitals of Leicester NHS Trust

V1 – November 2014

Stating the Facts

Your Guide to preparing and writing a witness statement in relation to a Patient Safety Incident (PSI), Staff Accident (SA), Complaint, Claim or Inquest

Writing a Statement

Having an effective incident reporting system/complaints management means that you may be asked to provide a statement. This should be viewed positively as it means that vital information is gathered whilst it is fresh in your mind, and if a complaint or claim arises the evidence is available to inform the investigation process.

It is important to write a statement as near as possible to the event as memories will fade.

There is a UHL NHS Trust Corporate Template available on Insite for the writing of a statement which should be used. However, if this is difficult to access for any reason, the following information should be followed:-

Staff Details:-

- Full Name
- Role
- Professional Qualifications
- Professional registration number
- Professional address
- Professional contact number

Details of Patient statement Relates to:-

- Name
- Date of Birth
- Date of Death (if appropriate)
- Date of Incident

The Statement must:-

- Indicate if it is in relation to a Patient Safety Incident, Inquest, Complaint or Claim
- Be a clear, straightforward narrative dealing with events in *chronological order*
- Simply relate to the facts of the event and not state opinions
- Be complete, thorough and honest
- Be as detailed as possible
- Contain only material facts
- Should state whether you are writing the statement from memory, from the notes or both, or simply your recollection from your standard practice at that time
- Include the following declaration:- "The contents of this statement are to the best of my knowledge and belief"
- Be signed and dated with name printed on each sheet of paper used.

Appendix E

INVESTIGATION REPORT

Incident Report Form Ref. No.

STEIS Log. No. 2015/

CMG Sign off by:

Electronic signature here

Print Name and Title…….

Investigation Chair Sign off by:

Electronic signature here

Print Name and Title ……..

Authors Title :

Date completed: *(month and year)*

To (e.g. Mrs. X, Mr. Y, Mrs. Z's family) we extend a sincere and heartfelt apology for the failings in care. We are genuinely sorry that this incident occurred and we would welcome the opportunity to meet with you further to discuss this report.

(this should be tailored to each individual case including use of your own wording)

CONTENTS

EXECUTIVE SUMMARY

(aim for one page)

Need to include:

- *Incident description and degree of harm as a result of the incident*
- *Level of investigation conducted*
- *Care and Service Delivery Problems*
- *Contributory Factors*
- *Rationale for Root Cause/s*
- *Recommendations*
- *Actions taken*

On ***…(insert date)***, this event was identified as a serious incident and escalated in accordance with UHL Policy for the Reporting and Management of Incidents (including the investigation of serious incidents) 2013 and a full investigation was instigated by the Corporate Patient Safety Team.

On, ***…(insert date)*****,** the incident was formally reported to the Trust Development Authorityand East Leicestershire and Rutland Clinical Commissioning Group in accordance with local and national policy.

A National Patient Safety Agency Level One ('Comprehensive') type of Patient Safety investigation was undertaken using Root Cause Analysis tools and techniques. The purpose of the incident investigation was to explore the reasons for the events leading to **[insert incident here]**. The Care Delivery Problems and Contributory factors are outlined in the main body of the report; the root causes being identified as:

- **[insert root cause if identified]**

Lessons have been learned and recommendations made to prevent a similar occurrence in the future; these are outlined in the action plan towards the end of the report.

The Incident Decision Tree was undertaken as part of this incident investigation and is referred to in more detail further on in the report.

MAIN REPORT

THE PURPOSE OF THE INVESTIGATION

UHL has a strong reporting culture and will always undertake to do a thorough, honest and robust investigation. The aim is to identify learning that reduces the risk of an incident recurring, and not to apportion individual blame. A "just culture" is nurtured and if during an investigation concerns of capability or recklessness are identified they will be referred to the appropriate agencies and will not form part of the patient safety investigation process.

BEING OPEN AND DUTY OF CANDOUR (INVOLVEMENT AND SUPPORT OF PATIENT AND RELATIVES)
[check patient status prior to sending out report]

This root cause analysis investigation report is provided to the patient / relatives concerned in the incident, and to the Trust's Commissioners as evidence of a thorough investigation into the facts. The Trust is committed to learning and improving and to an entirely open, transparent and honest communication with those involved in the incident.

