Patient Safety Incident Reporting Policy 2024/5

Department / Service:	Clinical Governance & Risk Management
Originator:	Associate Director of Clinical Governance and Risk
Accountable Director:	Chief Nursing Officer
Approved by:	Quality Governance Committee (QGC) on 25/01/2024 Fundamentals of Care Group (FOCG) on 09/04/2024
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Extension Approved:	
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Target Organisation(s):	Worcestershire Acute Hospitals NHS Trust
Target Departments:	All Divisions, Directorates, Departments & Wards
Target staff categories:	All staff – Trust employees, agency & contracted staff

Purpose of the document:

The Trust is committed to embracing the learning opportunities that arise from Patient Safety Incidents, accidents and near miss events reporting.

This policy sets out the responsibilities and processes for reporting these events within the Trust.

This policy applies to all staff (Trust employees, agency and contracted staff) and requires all incidents, accidents and near miss events to be reported through the Trusts reporting system.

This policy also describes which incidents are reported to external agencies and how.

Key amendments to this document:

Date	Amendment	By:
Oct 04	Introduction of a single incident recording form for all incidents, accidents and near miss events.	C Rawlings
Oct 04	Revised guidelines on reporting timescales Introduction of the Incident Decision Tree (IDT) RED Incident Checklist Flowcharts to show response to incidents and level of investigation required	C Rawlings
Aug 05	Addition of new Serious Untoward Incidents reporting process. Incident reporting process with reference to the new incident form. Revised guidelines on reporting timescales. Re ordering of sections to enhance clarity.	P Manyonga
Aug 06	Cervical Cytology QA inspection – add should an incident occur within the Cervical Cytology service then the Trust will adopt the NHSCSP Guidelines for Managing Incidents in the Cervical Screening Programme.	C Rawlings
May 07	Amendments re: West Midlands SHA Serious Untoward Incident Reporting Policy and Procedure January 2007. Inclusion of requirement to report ALL child deaths as incidents	P Ngundu B McLeod
Oct 08	Amendments to comply with: Trust Policy for Key documents; NHS West Midlands SUI Policy & Procedures; Findings of the Internal Audit report 2007; Needle stick Injuries; Introduction of electronic incident reporting system	C Rawlings B McLeod P Graham
July 10	Amended to reflect new organisational structure. Revised NPSA & NHS West Midlands Serious Incident Policies. Implementation of electronic incident reporting CQC & Human Tissue Authority and Information Governance incident reporting requirements	B McLeod
April 2011	Link to www.csp.nhs.uk website added to section 5.3 page 10	C Rawlings/ J Underhill
July 2012	Amended to reflect the revised Trust structure and responsibilities and changes to external reporting requirements	B McLeod / P Graham
Aug 14	Document extended for 3 months whilst under review	L Webb
Sept 14	Amendments to screening requirements	B McLeod
Nov 14	Amendment to reflect revised Trust structure, Removal of investigation process information Addition of Never Events & CCG SI Policy	B McLeod
Aug 16	Clarification of the incident grading process. Description of new committees and meetings. Changed definition for serious incidents following the NHS SI Framework	C. Rawlings W. Huxley Marko L. Wood
Oct 16	Contact number changed cancer screening programme for cervical screening.	K leach

Date	Amendment	By:
Feb 17	Incidents in NHS Screening Programmes added in to document	K leach
April 17	Change to section 5.8, cervical added into title of section	K Leach
Sept 2017	Document extended for 3 months as per TMC paper approved 22nd July 2015	TMC
Oct 2017	Section 3.20- to include more emphasis on the statutory duty of candour. P16- addition of quarterly report Changes to job titles Addition of TLG in 10.1 for approval of document Removal of NHS Protect Change to SHOT wording	S Lloyd
Oct 19	Document extended for 6 months whilst review process is completed	Dee Johnson
May 2020	Document extended for 6 months during COVID period	
7th Oct 2020	Document extended whilst review is undertaken	Denise Price/ Dee Johnson
7th Dec 2021	Document extended for 6 months whilst review process is completed. New review date 07/06/2022	CGG
April 2022	Document extended for a further 6 months whilst review process is completed - New review date 07/12/2022	CGG
December 2022	Document extended for 6 months whilst review process is completed. Currently working through the trust wide implementation of the National Patient safety Strategy and the Patient safety incident response Framework, there will be substantial changes to this policy once this has been implemented.	Allan Bailey
October 2023	• Introduction: Replace NRLS with LFPSE • 3.2: Amended description of PSI • 3.6: Remove Serious Incident description • 3.13: Insert definition of Patient Safety Incident • 3.14: Remove reference to Serious Incident and replace with SEIPS2 • 3.15: Insert incident learning responses • 3.16: Insert process for Patient Safety Incident Learning Review Group (PSIRG) • 3.17: Replace CCG with ICS • 4.2: Replace SIRLG with PSIRG • 5.12: Remove reference to Serious Incident process • 9: Insert updated never events list • Appendix 1: Delete Serious Incident process and amend SIRLG to PSIRG • Appendix 3: Remove reporting examples • Appendix 4: Insert revised Never events list	Allan Bailey
16th March 2026	Document extended for 6 months to allow time to review and update	Karen Apps

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1. Introduction

The Worcestershire Acute Hospitals NHS Trust (The Trust) is committed to improving the quality of patient care and ensuring high standards of health and safety. One way it does this is by providing a system of incident reporting which allows all staff to record any incidents which cause harm, damage or loss of service or has the potential to do so. Incident reporting provides an important opportunity to learn from past events and ensure steps are taken to minimise recurrences.

It is a requirement of the 'Health and Safety at Work Act' (HASAW) 1974, 'Reporting of Injuries, Diseases and Dangerous Occurrences (RIDDOR) Regulations' 2013 and the Learning from Patient Safety Events (LFPSE) that all incidents including near misses are reported. The Trust uses Datix (Risk Management software) in order to report and collate incidents and to use this information to improve systems and clinical care.

The Trust is aware that some staff might worry about the relationship between the reporting of incidents, accidents or near misses and the potential for disciplinary action. Key contemporary reports from Francis, Keogh, Berwick, and Ockenden recommend that in order to achieve the most benefit from incident reporting, an organisation has to operate in an open, fair and learning culture. This means that:

- Staff are open about incidents they have been involved in.
- Staff and organisations are accountable for their actions.
- Staff feel able to talk to their colleagues and superiors about any incident.
- NHS organisations are open with patients, the public and staff when things have gone wrong, and explain what lessons will be learned.
- Staff are treated fairly and supported following an incident.

By promoting the features of an open and fair culture, the Trust is reassuring staff that incident, accident and near miss reporting will rarely attract disciplinary action.

Communication with all people involved with an incident should be considered a major part of the process. This includes the patient, family, internal departments and external organisations and bodies and should follow the principles set out within the Being Open and Duty of Candour Policy.

The Trust will comply with the statutory requirements for reporting incidents as set out in Appendix 6.

2. Scope of this Policy

This Policy applies to all areas and all employees of the Trust, including individuals employed by a third party such as internal contractors, external contractors, voluntary workers, students, locums or as agency staff. It also compliments both the Risk Management Strategy and Health and Safety Policy. This policy is supported by related documents, policies and procedures as listed in section 9.

3. Definitions

3.1 Incident

Any untoward, unplanned or unwanted event or circumstance that caused harm, damage or loss of service affecting patients, staff, contractors, visitors, members of the public or property.

3.2 Patient Safety Incident (PSI)
A patient safety incident is any unplanned or unintended event or circumstance which could have resulted or did result in harm to a patient. This includes harm from an outcome of an illness or its treatment that did not meet the patient's or the clinician's expectation for improvement or cure.

3.3 Accident
An ***Accident*** is an unplanned event, other than a clinical procedure, that results in injury or ill health to people or damage/loss to property, plant, materials or the environment.

3.4 Near Miss
A Near Miss is a 'Prevented Patient Safety Incident' (NHSI).

3.5 Hazard:
A situation/factor that is known or has the potential to cause harm or make an incident more likely to happen.