(include description of contact made with patient/relatives during the investigation eg, issues raised/complaints/account of events)

INVOLVEMENT AND SUPPORT PROVIDED FOR STAFF INVOLVED

Example:

The staffare being supported by their line managers and are aware of the services of AMICA if required.
A copy of the final version of the investigation report will be shared with all of the staff involved in the incident for shared learning.

SUMMARY INCIDENT DESCRIPTION AND DEGREE OF HARM AS A RESULT OF INCIDENT

TERMS OF REFERENCE (must be included and specific to incident)

Example:

- *To establish the facts in relation to this incident*
- *To review any policies and guidelines relevant to this incident*
- *To identify any system or care delivery failures*
- *To identify any individual failings*
- *To ascertain areas of good practice*
- *To determine learning points*
- *To formulate recommendations and an action plan*
- *Scope and level of investigation*

[Consider adding patient/relative concerns/focus for investigation]

INVESTIGATION TEAM

Need to specify names, roles, qualifications, departments. Investigation Chair will be a nominated Director. Investigation Team Lead will be Patient Safety Team. Consideration of inclusion of Patient/Relative.

	Name	Role
Investigation Chair		
Investigation Team Lead		
Investigation Team Member/s		

INFORMATION AND EVIDENCE GATHERED *(a few suggestions have been inserted below)*

- *Interviews with key staff involved, conducted by …..(job title only), notes of which have been verified by the interviewees*
- *Statements obtained and reviewed from the nursing and medical staff involved in the incident, dated and signed*
- *Review of the Incident Report Form*
- *Review of medical and nursing records and electronic records where available*
- *Site visit carried out*
- *Review of current situation in relation to procedures and protocols in place*
- *Interview or written comments of Patient/Relative*
- *RCA Meeting held [insert date and attendees if multiple meetings]*
- *Serious Incident Review Group meeting held [insert date]*

ROOT CAUSE ANALYSIS TOOLS USED

- Such as tabular timeline, fishbone, change analysis, IDT

BACKGROUND AND CONTEXT TO THE INCIDENT (will not always be necessary to include)

A brief description of the service type, size, clinical team, care type, treatment provided. Outline of relevant local and national policy/guidance in place at the time.

FINDINGS

CHRONOLOGY OF EVENTS *(may be attached as an appendix if lengthy)*

[consider 'telling the story' of what happened here]

DETECTION OF INCIDENT

Note the point in the patients treatment AND the method by which the incident was identified.

CARE DELIVERY/SERVICE DELIVERY PROBLEMS *to be identified, and for each one, the* **Contributory Factors** *to be highlighted and discussed.* ***(Refer to the National Patient Safety Agency Contributory Factor Classification Framework)***

Patient factors
Individual(staff) factors
Task factors
Communication factors
Team factors
Education and training factors
Equipment and resources factors
Working condition factors
Organisational and strategic factors

INCIDENT DECISION TREE

The Incident Decision Tree was undertaken by **[insert role]** during the investigation and applied to **[insert staff role –i.e. Doctor 1, Nurse B]**. Appropriate management has been applied following the outcome of the Incident Decision Tree which includes **[add outcome]**

NOTABLE PRACTICE POINTS IDENTIFIED *(e.g. management of the incident was excellent; good documentation, etc)*

ROOT CAUSES

These are the most fundamental underlying factors contributing to the incident that can be addressed.

CONTRIBUTORY FACTORS

LESSONS LEARNED

These are the key things that were identified (good or bad - either in terms of the investigation or the incident) from which others can learn.

CONCLUSIONS

RECOMMENDATIONS

Recommendations should be directly linked to root causes and need to be clear but not detailed (bullet points). (Most Trusts agree that there should be no more than five recommendations). Must be evidenced and reasoned.

IMPLEMENTATION, MONITORING AND EVALUATION ARRANGEMENTS

The action plan identifies the recommended actions to minimise future risk, who should action them and the time frames for the actions. The action plan will be reviewed at the Patient Safety Team action plan tracker meeting monthly and at the Trust Adverse Events Committee to ensure compliance in relation to their application and lessons learnt. All outstanding actions are included in the Patient Safety reports shared at the CMG Quality & Safety Monthly Board Meetings.

ARRANGEMENTS FOR SHARING AND LEARNING

Describe how lessons learned have been or will be shared with staff and other organisations e.g. through bulletins, PSAT network, professional networks, etc. Add sharing and learning as actions on the plan.
Think about service delivery issues and sharing by service managers, general manager and heads of operations at their cross CMG meetings.

DISTRIBUTION LIST

Describe who (eg.patients, relatives and staff involved) will be informed of the outcome of the investigation and how.

ACTION PLAN FOR 2021/

Root Cause/ Contributing Factor	**Level of Risk**	**Agreed Action**	*Level of Recommendation* **I**ndividual, **T**eam, **C**MG, **O**rganisation	**By Whom**	**By When**	**Resources Required**	**Evidence of Completion and Progress**	**Monitoring & Evaluation Arrangements**
Sharing and Learning								

Sign off – action plan completed date:
Sign off by:

APPENDICES

(As appropriate, perhaps the chronology if documented as a tabular timeline or if lengthy, etc)

REFERENCES (if used)

GLOSSARY

Appendix 1 - Patient & Equality Act 2010 Information

Age	
Diagnosis	
Gender	
Disability	Yes ☐ No ☐
Marital/Civil Partnership Status	
Race	
Religion/Belief	
Sexual Orientation	
Pregnancy/Maternity Status	
Level of Harm	
GP Location	
Clinical Speciality Involved	
Clinical Management Group or Division	
Safeguarding Incident	Yes ☐ No ☐

This information must be included as an information sheet in all SI investigation reports and is a CCG requirement

Appendix F

Maternity Risk Management Policy

Patient Safety Internal Processes and External Referral Requirements

Contents

Background and Context

Maternity Services in the UK have faced additional levels of scrutiny in relation to Patient Safety for many years. It is arguable as to whether this has been due to different public perceptions and expectations around what is considered to be a normal physiological event, or the significantly high level of litigation value in this arena, a combination of the two or indeed other factors. NHS England provides a national steer aimed at safer maternity services across the UK, with standards reflected by the Care Quality Commission (CQC 2020, NHSE 2019, NHSE website). The most recent Ockenden review of maternity services at Shrewsbury and Telford Hospital NHS Trust (2020) has outlined very specific recommendations in relation to standards in Maternity Services.

All of the relevant Patient Safety processes utilised in the wider NHS are applicable for maternity services (The Serious Incident Framework 2015, Never Events Policy and Framework 2018). However there are specific pathways that apply solely and/or slightly differently to maternity and neonatal services which this guideline aims to describe.

AIM

- To provide clarity with regards to the maternity and neonatal specific internal and external reporting that is required to evidence compliance with the national standards.
- To outline UHL NHS Trust Patient Safety Processes and referral requirements within the Maternity services, with accompanying criteria.

This will include;

- MBRRACE-UK notifications of fetal loss, stillbirths, neonatal deaths and maternal deaths
- UHL Perinatal Mortality Review Panel
- Healthcare Safety Investigation Branch (HSIB)
- NHS Resolutions Early Notifications Scheme
- UHL Maternity/Neonatal Rapid Review
- UHL Perinatal Risk Group
- Perinatal Mortality Review Tool
- Management of Serious Incidents escalated as part of the HSIB referral criteria when HSIB decline to investigate or no consent is obtained and no care or service delivery issues are identified in Rapid Review, PRG or PMRP review processes.

Abbreviations:

CQC:	Care Quality Commission	HIE:	Hypoxic Ischaemic Encephalopathy
KLOE:	Key Lines Of Enquiry	MRI:	Magnetic Resonance Imaging
MBRRACE:	Mothers and Babies - Reducing Risk through Audits and Confidential Enquiries	NOK:	Next of Kin
HSIB:	Healthcare Safety Investigation Branch	NICU:	Neonatal Intensive Care
UHL:	University Hospitals of Leicester	NNU:	Neonatal Unit
CMG:	Clinical Management Group	ITU:	Intensive Care Unit
PMRP:	Perinatal Mortality Review Panel	MOH:	Massive Obstetric Haemorrhage
PRG:	Perinatal Risk Group	EFW:	Estimated Fetal Weight
PMRT:	Perinatal Mortality Review Tool	SFH:	Symphysis Fundal Height
CDOP:	Leicester, Leicestershire &	CTG:	CardiotocoGraphy