3.6 Never Events
Never Events are a particular type of serious incident that meet all the following criteria:

- They are wholly preventable, where guidance or safety recommendations that provide strong systemic protective barriers are available at a national level, and should have been implemented by all healthcare providers.
- Each Never Event type has the potential to cause serious patient harm or death. However, serious harm or death is not required to have happened as a result of a specific incident occurrence for that incident to be categorised as a Never Event.
- There is evidence that the category of Never Event has occurred in the past, for example through reports to the National Reporting and Learning System (NRLS), and a risk of recurrence remains.
- Occurrence of the Never Event is easily recognised and clearly defined – this requirement helps minimise disputes around classification, and ensures focus on learning and improving patient safety.

Further details are available at Appendix 2

3.7 SUDIC (sudden unexpected death in childhood)
The death of any patient under the age of 18. These must be reported on Datix regardless of whether the death was expected or unexpected. These will then be reviewed and considered as potential patient investigations.

3.8 Information Security / Confidentiality
Any breach of information security including the confidentiality, integrity or availability of data (both hard copy and electronic including clinical and non-clinical data).

3.9 Inquest:
A judicial inquiry into any case of sudden of violent death co-ordinated via the Coroner's Office

3.10 Claim:
A claim for compensation and/or clinical negligence or any other reason made against the Trust by or on behalf of a patient, or a member of staff.

3.11 Complaint:
A **complaint** is an expression of dissatisfaction requiring a response

1. A **FORMAL** complaint can be in writing or verbal, and is made within twelve months of the incident or its sequelae

   Local Resolution (of concerns)
   One of the underlying principles of the WAHT complaints process is that complaints are resolved at the earliest opportunity without escalating to the formal procedure. In most cases, complaints will be managed on an informal basis in the first instance. This is intended to provide the complainant with a quick, amicably and satisfactory resolution.

3.12 Patient safety Investigation:
The primary aim of a good quality patient safety incident investigation is to accurately and thoroughly identify what happened (problems arising) and why (contributory and causal factors); and recommend strong/effective systems-based improvements to prevent or significantly reduce the risk of a repeat incident.

Standards for PSII that align with the PSIRP or National mandated investigation will follow the following principles:

Principles and Standards for systems-based patient safety Incident investigation (PSII)	
BOARD OVERSIGHT and GOVERNANCE	• An environment of just culture, learning and continuous improvement from patient safety incidents is encouraged by supporting and promoting these principles and standards. • Time and resources will be invested to support PSIIs and subsequent delivery of improvement actions. • Development of information governance agreements which allow patient safety information sharing between local organisations.
PROACTIVE PLANNING of each investigation	• All PSIIs are planned and have specified terms of reference (ToR) which align with national policy.
FOCUS ON QUALITY OVER QUANTITY	• The local PSIRP describes how PSIIs will be conducted on a range of incident severity outcomes, selected on the basis of risk and learning potential (following intelligence gathering and triangulation of safety data/metrics and links to the Learning from Deaths programme). • The local PSIRP identifies the top 3–10 patient safety incident areas of concern – using past reported data and selected based on level of risk and learning potential – and sets out plans to pool findings from 5–10 full, good quality investigations into incidents arising in each category. • The local PSIRP includes the use of other more appropriate methods of managing incident reports than investigation. (see 3.15)
TIMELY and RESPONSIVE	• The local PSIRP describes the timescale for the start of PSIIs and for their completion. The aim is that PSIIs start as soon as possible after the incident is identified. PSIIs should be completed within 60 days, in consultation with the patient/family. No local PSII should take longer than 6 months.
RESOURCED	• All PSIIs are led, chaired or overseen by those with seniority equivalent to Band 8a or above. All PSIIs are led or chaired only by those with at least two days' formal training and skills development in a 'systems approach' to PSII.

	• PSII teams have access to administration, communications and legal support. • Clinical subject matter experts that have relevant knowledge and skills and are involved throughout PSIIs to provide clinical review, advice and proofreading.
SYSTEMIC,DEEP-SEATED, INTERCONNECTED, CAUSAL FACTORS identified and acted on to sustainably prevent or measurably reduce recurrence	• PSIIs are conducted for the sole purpose of learning and identifying improvements which prevent or significantly reduce recurrence. • PSIIs are conducted entirely separately from investigations that seek to determine avoidability/ preventability/ predictability; legal liability; blame; professional conduct/ competence/ fitness to practise; criminality; or cause of death.
FAIR and JUST	• Where investigators believe that an individual professional may be subject to criticism following a patient safety incident, the professional will be referred to HR for individual management/ performance review with reference to the "A just culture guide". • Unfair blame is avoided. • Referral for individual management/performance review or disciplinary action is only appropriate for acts of wilful harm or wilful neglect. • Bias and discrimination are avoided for staff with different protected characteristics (eg BAME groups) that have traditionally faced disproportionate disciplinary actions.
PATIENTS/FAMILIES/CARERS are ACTIVE and SUPPORTED PARTICIPANTS	• IF A PSII IS TO BE CONDUCTED, THEN PATIENTS/FAMILIES/CARERS ARE: • Given the opportunity to receive information at the outset on whether there will be a PSII and what to expect from the process. • Given the opportunity to receive local support throughout a PSII to aid recovery (including that enabling meaningful understanding of what happened; agreement on ToR; and discussion of final findings, clinical issues and contributory/causal factors identified). • Given the opportunity to review the PSII report with a member of the investigation team while it is still in draft.
TRUSTWORTHY	• Our investigations will Use the widest range of sources and viewpoints (patient/family/carer testimony – verbal and written; staff testimony – verbal and written; documents; medical records; site visit; other agencies, etc.). • And Involve SITE VISITS conducted to gather and preserve information and evidence. • And Involve RESEARCH of POLICY to identify and reference national and local good practice guidance and protocols to determine what was expected to happen (work as imagined). •And Involve OBSERVATION of PRACTICE to determine what normally happens (work as done).
ADEPT – conducted by investigation teams with deep knowledge of safety investigation, human factors, improvement science,5 health policy and clinical practice to command the confidence of patients/families/carers, the public and staff	• Incident findings will be made using established approach/techniques consistent with systems-based safety investigation. • Investigators will use GUIDANCE (national and local) to identify whether these adequately cover the issues encountered in the incident and investigation. • Findings and recommendations will be based (wherever available) on analysis from more than one example of very similar (narrow focus) incidents wherever available.

	• And will be designed to be strong/effective (apply improvement science principles to measurably and sustainably reduce or prevent recurrence of identified risks and/or incidents). • Finding are written in a way that professionally and effectively communicates the findings of a PSII. • The national investigation report template is used, unadapted, to document every PSII (for quality assurance and shared learning purposes). • Reports are written succinctly in plain English. • Each PSII has a single report which can be shared in full (unadapted and unredacted). • All specialist vocabulary, acronyms and abbreviations are explained in the report or in a glossary or footnotes. • An executive summary sets out the main issues, findings and conclusions/recommendations. • A summary incident chronology/timeline is included in the report to illuminate key points; where the full chronology/timeline is included it is attached as an appendix. • Reports provide clear reasons for any missing information or information not made available to the reader. • Specific questions from the patient/family/carer set out in the ToR are answered and where this was not possible, the reason is explained in the report. • The report is clear about where available information was limited and identifies consequent uncertainties. • Incidental findings that affect quality of care but lie outside the ToR for the PSII are documented and referred to appropriately.

3.13 Systems Engineering Initiative for Patient Safety (SEIPS) 2

SEIPS is a framework for understanding outcomes within complex socio-technical systems. Patient safety incidents result from multiple interactions between work system factors. SEIPS prompts us to look for interactions rather than simple linear cause and effect relationships. When a learning response thoroughly examines the different work system components and their interactions safety actions can focus on wider system issues, not individuals.

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3.14 Incident Learning Responses:

The nature, severity and complexity of incidents vary on a case by case basis and therefore the level of response should be dependent on, and proportionate to the circumstances of each specific incident. The Patient Safety Incident, Review and Learning Group and ultimately the Chief Medical Officer / Chief Nursing Officer will use the information obtained from Datix and the Patient Safety Rapid Response (fact finding) to decide the level of investigation based on the Patient Safety Incident Response Plan. (PSIRP). In all cases where it is determined that a PSII will be conducted and a roundtable is to be implemented, the CNO (if not in attendance at the PSIRG meeting) MUST be made aware of the details of the roundtable at the earliest opportunity.