	Rutland Child Death Overview Panel
LMNS:	Local Maternity and Neonatal System
HIMS:	HSIB electronic secure system
EN:	Early Notification Scheme
NHSR:	NHS Resolution
CNST:	Clinical Negligence Scheme for Trusts
ATAIN:	Avoiding Term Admission Into the Neonatal unit
SI:	Serious Incident

MBRRACE-UK

MBRRACE (Mothers and Babies - Reducing Risk through Audits and Confidential Enquiries)

Stillbirths, neonatal deaths and perinatal mortality rates for the UK are published by MBRRACE-UK in Perinatal Mortality Surveillance Reports. These reports publish stabilised and adjusted mortality rates to adjust for chance variation due to small numbers and for key factors known to increase the risk of perinatal mortality such as mother's age, socio-economic deprivation, baby's ethnicity, baby's sex, multiple births and gestational age at birth (for neonatal deaths only).

MBRRACE issues individual reports to NHS Trusts indicating the local perinatal mortality rates. These Trust-specific reports recommend that Trusts should review existing records regarding the deaths to ensure any avoidable factors have been identified and appropriate changes to care have been implemented.

In order for this to occur UHL Maternity Services must:

- Report all UHL cases of stillbirth, neonatal death* and fetal loss from 22 weeks of pregnancy that occur to MBRRACE-UK within 7 working days of the death/delivery (*neonatal deaths included are those live born babies of any gestation that die up to and including 28 days of age and all babies that have died on the neonatal units without having been discharged from neonatal care since birth). Further information about the birth should be entered into the MBRRACE-UK surveillance system within 4 months of the death/delivery.
- Subsequently, detailed multi-disciplinary reviews of these deaths must be input via the Perinatal Review Tool section of the MBRRACE-UK website– This is completed through the Perinatal Mortality Review Panel (details below)

- Report all maternal deaths via the PMRT. Maternal death is a death from any cause during pregnancy and up to 1 year after the end of the pregnancy (births, miscarriages, ectopic pregnancies and terminations of pregnancy are all included).
- Upload medical records for cases of maternal death to MBRRACE-UK. This includes cases where deaths may have occurred outside of UHL maternity services, or where the pregnancy care may have been outside of UHL maternity services but the woman received care at UHL at some point between pregnancy care being initiated and her death.

Additional detail can be found at https://www.npeu.ox.ac.uk/mbrrace-uk

PERINATAL MORTALITY REVIEW PANEL (PMRP)

The purpose of this monthly meeting is to:

- Provide an in depth, multi-disciplinary investigation into inborn stillbirths and neonatal deaths and infant deaths on the neonatal unit.
- Provide an analysis of quality of care and preventability.
- Identification of trends and themes for further investigation
- Identification and dissemination of lessons and recommendations arising from the reviews
- Provide quarterly reports to the Mortality Review Committee, Trust Board, CMG Board, Maternity and Neonatal Governance meetings.
- Provide a report for the Leicester, Leicestershire & Rutland Child Death Overview Panel (CDOP).
- Provide information to MBRRACE
- Ensure compliance with the national requirements in relation to mortality cases and the Perinatal Mortality Tool
- Generate reports for bereaved parents and/or family members

An overview of the cases reviewed by the Perinatal Mortality Review Panel will be included in the Maternity Quality and Safety report which is shared at CMG Women's Governance Board, Local Maternity & Neonatal System (LMNS), Maternity Governance meeting, Delivery Suite Forum, Nursing and Midwifery Board, and other relevant UHL meetings.

HEALTHCARE SAFETY INVESTIGATION BRANCH (HSIB)

The referral criteria are in 2 parts. The initial criteria that must be met are:

- 37+0 and above weeks of pregnancy
- Signs of labour (this includes latent phase, rupture membranes and/or commencement of induction of labour – does not have to be established labour)
- Baby thought to be alive at the start of labour (no evidence to the contrary)

If the above are met, then any of the following outcomes would warrant a referral to HSIB:

- Intrapartum stillbirth
- Hypoxic Ischaemic encephalopathy (HIE) Grade 3
- Neonatal cooling commenced
- Early neonatal death (within 6 days of birth)

Babies whose outcome was the result of congenital anomalies are not investigated by HSIB. Babies who have been cooled but subsequently have MRIs that show no hypoxic brain injury are currently not investigated by HSIB due to COVID19 transformation of services. Referral is still required in this instance.

HSIB will also investigate Maternal Deaths. These are all maternal deaths that occur during pregnancy and up to and including 42 days post-partum.

Additional detail can be found at www.hsib.org.uk/maternity

In order to comply with the requirement to refer all qualifying cases to HSIB UHL must:

- Identify qualifying cases, via Datix referrals, staff referrals, notes reviews and discussions with the mother/family
- Make initial contact with HSIB and initiate referral
- Explain HSIB and NHS Resolution Early Notification Scheme (where relevant) to mother or Next of Kin (NOK)
- Obtain maternal or NOK consent to share contact information and medical records
- Scan and upload all records and other requested information to HIMS (HSIB electronic secure system)

In order to support the Investigation process UHL must:

- Share UHL contact details of staff that HSIB have identified for interview.
- Continue to provide additional information as requested by HSIB in relation to specific cases. This may include but is not limited to local guidance, contact details of other staff/services, equipment logs, electronic rostering and acuity data.
- On receipt, circulate the draft report to the staff who have been interviewed and share with the CMG Management team and request feedback and factual accuracy comments.
- Upload any factual accuracy feedback within the allotted time frame.
- On receipt, circulate the final Report to the staff involved, the CMG Management Team, Trust Head of Patient Safety, the Trust Director of Quality and Governance, and the Trust litigation team in relevant circumstances.
- Generate an Action Plan and a Learning Bulletin to address the Safety Recommendations and Findings within the Report.
- Circulate the Report, Action Plan and Learning Bulletin to the Trust Board (Executive and Non-Executive), the Clinical Commissioning Group and NHS England/Improvement in accordance with the Serious Incident process.

- Share the Report and Actions at the Adverse Events Committee, CMG Governance Board, Local Maternity and Neonatal System (LMNS) and other relevant meetings and groups within the CMG.

All cases that meet HSIB referral criteria will be escalated to the Clinical Commissioning Group and NHSE/I as a Serious Incident for Investigation in accordance with national guidance. UHL Corporate Patient Safety Team is responsible for ensuring Duty of Candour compliance in relation to these incidents.

Following initial referral there are 3 possible ways the investigation may proceed;

1. HSIB accept and undertake the investigation (including Early Notification where applicable, see below)

2. HSIB reject the case or no consent is obtained. Where care or service delivery issues HAVE been identified at Rapid Review and/or Perinatal Risk Group or Perinatal Mortality Review Panel, UHL undertake full Root Cause Analysis investigation and generate a comprehensive report to be managed and shared in accordance with Trust Incident Reporting policy for serious incidents.

3. HSIB reject the case or no consent is obtained. Where care or service delivery issues HAVE NOT been identified at Rapid Review, UHL undertake a multi-disciplinary review via the Perinatal Risk Group or Perinatal Mortality Review Panel and in the absence of any new concerns about care being raised, a concise report is generated to share with the family, CCG and NHSE/I. These will be overseen by the Executive Board lead for Maternity.

NHS RESOLUTIONS EARLY NOTIFICATIONS

The Early Notification (EN) scheme is a national programme for the early reporting of infants born with a potentially severe brain injury following term labour to NHS Resolution (NHSR). The EN scheme requires Clinical Negligence Scheme for Trusts (CNST) members to notify NHSR of maternity incidents that have the potential to become high value claims. The criteria for referral is outcome based.

This scheme applies to all babies born at term (≥37 completed weeks of gestation), following labour, that had a potentially severe brain injury diagnosed in the first seven days of life and:

- Was diagnosed with grade III hypoxic ischaemic encephalopathy (HIE) or
- Was therapeutically cooled (active cooling only) and there is evidence of or the potential for a hypoxic brain injury
- Had decreased central tone AND was comatose AND had seizures of any kind.

NHSR (online) defines hypoxic brain injury as:

"Babies who have an abnormal MRI scan where there is evidence of changes in relation to intrapartum hypoxic ischaemic encephalopathy (HIE)".

Babies with MRI findings that fall outside of the clinical definition of a brain injury may still be accepted by the EN scheme.