3.15 Initial (Rapid Review):

An organisational tool to record incident description, find initial facts and immediate actions taken to provide an initial summary of the incident. If following the completion of an initial review i.e. Rapid review or an after action review and or if the incident meets the criteria for a Patient Safety Incident Learning Response or the incident falls within the prescribed National reporting requirements, the incident will be presented for discussion at the next PSIRG. As per the flow chart (appendix)

3.16 External Agency
Some classes of incident, complaints or near misses must be reported to external agencies who may carry out their own investigation.
External agencies include:

- ICS
- Health & Safety Executive
- The Police, HM Coroner
- The Care Quality Commission
- Public Health England
- MHRA
- NHS Improvement
- NHS England
- NHS Resolution
- Information Commissioner's Office.

3.17 Memorandum of Understanding:
A protocol for liaison and effective communication between the NHS, Association of Chief Police Officers and the HSE to be followed when investigating incidents involving unexpected death or serious untoward harm.

3.18 Duty of Candour:
The Duty of Candour is a legal duty on hospital, community and mental health trusts to inform and apologise to patients if there have been mistakes in their care that have led to moderate or above harm. This should be done verbally followed with a letter within 10 days.

3.19 Datix
Risk Management software utilised by the Trust to record and manage all incidents and complaints.

3.20 DIF 1 (Datix Incident form 1)
This is the electronic form on which incidents are reported.

3.21 DIF 2 (Datix Incident form 2)
This is the electronic form on which incident investigations are recorded and to which evidence and other documents can be attached.

4. Responsibility and Duties

4.1 All Staff
All staff, including agency and contracted staff are required to report incidents, accidents and near misses to the senior member of staff on duty within their ward or department and record the event using Datix.

WHERE DEATH OR SERIOUS INJURY OCCURS AS A RESULT OF AN INCIDENT OR THERE IS A SIGNIFICANT IMPACT ON THE DELIVERY OF SERVICES, THIS MUST BE REPORTED IMMEDIATELY TO A SENIOR MEMBER OF STAFF AND THE PATIENT

SAFETY TEAM / HEALTH AND SAFETY MANAGER (IN HOURS) OR SENIOR MANAGER ON-CALL (OUT OF HOURS)

All staff, including contract and agency staff have a duty to assist fully with an investigation in relation to an incident, accident or near miss and will respond to any request from the Lead Investigator, for information or assistance, in a timely manner and attend meetings as required to assist with the investigation.

4.2 Department / Ward managers

The ward/ department manager has responsibility for ensuring that the processes described in this policy are implemented within their own area of responsibility. This will include:

- Actively promote and train staff in the reporting of all incidents and near misses.
- Review Patient safety incidents for their area of responsibility and monitor the quality of learning response reports received.
- Ensure that all necessary immediate action has been taken including quarantine of any equipment involved.
- Ensure escalation of Patient Safety Incidents to the PSIRG as necessary.
- Ensure lessons are fed back to staff.

4.3 Divisional Quality Governance Teams / Facilitators

- Support teams with the Patient Safety Incident response process.
- Provide reports to Divisional Committees and assist wards /departments / directorates to collate reports.
- Monitor incidents reported via Datix for the division and ensure they are correctly coded and appropriately responded to within the set KPI.
- Monitor and track evidence to support actions assigned to the division from incident learning
- Support the DMT to have oversight of learning / themes and trends arising in the division

4.4 Directorate Managers / Matrons / Clinical Directors

Directorate Managers, Matrons and Clinical Directors will ensure that their Directorates have processes in place and individuals identified to undertake a co-ordinating role in order to:

- Review incidents and seek further information if required.
- Review actions taken in response to the event (to ensure that they are suitable and appropriate).
- Report Patient safety incidents to Directorate Management / Clinical Governance meetings.
- Give final approval to incidents in order to achieve closure.
- Ensure risk assessments related to the incidents are updated or created as necessary following appropriate learning response.

4.5 Divisional Management Teams

(Divisional Director of Operations / Divisional Medical Director / Divisional Head of Nursing)

- Ensure effective implementation of this policy within their division.
- Identify a lead investigator for any necessary patient safety investigation (PSI): Rapid Review or Internal Comprehensive Review (ICR) or after action review (AAR) within 1 working day of request.
- Ensure notification of Divisional PS ICR to relevant staff and stakeholders.
- Ensure that actions identified are completed in a timely manner.
- Ensure that directorates are complying with this policy and the reporting processes.

- Participate in weekly Divisional Patient Safety Incident Review and Learning meetings to review each PSI report and agree which require escalation to the Trust Patient Safety Incident Review and Learning Group (PSIRG).
- Ensure that action plans generated from incidents within the Division are followed through to completion.

4.6 Patient Safety Team

Provide the systems and training to support incident recognition, reporting and Learning responses.

- Train staff in the use of Datix and other tools to support risk and patient safety management.
- Monitor incidents and raise any potential PSII with Divisions and the Patient Safety Incident Review and Learning Group where these have not been raised by a Division and undertake further enquiries as required.
- Once an incident has been confirmed as requiring a PSII, the Patient Safety Team will notify relevant staff both internally and externally.
- Support and facilitate the completion of PSII from within the PST
- Liaise with the DCMO and the legal team to ensure adequate information is available for upcoming inquests that identify areas for learning from patient safety events.
- Liaise with the legal team to ensure learning from claims that have arisen from patient safety events.
- Liaise with the complaints team / claims and PALS teams to ensure triangulation of themes and trends arising from patient safety incidents.
- Quality control data and sample the completeness and accuracy of incidents reported.
- Export data as required to the Learn from Patient Safety Incidents (LFPSE) system.
- Notification of incidents in accordance with CQC requirements in regulations 16, 17 & 18 of the CQC (registration) regulations 2009.
- The Patient Safety Team will liaise with the Health & Safety Manager to monitor the incident reporting process and ensure that the wider context of risk or any trends apparent from separate incidents are brought to the attention of senior managers and /or committees for review.
- Monitor the incident reporting process and report trends to the Clinical Governance Group (CGG) or Health & Safety Committee or Risk Management Group.
- Feed into other committees and meeting (e.g. D.R.E.A.M.S. / nutrition & hydration) where there is learning, themes or trends arising from patient safety incidents.

4.7 Medicines Safety Officer (MSO)

- Promote the safe use of medicines across their organisations and be the main expert in this area.
- In addition to improving the quality of reporting, the MSO will serve as the essential link between the identification and implementation of (local and national) medication safety initiatives and the daily operations to improve patient safety with the use of medicines.

4.8 Participants in the Senior Managers / Executive Director on call rota

- Senior Managers - receive reports of Patient safety incidents outside normal working hours, review incident and inform PST the next working day for it to be managed as per process. No reporting of a PSII outside of normal hours is required. If there is a patient safety risk, then this should be managed accordingly.
- Executive Director - determines whether incidents reported to them requires any immediate intervention to provide support to the staff or / and to ensure patient safety.

- The Patient Safety Team will pick this up the next working day.

4.9 Executive Directors

- To have overall responsibility for the provision of adequate systems for reporting and managing incidents, accidents and near miss events.
- To inform and involve external agencies in the investigation of adverse events as required

4.10 Committees and Meetings

Quality Governance Committee (QGC)

- Receive assurance regarding PSII report findings and analysis.
- The Chair will report on an exception basis any matters relating to incident reporting, including Never Events to the Trust Board.

Improving Safety Actions Group (ISAG)

- Receive reports on the management of PSII and outcomes and learning.
- Receive analysis of Patient Safety incidents four times per year to include trends.
- Provide monthly reports to the QGC.