Prior to April 2020 UHL were required to obtain consent and undertake the NHSR EN referral for all qualifying cases in order to comply with CNST requirements. This included ALL cooled babies that met the initial criteria. Change made in response to the Covid-19 pandemic has resulted in a different process that means that all qualifying cases that HSIB are investigating are referred by HSIB directly to NHSR.

There will be a cohort of women who HSIB will not refer, either because a woman does not give consent, or subsequently withdraws consent for an HSIB investigation. UHL must ensure that EN referrals are made for these cases to comply with CNST requirements.

UHL Womens and Children's CMG Quality and Safety Team are responsible for ensuring that the Duty of Candour letter highlights the involvement of NHSR.

Additional detail can be found at https://resolution.nhs.uk/

PERINATAL RISK GROUP (PRG)

Purpose and methods

To be a cross-site, expert, multidisciplinary group which incorporates non UHL staff, that undertakes a detailed review of the care provision in relation to incidents that have triggered to warrant this level of review. A suggested checklist for cases requiring review at PRG is provided below, but this is not exhaustive.

The group's aim is to provide advice to the Women's and Childrens CMG about incidents and risk issues pertaining to the maternity & neonatal services and to make recommendations to shape the service and improve the care we deliver.

The group will achieve this by:

- Reviewing relevant adverse incidents, complaints if indicated, and reviewing cases that have been referred for PRG following Rapid Reviews, routine Datix reviews and any other review that has highlighted an indication for more detailed review.

- Reviewing individual cases involving near misses, poor outcome or sub-optimal care. A "thematic" approach using specific clinical criteria for review may be appropriate to consider.

- Reviewing every baby born within UHL who is diagnosed with Hypoxic Ischaemic Encephalopathy (HIE) that has not already been accepted for investigation by HSIB, or is being reviewed as part of the perinatal mortality review process.

- Contributing to the production of case reports and action plans

- Outcomes that should/may illicit consideration for PRG review:

  - Unexpected admissions to NICU/NNU – particularly if poor condition/poor cord gases at or soon after birth (exclude routine ATAIN cases)

- Avoidable MOH as per DATIX and Rapid Review
- Significant MOH if review identifies moderate learning points
- Returns to theatre
- Maternal ITU admissions
- Significant concerns about CardiotocoGraphy interpretation and or management
- Significant concerns about the general management of care (antenatal, intrapartum, peri-operatively or postpartum)
- Delay in recognition of deteriorating patient (woman or baby)
- Issues with neonatal resuscitation
- Excessive neonatal trauma attributed to birth
- Cases that meet the HSIB referral criteria but HSIB are not investigating and the Rapid Review has not identified significant care or service delivery concerns
- Unplanned hysterectomy
- Maternal death
- Significant anaesthetic problems
- Neonatal collapse or deterioration
- Significant medication errors
- Near misses, recognised care or service delivery issues but poor outcome avoided.

Cases not expected to be reviewed at PRG would be:

- Cases already identified as SIs
- Cases accepted by HSIB
- Cases that are due to be reviewed at Perinatal Mortality Review Panel unless there are other issues deemed to warrant PRG review.

RAPID REVIEWS

Maternity Services come under a different level of scrutiny to other areas of health care in relation to incidents and poor outcomes, and as such there is a need for a basic list to guide what outcomes warrant a Rapid Review. The list is not exhaustive but aims to assist colleagues in ensuring that the processes are clear, robust and stand up to scrutiny. It is also intended to ensure that UHL are not criticised for delayed escalation and/or failing to correctly grade incidents in accordance with harm and so complying with CQC Key Lines of Enquiry (2018).

- Stillbirths (all gestations, including known fetal anomalies)
- Unexpected admissions to NICU/NNU – particularly if poor condition at or soon after birth (exclude babies that are reviewed as part of Avoiding Term Admission Into the Neonatal unit (ATAIN) criteria unless additional issues present relating to peripartum events/care delivery issues)
- Cord gases <7.0
- Massive Obstetric Haemorrhage (MOH) >2 litres
- Unplanned hysterectomy
- Maternal return to theatre
- Maternal collapse/deterioration
- Maternal ITU admissions
- Maternal death

- Significant anaesthetic problems
- Unexpected fetal abnormality at birth
- Neonatal collapse/deterioration
- Significant medication errors
- Near misses or recognised care or service delivery issues where poor outcome is avoided.

The purpose of the Rapid Review is to demonstrate that significant outcomes are reviewed appropriately, by the right individuals, in a timely manner with swift recourse for escalation and/or referral if indicated. Reviewing poor outcomes is an essential part of the learning culture of maternity services (*NHS England, 2016*).

Completing a Rapid Review

The Rapid Review is to be undertaken on the correct document (Appendix 2) and forwarded to the CMG Quality and Safety Team. This evidence is collated with a brief summary and any themes highlighted shared with the CMG Board, Trust Board and the LMNS as part of the monthly Maternity Governance Board paper. This allows UHL to demonstrate that a timely review has been undertaken, by whom and what the findings were. The completed rapid review document must be attached to the Datix Incident Report Form.

The Rapid Review should ideally be undertaken within 72 hours of the incident being identified. The review should be undertaken by 2 of the following:

- Obstetric Consultant (essential unless midwifery led care throughout)
- Relevant Midwife Band 7 or above
- Patient Safety Coordinator/Quality & Safety Manager
- Obstetric Anaesthetic Consultant
- Neonatal Consultant

The appropriate review team is dependent on the incident and it may be necessary to include more than 2 individuals to ensure that care has been reviewed adequately.

The Rapid Review should demonstrate a review of ALL of the care such as antenatal care pathways, medications, scans and plotting of estimated fetal weight (EFW)/symphysis fundal height (SFH), hospital attendances. There is no requirement to detail every contact in the written Review, but it must be clear that the Review has included ALL of the care, not just the immediate care at the time of the reported incident.

If the reviewers are in agreement that the care was appropriate this should be clearly stated.

If minor issues are identified that are not causative or contributory to the outcome, these should be highlighted and a clear outline of what action has been initiated should be recorded. For example, feedback may be provided to individual staff or review of relevant guideline recommended.

If significant care or service issues are identified, these should be bullet pointed and a clear outline of actions and escalation should be recorded. Reference to meeting HSIB and/or PMRT criteria is required as well as demonstrating any recommendations for escalation as a Serious Incident and/or a Perinatal Risk Group review.

Rapid Reviews can be accessed and added to as part of either a Perinatal Risk Group and/or Perinatal Mortality Review Panel Review, via request to the CMG Quality and Safety Team.

Reporting structure

An overview of the cases reviewed by The Perinatal Risk Group will be included in the Maternity Quality and Safety report which is shared at CMG Women's Governance Board, LMNS, Maternity Governance, Delivery Suite Forum, Nursing and Midwifery Board, and other relevant UHL meetings.

Any issues of concern are to be highlighted to the Maternity Governance meeting, the Obstetric Consultant meeting and/or the NNU Governance meeting (others as indicated).

Recommendations for individuals will be fed back through an appropriate peer or manager in confidence as appropriate.

Any serious concerns will be managed via the Head of Service, Head of Midwifery or their deputies.

Clinicians representing specialities from other Clinical Management Groups (CMG's) will feed pertinent issues back to their own clinical governance groups.

Important lessons will be communicated to the medical and midwifery staff via a regular newsletter.

References

Care Quality Commission (2020) Getting Safer Faster: key areas for improvement in maternity services 12 March https://www.cqc.org.uk/publications/themed-work/getting-safer-faster-key-areas-improvement-maternity-services

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NHS England (2018) Never Event Policy and Framework https://www.england.nhs.uk/wp-content/uploads/2020/11/Revised-Never-Events-policy-and-framework-FINAL.pdf

NHS England (2019) Saving Babies Lives Care Bundle 2 https://www.england.nhs.uk/wp-content/uploads/2019/07/saving-babies-lives-care-bundle-version-two-v5.pdf