Divisional Quality Committees / Management Committees

- Monitor and manage compliance with this policy within the Divisions
- To review information regarding reported incidents.
- Manage the Learning response process and actions to support learning from incidents

Directorate Clinical Governance and/ or Management Meetings

- Review the incidents reported within the directorate, including analysis, and ensure the requirements of this policy are implemented within the Directorate.
- Discuss the trends in Patient Safety incident reporting with in the division
- Discuss completed Learning responses and monitor action plans

Patient Safety Incident Review and Learning Group (PSIRG)

- Review and provide final 'sign off' for PSII and discuss and agree newly presented ICRs.
- Report concerns and analysis to the CGG for consideration and action.

Divisional Quality Governance meetings

- Review all Learning responses to determine which require escalation to the Trust PSIRG.
- Review progress with actions and provide support if the team require it.

Trust Infection Prevention and Control Committee (TIPCC)

- To review incidents related to infection control
- Sign off Healthcare Associated Infections (HCAI) reviews.

Health & Safety Committee

- To review incidents related to health and safety.

Medicines Optimisation Committee

- Support the safe use of medicines in the organisation
- Improving reporting and learning of medication error incidents in the organisation;
- Analysing incident data, audit and other data to identify, prioritise and address medication risks to minimise harm to patients;

- Coordinating education and training support to improve the quality of medication error incident reports and safe medication practices;

Further details can be found in each meeting's Terms of Reference

5. Incident Reporting Process

5.1 Recognising an Incident

The reporting process begins with the recognition that a Patient Safety Incident has occurred. This can include any error or omission regarding patient care, falls, staff injury, fire, infection control, security incidents.
For further details, refer to:

- Reportable Work Related Incidents and III-health and events which must be reported to the Health and Safety Executive. (Appendix 2)
- Duty of Candour (Appendix 5)

Most incidents are recognised and recorded immediately. Others may take time to come to light. These must be reported as soon as they are recognised, following the procedure described below.

Incident reporting database reports directly to LFPSE and has an additional question relating to any psychological harm – there is a matrix for this on the Datix home page

5.2 Incident Management

Incidents are responded to in proportion to the level of learning that can be gained. (Appendix 5).

Immediate Action

The immediate safety or well-being of the patient, staff member, or visitor affected or involved in an incident is paramount. Any remedial first aid or emergency treatment must be given and in the event of patient safety incidents, the patient's medical team must be informed.
The member of staff in charge of an area or the on-call manager is responsible for ensuring that appropriate action has been taken to make the area safe following any incident and that the incident is reported at the earliest opportunity.
Any equipment involved in the accident / incident must be made safe and retained for the purposes of any further investigation
Help and advice is available from the Patient Safety Team.

5.3 Major Incidents

Where the incident involves several patients or staff, then a helpline will be implemented. This is to ensure that resources are available to deal with multiple enquires from patients / relatives, every effort must be made to inform patients and/or relatives before the media and media communications are managed effectively.

Helpline Arrangements / Multiple Enquiries

The Executive Team with support from Communications and Estates will be responsible for establishing a Helpline for receipt of telephone enquiries from members of the public, where deemed necessary. This will include the provision of extra phone lines and staff to deal with the expected telephone calls. Records will be kept of the received calls and the advice given.

5.4 Reporting Incidents

The Incident Reporting Record and process is in two parts:

The Datix Incident Reporting Form (DIF1) is to be completed electronically via the intranet, as soon as possible after the event occurs (when safe to do so) or **immediately** a member of staff becomes aware that an event has occurred, ideally by the member of staff who first becomes aware of the event. The Trust's standard is to report within one day of the incident occurring. Only known facts are to be recorded – not opinions.

Where the member of staff is unable to complete the incident reporting form, then the manager or senior person in charge is required to complete the form on their behalf.

Completing the Trusts' Incident Reporting Form does not constitute an admission of legal liability by any person.

Staff are required to put an initial grading of the level of physical and psychological harm which has resulted from the incident based on the information available to them at the time. This may be re-graded as more information becomes available. The level of harm is taken from the LFPSE guidance and can be found in Appendix 5.

Where staff feel they have serious concerns about patient or staff safety which cannot be raised through the incident reporting process, the Public Interest Disclosure (Whistleblowing) Policy provides guidance on the process and who to contact in confidence. These details are also available within the Datix pages on the Trust intranet. Alternatively, there is the Freedom to Speak Up portal which provides a platform to raise concerns anonymously in a safe and supportive environment.

Datix Investigation Form (DIF2*)*

The Incident Investigation Form is completed by the person(s) with delegated responsibility for incident and near miss investigation within the ward / department. Appropriate action will be taken at the time and the incident escalated, dependent on its severity.

In addition to this, an incident within a Cancer Screening Programme will be managed in accordance with the guidance for this programme (see Appendix 5).

5.5 Receipt of the Incident Report by the Patient Safety Team

All incidents which are reported as resulting in severe harm or death will generate an automated email to the Patient Safety Team and other designated staff. These will be reviewed the same day (within office hours) or the following working day if reported out of office hours. Further information will be requested to determine the severity / consequence of the incident.

All incidents reported will be reviewed (by divisions) within three working days of receipt and moved / allocated from the 'holding area' on Datix. With oversight from the PST.

All incidents should be reviewed and actioned (Datix updated / closed) within 20 working days (except for those requiring further investigation). Progress and updates should be kept on the Datix Notepad.

All patient safety incidents are reported (uploaded directly) to the LFPSE but does not include any personal identifying details of staff, patients, visitors or contractors.

Other external parties that need to be informed will also be identified by the Patient Safety Team / Executive directors at this stage and informed, if they have not been informed previously.

The Health & Safety Manager will ensure that the Health & Safety Executive (HSE) are informed of any incidents in compliance with RIDDOR and inform the Director responsible for health and safety and the relevant Directorate Manager of any incidents which are serious or where public concern may ensue.

5.6 Non Clinical Incidents

Where the incident results in death, is a major incident or a dangerous occurrence, **immediately** report the incident to the Health & Safety Manager. Outside normal office hours, the ward/ department managers must **immediately** inform the on-call Manager who will inform the on-call Executive Director. The on-call Executive Director must inform the HSE by calling the incident contact centre and the Health & Safety Manager is to be notified as soon as possible thereafter.

For emergency situations the Health & Safety Manager is available for advice out of hours via switchboard.

Where absence from work for staff was not anticipated when the event was reported, but which subsequently occurs, the Health & Safety Manager is to be informed if the absence exceeds 7 consecutive days (RIDDOR reportable).

Staff sustaining a needle stick injury must report the incident on Datix and contact the Occupational Health Department (during office hours) or the Accident & Emergency Department (out of hours) as soon as possible. See Needle Stick Policy and Infection Control Manual Section D Protocol 2 – Inoculation Injury Protocol.

For details of incidents which must be reported to the HSE, refer to appendix 2.

When an incident has occurred, any risk assessment associated with the incident must be reviewed and amended where necessary and staff informed of changes.

5.7 Patient Safety Incidents

For events directly affecting patients, staff are required to complete the clinical records with details of the incident. These entries are to be made in line with good record keeping practice and written as soon after an event has occurred. The incident form does **not** form part of the health care records and therefore should not be copied and placed within them.
If an injury is detected following submission of the incident form, the Patient Safety Team must be notified immediately and the Datix record updated.

5.8 Incidents in NHS Screening Programmes

(Breast, Bowel Cervical and AAA Screening)

An incident within a NHS Screening Programme will be reported, investigated and managed in accordance with both Trust and National NHS Screening Guidance for Managing Safety Incidents in NHS Screening Programmes
https://www.gov.uk/government/publications/managing-safety-incidents-in-nhs-screening-programmes.

5.9 Informing the Patients and/or Relatives

When things go wrong, patients and their families expect an apology and to be communicated with in an open and honest manner as soon as possible following a Patient Safety incident or event. It may be that all the facts are not known about the incident and this should also be communicated.

Being open about what happened and discussing incidents promptly, fully and compassionately can help patients, and staff, cope better with the after effects and can prevent such events becoming formal complaints and litigation claims.

Incidents graded as moderate or above (significant harm) will follow statutory Duty of Candour requirements (see **Being Open (Duty of Candour) Policy**) including apology given must be clearly documented in the patient notes. The apology must be followed with a letter confirming discussion and the name of a Trust contact provided.