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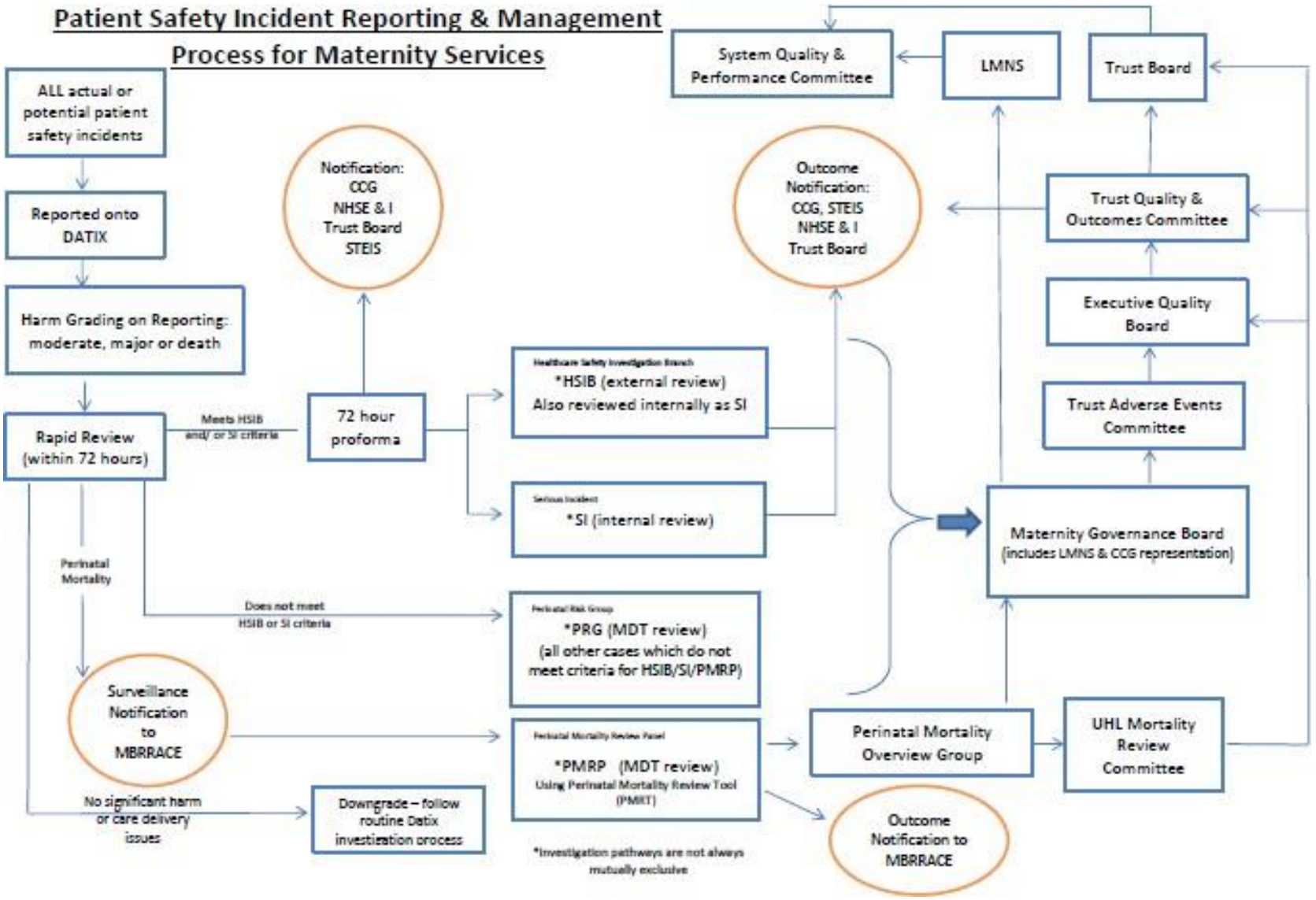
NHS Resolution (online) About the Early Notification Scheme https://resolution.nhs.uk/services/claims-management/clinical-schemes/clinical-negligence-scheme-for-trusts/early-notification-scheme/support-for-nhs-trusts-or-member-organisations/

Ockenden Report (2020) Review of maternity services at Shrewsbury and Telford Hospital NHS Trust https://www.donnaockenden.com/downloads/news/2020/12/ockenden-report.pdf

Appendix 1: Safety reporting process for maternity services



Appendix 2*:* Incident Review Tool

Datix Number:	
Date of Incident:	
Date incident reported:	
Summary of Incident:	
Current status of patient:	
Actual harm:	
Executive review panel members:	
Date of review:	
Outcome and rationale for decision:	