If it is likely that the media will become aware of the incident, it is essential that the patient and/or the patient's next of kin be informed in advance of the media. On occasions, particularly where many patients have been involved or the incident has come to light some months later, it may not always be possible to inform the patient in advance of the media although every effort to do so should be made and recorded. Members of staff involved in the incident/care of the patient will be informed in advance of any media involvement. The Chief Medical Officer and the Chief Nursing Officer will identify the appropriate person for informing staff members.

In some cases, it may be necessary to appoint a Family Liaison Officer. He/she will be appointed by the Chief Nursing Officer (or other Executive). It is their role to keep the patient/ family/ member of staff informed of progress at all stages of the investigation.

5.10 Timescales
Incidents should be reported as soon as reasonably practicable/ within one day of staff being aware of the occurrence.

5.11 Record Keeping About the Incident
Contemporaneous records of the event must be maintained i.e. records must be created at the time of the event and at the time decisions are made or actions taken to treat the patient. The most appropriate place for this is the 'notepad' function of Datix. Notepad is where informal notes can be recorded, not strictly part of the official investigation, but for tracking & memo purposes.

It is the responsibility of the clinical staff and managers involved to ensure that:

- Records are made of the decisions made, when, why and who made them and exactly what was decided
- Records are factual, consistent, accurate and written as soon as possible after the event has occurred.
- Datix Incident Record Form is completed
- The security of all records relating to the incident is maintained.
- That medical records are photocopied for the purpose of the investigation if they are required for on-going treatment.

5.12 Keeping Individuals and Agencies Informed
The Patient Safety Team and the Health & Safety Manager will ensure that relevant senior staff / stakeholders are informed of PSII and ICRs as required (Refer to Appendix 6 for list of stakeholders).

The following staff and stakeholders will receive notification of a PSII or ICR from the Patient Safety Team including:

- Executive Directors
- Divisional Management Team
- Clinical Director
- Directorate Manager

- Matron
- Consultant (if applicable)
- Ward / Department Manager (if applicable)
- Head of Clinical Governance

Media Relations
If required, the Director of Communications will be briefed by the Chief Nursing Officer and/or the Chief Medical Officer and will be responsible for the preparation of a "press brief" following agreement with the Chief Executive.
The Director of Communications will advise and support on internal and external communications.

6. Implementation of Key Documents

6.1 Plan for Implementation
This policy is already implemented. Changes made in this version will be implemented by the managerial staff who will be made aware of these through the dissemination process.

6.2 Dissemination
The Patient Safety Incident Reporting Policy will be made available on the Trust Intranet.
A bulletin board notice and Trust wide email will be used to announce the revision.
Key managerial and clinical staff will be e-mailed details of changes to the policy.

6.3 Training and Awareness
Training will be provided as set out in the Trust's Training Needs Analysis.
Access to Datix and incident reporting is discussed at induction and training sessions for new Datix users.

Roles and responsibilities are emphasised during training to ensure that all staff are aware of the role they play in Duty of Candour.

7. Monitoring and Compliance
The effectiveness of this policy will be assessed on a continual basis by the Patient Safety Team and the Health & Safety Manager. Monitoring reports are described below.

- The Divisions review all Patient Safety incident reports for accuracy and completeness
- The Patient Safety Team / Health & Safety Manager quality assure for accuracy and completeness. Anomalies are followed up with the staff reporting incidents or their managers.

Monitoring of the incident reporting process is included in reports to Trust Committees to enable them to monitor compliance with the policy.

- A review of patient safety incidents is undertaken four times a year and presented to the Clinical Governance Group (CGG). The Quality Governance Committee receives assurance from the CGG on behalf of the Board. The report includes monitoring of the number of incidents reported, type and location with analysis and breakdown to demonstrate trends and hot spots.
- Weekly data on incidents awaiting review in the holding area and incidents remaining open after 20 working days is produced as a key performance indicator and included in the monthly Divisional Quality Dashboard and weekly SitRep.

- Twice yearly the Patient Safety Team monitors the timeliness of reporting within 24 hours of an incident.
- A review of all non-clinical Incidents is undertaken and presented to the Trust H&S Committee four times a year. An annual H&S report is provided for the Board summarising the events of the year.
- This information is used in the annual Quality Account report.

Whistle blowing events will be reviewed on an individual basis as they arise.
The Chief Nursing Officer in conjunction with the Associate Director of Clinical Governance and Risk and the Executive Team will take action to improve the incident reporting process should the monitoring described above identify deficiencies.

In addition to local reporting, the Trust participates in national reporting via the Learn from Patient Safety Events (LFPSE) system.

8. Policy Review

This policy will be reviewed 1 year following approval.

9. References

Revised Never Events Policy and Framework, DH, March 2015
Managing Incidents in National NHS Screening Programmes UK National Screening Committee guidelines (October 2015)
Checklist Guidance for Reporting, Managing and Investigating Information Governance Serious Incidents Requiring Investigation (IG SIRI) May 2015
Never Events list 2018 First published January 2018 (last updated February 2021)
Caldicott Guardian Manual 2012 www.dh.gov.uk/publications
Department of Health (2000) An organisation with a memory, Stationary Office, London. ISBN 011 322441 9.
Department of Health (2001) Building a safer NHS for patients. www.doh.gov.uk/buildsafenhs.
NHSLA Risk Management Standards for Acute Trusts, 2013-14
ALARM/UCL (1999) Protocol for the analysis of clinical incidents.
7 Steps to Patient Safety – (2004) NPSA
Incident Decision Tree – NPSA - http://www.npsa.nhs.uk/health/resources/incident_decision_tree
National Framework for Reporting and Learning from Serious Incidents Requiring Investigation (NPSA 2010)
National Reporting and Learning System (NRLS) NHS Improvement
Memorandum of Understanding: Investigating Patient Safety Incidents involving unexpected death or serious untoward harm (2006)
Being Open - http://www.nrls.npsa.nhs.uk/resources/?entryid45=65077
NHS Counter Fraud & Security Management Service
Guidance for notifying the HTA of serious untoward incidents in the post mortem sector –May 2010
CQC - Essential Standards of Quality and Safety as contained within the Health & Social Care Act 2008 (Regulated Activities) Regulations 2010 & the CQC (Registration) Regulations 2014
NHS/PSA/D/2014/005 Stage Three: Directive - Improving medication error incident reporting and learning 2014
https://www.gov.uk/government/publications/managing-safety-incidents-in-nhs-screening-programmes.
August (2013) Independent report, Berwick review into patient safety Recommendations to improve patient safety in the NHS in England.
February (2013) Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry This document contains the following information: Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry.
August (2015) Transforming urgent and emergency care services in England Safer, faster, better: good practice in delivering urgent and emergency care: A guide for local health and social care communities

December (2020) Ockenden review of maternity services at Shrewsbury and Telford Hospital NHS Trust Emerging findings and recommendations from the independent review of maternity services at the Shrewsbury and Telford Hospital NHS Trust.
DoH (2019) The National Patient Safety Strategy
NHSE (2019) The Patient safety Incident Response Framework

Related Trust Documents .

Risk Management Strategy
Security Policy (WAHT-CG-034)
Being Open (Duty of candour)
Complaints and PALS Policy
Supporting Staff involved in Traumatic / Stressful Incidents, Complaints & Claims (WAHT-HR-002)
Health and Safety Policy
COSHH Policy
Medical Devices Policy
Obstetric Risk Management Strategy
Risk Register (Datix)
Public Interest Disclosure (Whistle blowing) Policy
Disciplinary Policy
SUDIC –Investigations of sudden & unexpected deaths in children under 18 years
Infection Control Manual Inoculation Injury Protocol

10. Background

10.1 Consultation

Key individuals involved in incident reporting have been consulted during the development of this policy. These include the Divisional Management Teams, Divisional Quality Governance Committees, members of the Serious Incident & Learning Group, Members of the Clinical Governance Group, Medicines Safety Officer and Health & Safety Manager

10.2 Equality requirements

The content of this policy has no adverse impact on equality and diversity. A copy of the completed equality assessment form can be found in supporting document 1.

10.3 Financial risk assessment

This policy has no adverse financial impact. The assessment is found in supporting document 2.

Appendix 1

Reportable (non-clinical) Work-Related Accidents and Ill-Health

1 The following incidents are reportable to the Health and Safety Executive under Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995: -

- Death
- Any specified injury (see below)
- A person not at work suffers an injury/major injury as a result of an accident arising out of or in conjunction with work and is taken to hospital for treatment in respect of that injury
- Any Dangerous occurrence (see below).
- An 'over 7 days' injury which applies to a person who is incapacitated from work of any kind which they may be expected to do, for more than seven consecutive working days (excluding the day of the injury but includes weekends and rest days)

2 **Any of the outcomes above** must be reported immediately to the appropriate manager and recorded as RIDDOR Reportable on the Datix Form. The Health & Safety Manager will then report the injury to the Health and Safety Executive at the earliest opportunity.

3 Where an employee, as a result of an accident at work, has suffered an injury and this results in his death within one year from the date of the accident, the Trust shall inform the Health and Safety Executive in writing of the death as soon as it comes to the Trust's knowledge, whether or not it was previously reported.

4 Where an employee contracts an occupational disease attributable to work and a Doctor's written diagnosis is received, this will be reported to the HSE by the Occupational Health Department. Occupational asthma, occupational dermatitis, Infectious diseases, blood disorders and repetitive strain injury, all are reportable. Deaths or injuries which arise from medical treatment or examinations carried out by a registered medical practitioner or registered dentist are not reportable under the RIDDOR Regulations. Occupational diseases identified during health surveillance are not reportable either.

5 The following specified injuries must be reported:

- fractures, other than to fingers, thumbs and toes
- amputations
- any injury likely to lead to permanent loss of sight or reduction in sight
- any crush injury to the head or torso causing damage to the brain or internal organs
- serious burns (including scalding) which:
  - covers more than 10% of the body
  - causes significant damage to the eyes, respiratory system or other vital organs
- any scalping requiring hospital treatment
- any loss of consciousness caused by head injury or asphyxia
- any other injury arising from working in an enclosed space which:
  - leads to hypothermia or heat-induced illness
  - requires resuscitation or admittance to hospital for more than 24 hours

6 Dangerous occurrences include incidents involving the collapse or overturning of lifting machinery (or the failure of any load-bearing part), the failure of pressure systems, electric short circuits or overloads which result in the stoppage of plant for more than 24 hours, incidents involving explosives, release or escape of biological agents, malfunctioning of radiation generators, malfunctioning of breathing apparatus while in

use or being tested prior to use, the collapse of scaffolding, the collapse of a building or structure, an explosion or fire, the escape of flammable substances, and the escape of any substance likely to cause injury, death or any other damage to the health of any person.

7 The following diseases will be reported by the Occupational Health Department to the Health & Safety Executive: -

- Repetitive Strain Injury i.e. carpel tunnel syndrome relating to prolonged periods of writing, typing, repetitive movements of hands/fingers or arms.
- Inflammation, ulceration, malignant disease, blood dyscarasia due to ionising radiation
- Infections due to biological agents, i.e.: - Hepatitis A/B/C, Tuberculosis, Tetanus, Legionella, HIV/AIDS and any infection that can be reliably attributable to specific work with micro-organisms i.e. work with live or dead human beings involving exposure to blood and body fluids. NB diarrhoea, cold bronchitis cannot usually be attributed to work activity and is not reportable however if there is circumstantial evidence i.e. infectious agent in Laboratory work a report should be made.
- Occupational Asthma relating to Glutaraldehyde and Latex.
- Occupational Dermatitis relating to Glutaraldehyde and Latex, antibiotics and other Pharmaceutical products, biocides anti bacteria's, preservatives and disinfectants and Formaldehyde.

Appendix 2 Never Events

Never Events are a sub-set of Serious Incidents and are defined as serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented by healthcare providers.

Never Events may highlight potential weaknesses in how an organisation manages fundamental safety processes. Regardless of the outcome of an individual Never Event, they are always considered serious incidents as described in the Serious Incident Framework.

Further detail can be found in the Revised Never Events Policy and Framework (March 2015) https://www.england.nhs.uk/wp-content/uploads/2015/03/never-evnts-list-15-16.pdf

Never Event List 2018applicable to WAHT

1. **Wrong site surgery:** *An invasive procedure1 performed on the wrong patient or at the wrong site (eg wrong knee, eye, limb). The incident is detected at any time after the start of the procedure.*
2. **Wrong implant/prosthesis:** *Placement of an implant/prosthesis different from that specified in the procedural plan, either before or during the procedure. The incident is detected any time after the implant/prosthesis is placed in the patient.*
3. **Retained foreign object post-operation:** *Retention of a foreign object in a patient after a surgical/invasive procedure.*
4. **Mis-selection of a strong potassium-containing solution:** *when a patient is intravenously given a strong3 potassium solution rather than the intended medication.*
5. **Wrong route administration of medication (IV chemotherapy via intrathecal route, oral/enteral medication or feed/flush by a parenteral route, IV medicine via epidural route):** *The patient is given one of the following: • intravenous chemotherapy by the intrathecal route • oral/enteral medication or feed/flush by any parenteral route • intravenous administration of an epidural medication that was not intended to be administered by the intravenous route**
6. **Overdose of Insulin due to abbreviations or incorrect device:** *Overdose refers to when: • a patient is given a 10-fold or greater overdose of insulin because the words 'unit' or 'international units' are abbreviated; such an overdose was given in a care setting with an electronic prescribing system4 • a healthcare professional fails to use a specific insulin administration device – that is, an insulin syringe or pen is not used to measure the insulin • a healthcare professional withdraws insulin from an insulin pen or pen refill and then administers this using a syringe and needle.*
7. **Overdose of methotrexate for non-cancer treatment:** *Overdose refers to when: • a patient is given a dose of methotrexate, by any route, for non-cancer treatment that is more than the intended weekly dose; such an overdose was given in a care setting with an electronic prescribing system3 (see footnote 3 on previous page).*
8. **Mis-selection of high strength midazolam during conscious sedation:** *Mis-selection refers to when: • a patient is given an overdose of midazolam due to the selection of a high strength preparation (5 mg/mL or 2 mg/mL) instead of the 1 mg/mL preparation, in a clinical area performing conscious sedation • excludes clinical areas where the use of high strength midazolam is appropriate; these are generally only those performing general anaesthesia, intensive care, palliative care, or areas where its use has been formally risk-assessed in the organisation.*
10. **Failure to install functional collapsible shower or curtain rails:** *Involves either: • failure of collapsible curtain or shower rails to collapse when an inpatient attempts or completes a suicide • failure to install collapsible rails and an inpatient attempts or completes a suicide using non-collapsible rails*
11. **Falls from poorly restricted windows:** *A patient falling from a poorly restricted window. 5 This applies to:* *• windows 'within reach' of patients; this means windows (including the window sills) that are within reach of someone standing at floor level and that can be exited/fallen from without needing to move furniture or use tools to climb out of the window* *• windows located in facilities/areas where healthcare is provided and that patients can and do access* *• where patients deliberately or accidentally fall from a window where a fitted restrictor is damaged or disabled, but not where a patient deliberately disables a restrictor or breaks the window immediately before they fall* *• where patients can deliberately overcome a window restrictor using their hands or commonly available flat-bladed instruments as well as the 'key' provided.*

11. **Chest or neck entrapment in bedrails:** *Entrapment of a patient's chest or neck between bedrails or in the bedframe or mattress, where the bedrail dimensions or the combined bedrail, bedframe and mattress dimensions do not comply with Medicines and Healthcare products Regulatory Agency (MHRA) guidance.*
12. **Transfusion or transplantation of ABO-incompatible blood components or organs:** *Unintentional transfusion of ABO-incompatible blood components. Excludes:* • *where ABO-incompatible blood components are deliberately transfused with appropriate management. Unintentional ABO-mismatched solid organ transplantation. Excludes:* • *situations in which clinically appropriate ABO-incompatible solid organs are deliberately transplanted.*
13. **Misplaced naso or oro-gastric tubes:** *Misplacement of a naso- or oro-gastric tube in the pleura or respiratory tract that is not detected before starting a feed, flush or medication administration*
14. **Scalding of patients:** *Patient scalded by water used for washing/bathing.*

Appendix 3

Incident Grading Duty of Candour

The **Duty of Candour** applies to any incident causing **SIGNIFICANT HARM** i.e. **Moderate, Severe or Death**.			**Duty of Candour applies?**
No Harm		• Incident prevented / near miss. • Incident not prevented but no harm was caused	**No**
Minor Harm		**Any patient safety incident that required extra observation or minor treatment and cased minimal harm to one or more patients** • e.g. first aid, additional therapy or additional medication **It does not include:** • any extra stay in hospital or any extra time as an outpatient, or continued treatment over and above the treatment already planned; • nor does it include a return to surgery or readmission.	**No**, but provide a verbal apology
Significant Harm	**Moderate Harm**	**Any patient safety incident that resulted in a moderate increase in treatment and that caused significant but not permanent harm to one or more patients** Moderate increase in treatment is defined as • a return to surgery, • an unplanned readmission, • a prolonged • episode of care, • extra time in hospital or as an outpatient, • cancelling of treatment, or • transfer to another area such as intensive care **as a result of the incident.**	**YES** **Duty of Candour applies** **Implement Being Open process**
	Severe Harm	**Any patient safety incident that appears to have resulted in permanent harm to one or more patients** Permanent harm directly related to the incident and not related to the natural course of the patient's illness or underlying condition is defined as: • permanent lessening of bodily functions, sensory, motor, physiological or intellectual, including removal of the wrong limb or organ, or brain damage.	
	Death	Any patient safety incident that directly resulted in the death of one or more patients • The death must be related to the incident rather than to the natural course of the patient's illness or underlying condition.	

Being Open Process – Significant Harm

STAGE 1	**Incident detection or recognition** 1. The first priority is prompt and appropriate clinical care and the prevention of further harm 2. Complete an incident form in Datix
STAGE 2	**Preliminary Team Discussion:** 1. Appoint a member of staff (experienced and with expertise) to lead on communication with the patient or service user/carer – usually the most senior clinician with responsibility for the patient's care 2. Establish which other staff members should attend. 3. Establish a time line. 4. Establish the aims of the meeting. 5. Offer support and counselling for staff involved if required.
STAGE 3	**The Initial Discussion** Within 10 working days of the incident: 1. Establish how to contact patient or service user/carer. 2. Verbally inform the patient, provide an apology and follow-up in writing 3. Agree venue and time for a meeting with patient or service user/carer. Meeting: 4. Introduce everyone in the meeting, including what their roles are. 5. Provide factual details to date. 6. Offer practical and emotional support. 7. Provide contact details of who to contact if patient or service user/carer have further questions. 8. Identify and agree next steps.
STAGE 4	**Follow-up Discussions** 1. Keep patient or service user/carer informed of how the investigation is going 2. Consider keeping in touch on a regular basis with the service user/carer. 3. Respond to any queries as sufficiently as possible
STAGE 5	**Completing the Process** 1. Within 10 working days of the investigation being signed off as complete, a copy must be supplied to the patient / relative with an offer to meet to discuss it. 2. Consider the best way to provide the findings of the investigation to the patient 3. Provide: a repeated apology; a chronology of facts and findings of the investigation; a summary of contributing factors; what is, or will be done to avoid a recurrence 4. Arrangements for continuity of care where required should be agreed 5. Share the key findings / summary with all staff concerned 6. Make arrangements to monitor the plans 7. Share the learning with staff in the Trust
All discussion with the services user, their family and carers should be documented at all times by the key contact / senior clinician	

Appendix 4

Key Stakeholders Requiring Information on Selected Incidents

Worcestershire Clinical ICS

Worcestershire ICSs are to be informed of all PSII. Reporting will be undertaken by The Patient Safety Team or an Executive Director.
Quarterly Patient Safety Incident Statistic reports are also provided.

Health & Safety Executive

Under the Reporting of Injuries, diseases and Dangerous Occurrences Regulation 1995, (RIDDOR), the Trust has a legal duty to formally notify the Health & Safety Executive (HSE) with details of certain incidents that occur in the course of work activities. The type of incidents that could be reported is quite extensive, The Health & Safety Manager is responsible for ensuring that the Trust complies with the requirements of the regulations within the specified timescales. Requirements for reporting serious injuries and dangerous occurrences are **immediately** for death and major injury and **15 days** for over seven-day absence from work for staff injured in a work-related incident. It is therefore important that managers use appropriate means to notify The Health &, Safety Manager i.e. phone, fax or e-mail for all untoward incidents (whether actual or near miss).

Learn from Patient Safety Events (LFPSE)

All patient incidents, accidents and near miss events are reported to the LFPSE. Their function is to collect and analyse incidents and other patient safety information and provide timely and relevant feedback to healthcare organisations, professionals and patients/carers in a way that promotes learning and risk reduction through environmental and/or system changes, and/or changes in organisational, management or clinical practice.

NHS Resolution

NHS Resolution requires notification of any staff incident which may result in a potential claim as soon as possible. This will allow them to assess the incident and take pro-active steps to commence appropriate investigations. The Legal Services Department reports to the NHS Resolution on behalf of the Trust (refer to Claims Handling Policy for further detail).

When a significant litigation risk has been established and a realistic valuation of a possible claim has been made the matter becomes reportable to the NHS Resolution. There are four situations when this will occur (refer to Claims Handling Policy for further detail).

Medicines and Healthcare Products Regulatory Agency (MHRA)

The Trust is required to report adverse incidents that involve medical devices to the Medicines and Healthcare Products Regulatory Agency (MHRA). Where medical equipment is involved in an incident, and there has been or is the potential for harm to occur to the patient or the user of the equipment, the MHRA must be notified before any repairs/modifications are made to the medical device. Manufacturers are not allowed to inspect such equipment until permission has been granted by the MHRA. Where circumstances allow, medical devices are to be removed from the department and taken into the quarantine section of clinical engineering. If equipment cannot be moved due to size, fixtures etc. it must be clearly labelled and staff notified of the problem.

The Trust Health & Safety Manager is responsible for MHRA reporting, ensuring that efficient communication takes place between MHRA, manufacturers and Trust management and that all necessary actions are taken to ensure the safety of patients and staff.
For further details, please refer to the Medical Devices Policy (WAHT-CG-022).
For Adverse Drug Reactions, please follow MedPolSOP15, which includes details of the 'Yellow Card' Scheme. Further advice is available from the Medicines Information Service (Pharmacy Ext 30235) and the MHRA.

Public Health Laboratory Service

The reporting of adverse incidents relating to food is to be initially reported to the Infection Control Team. Such incidents are those relating to food supplied by the hospital whether this affects patients or staff. This will include special foods such as enteral food preparations and ready to feed preparations as well as normal patient service foods and foods supplied in the Trust restaurant facilities. Facilities/ISS will assist with any subsequent investigation relating to service provisions. The Patient Safety Team / Health &, Safety Manager will be notified of the incident and will liaise with the appropriate Trust Managers to ensure reporting to the appropriate external agency eg Public Health Laboratory Service. Incidents relating to the service delivery of foods etc. supplied by the Trust will be reported via the Incident Record form and investigated by Facilities/ISS and The Patient Safety Team / Health & Safety Manager as appropriate.

Serious Adverse Blood Reactions and events and Serious Hazards of transfusion

The transfusion laboratories are externally regulated by the MHRA (Medicines and Healthcare Products Regulatory Agency). As part of this regulation the trust is required to report any transfusion incident that may do the patient harm. There are two linked reporting sites. Entry to both sites is via the MHRA homepage. The MHRA reporting site for transfusion is, Serious Adverse Blood Reactions and Events (SABRE). SABRE focuses on any incident that occurs within the transfusion laboratory. All other clinical incidents that occur outside of the transfusion laboratory are reported to Serious Hazards of transfusion (SHOT). The Transfusion Practitioners are responsible for reporting transfusion incidents to SABRE and SHOT.

Worcestershire Safeguarding Children Board

In the event of an incident affecting/ or having the potentially to affect a child, consideration needs to be given to informing the W.S.C.B. This will be through the Named Children's Nurse and/or the Chief Nursing Officer.

Care Quality Commission

Certain incidents must be notified to the CQC in accordance with the Care Quality Commission (Registration) Regulations 2009. In most cases this requirement is met by the trust reporting incidents to NRLS/NPSA, from whom the CQC extracts the details it requires. In these cases, there is no requirement to report directly to the CQC.

From time to time the CQC makes changes to the types of incident it wishes to be notified of, and therefore this policy does not contain specific details. However operational processes will be amended, as necessary and appropriate, to ensure that the CQC notification requirements are met.

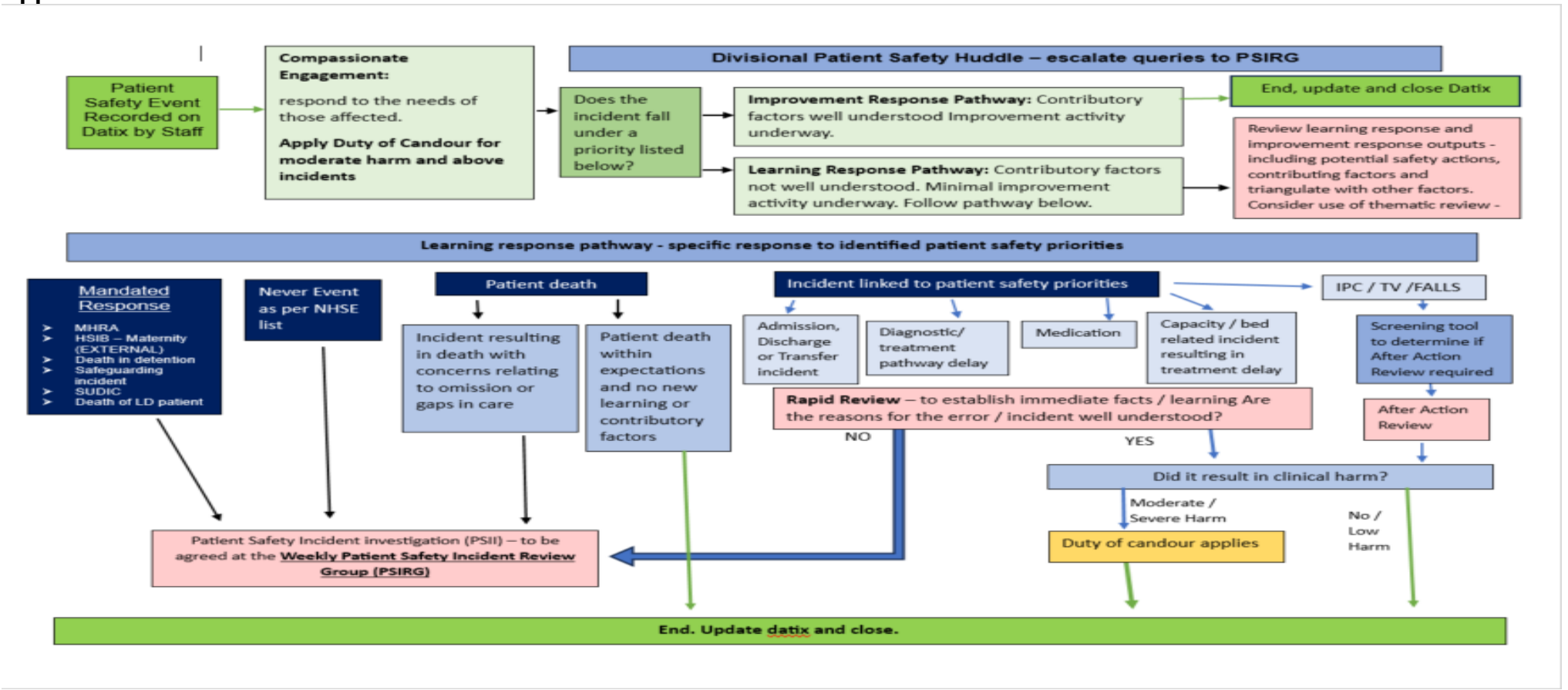
Human Tissue Authority

From May 2010, the HTA must be notified of all serious untoward incidents (SUI) that occur at establishments in the post mortem sector holding an HTA licence. Incidents that must be notified to the HTA are presented in Section 3 of the HTA Policy.

Information Commissioner

Information security incidents are reporting in accordance with the Health and Social Care Information Centre - Checklist Guidance for Reporting, Managing and Investigating Information Governance Serious Incidents Requiring Investigation

Appendix 5


Patient Safety Event Recorded on Datix by Staff
Compassionate Engagement:
respond to the needs of those affected.
Apply Duty of Candour for moderate harm and above incidents
Divisional Patient Safety Huddle – escalate queries to PSIRG
Does the incident fall under a priority listed below?
Improvement Response Pathway: Contributory factors well understood Improvement activity underway.
End, update and close Datix
Learning Response Pathway: Contributory factors not well understood. Minimal improvement activity underway. Follow pathway below.
Review learning response and improvement response outputs - including potential safety actions, contributing factors and triangulate with other factors. Consider use of thematic review -
Learning response pathway - specific response to identified patient safety priorities
Mandated Response
MHRA
HSIB – Maternity (EXTERNAL)
Death in detention
Safeguarding incident
SUDIC
Death of LD patient
Never Event as per NHSE list
Patient death
Incident resulting in death with concerns relating to omission or gaps in care
Patient death within expectations and no new learning or contributory factors
Incident linked to patient safety priorities
Admission, Discharge or Transfer incident
Diagnostic/ treatment pathway delay
Medication
Capacity / bed related incident resulting in treatment delay
IPC / TV /FALLS
Screening tool to determine if After Action Review required
After Action Review
Rapid Review – to establish immediate facts / learning Are the reasons for the error / incident well understood?
NO
YES
Did it result in clinical harm?
Moderate / Severe Harm
No / Low Harm
Duty of candour applies
Patient Safety Incident investigation (PSII) – to be agreed at the Weekly Patient Safety Incident Review Group (PSIRG)
End. Update datix and close.

Supporting Document 1
Equality Impact Assessment Tool

		Yes/No	Comments
1.	**Does the policy/guidance affect one group less or more favourably than another on the basis of:**		
	• Race	No	
	• Ethnic origins (including gypsies and travellers)	No	
	• Nationality	No	
	• Gender	No	
	• Culture	No	
	• Religion or belief	No	
	• Sexual orientation including lesbian, gay and bisexual people	No	
	• Age	No	
2.	**Is there any evidence that some groups are affected differently?**	No	
3.	**If you have identified potential discrimination, are any exceptions valid, legal and/or justifiable?**	No	
4.	**Is the impact of the policy/guidance likely to be negative?**	No	
5.	**If so can the impact be avoided?**	n/a	
6.	**What alternatives are there to achieving the policy/guidance without the impact?**	n/a	
7.	**Can we reduce the impact by taking different action?**	n/a	

If you have identified a potential discriminatory impact of this key document, please refer it to Assistant Manager of Human Resources, together with any suggestions as to the action required to avoid/reduce this impact.

For advice in respect of answering the above questions, please contact Assistant Manager of Human Resources.

Supporting Document 2
Financial Risk Assessment

To be completed by the key document author and attached to key document when submitted to the appropriate committee for consideration and approval.

	Title of document:	Yes/No
1.	Does the implementation of this document require any additional Capital resources	No
2.	Does the implementation of this document require additional revenue?	No
3.	Does the implementation of this document require additional manpower?	No
4.	Does the implementation of this document release any manpower costs through a change in practice	No
5.	Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programmes or allocated training times for staff?	No
	Other comments:	Covered by existing budget

If the response to any of the above is yes, please complete a business case and which is signed by your Finance Manager and General Manager for consideration by the Accountable Director before progressing to the relevant committee for approval