Trust Policy

Worcestershire Acute Hospitals NHS Trust

Incident Reporting Policy

Department / Service:	Clinical Governance & Risk Management
Originator:	Head of Clinical Governance & Risk Management. Update by Patient Safety and Risk Manager
Accountable Director:	Chief Nursing Officer
Approved by:	Key Documents Approval Group
Date of Approval:	Approved SI meeting 26th October 2017. Approved TLG 8 November 2017.
Review Date: **This is the most current document and is to be used until a revised version is in place**	6th November 2020
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 incident, accident and 'near miss' event 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:
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
Nov 14	Amendment to reflect revised Trust structure, Removal of investigation process information Addition of Never Events & CCG SI Policy	B McLeod
Sept 14	Amendments to screening requirements	B McLeod
Aug 14	Document extended for 3 months whilst under review	L Webb
July 2012	Amended to reflect the revised Trust structure and responsibilities and changes to external reporting requirements	B McLeod / P Graham
April 2011	Link to www.csp.nhs.uk website added to section 5.3 page 10	C Rawlings/ J Underhill
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
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
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
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
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
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
Oct 04	Introduction of a single incident recording form for all incidents, accidents and near miss events.	C Rawlings
Oct 16	Contact number changed cancer screening programme for cervical screening.	K leach
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

Date	Amendment	By:
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	

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Supporting Documents

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 'National Reporting and Learning System' (NRLS) 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 and Berwick 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
Any unintended or unexpected incident which could have or did lead to harm for one or more patients receiving NHS care. (NPSA).

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 Serious Incident (SI)
Serious Incidents (SIs) 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. These are reportable to external stakeholders. Detailed information regarding serious incidents can be found in the Investigating Serious Incident Policy and are further defined in Appendix 1..

3.7 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 4

3.8 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 SIs.

3.9 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).

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

3.11 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.

3.12 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.

3.13 Investigation:
An investigation is a detailed enquiry or systematic examination with a purpose of uncovering and clarifying issues, thereby making it easier to establish facts, context and root causes, enabling the identification of a solution.

3.14 Root Cause Analysis (RCA)
A problem solving methodology for discovering the real causes of the problems, or difficulties, identified via a range of activities including incident/event management.

3.15 Levels of investigation:
The nature, severity and complexity of serious 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 Serious Incident, Review and Learning Group and ultimately the Chief Medical Officer / Chief Nursing Officer will use the information obtained from Datix and the Initial Case Review (ICR) to decide the level of investigation based on the NHS England SI Framework definitions of concise, comprehensive and external.

3.16 Initial Case Review (ICR):
An organisational tool to record incident description and immediate actions taken to provide an initial summary of the incident and/or the formulation of a 72 hour report.

3.17 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:

- Clinical Commissioning Groups
- Health & Safety Executive
- The Police, HM Coroner
- The Care Quality Commission
- Public Health England
- MHRA
- SHOT/SABRE
- NHS Improvement
- NHS England
- NHS Resolution
- Information Commissioner's Office.

3.18 HSE:
Health and Safety Executive

3.19 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.

3.20 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 significant harm.

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

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

3.23 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 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 incidents for their area of responsibility and monitor the quality of incident reports received.
- Ensure that all necessary immediate action has been taken including quarantine of any equipment involved.
- Escalate serious incidents as necessary.
- Ensure lessons are fed back to staff.

4.3 Divisional Quality Governance Facilitators

- Support leads with the investigation process.
- Provide reports to Divisional Committees and assist wards /departments / directorates to collate reports.

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 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 investigation.

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 each Serious Incident (SI) or Internal Comprehensive Review (ICR) within 1 working day of request.
- Ensure notification of Divisional ICR to relevant staff and stakeholders.
- Ensure that investigations and actions identified are completed in a timely manner.
- Ensure that directorates are complying with this policy and the reporting and investigation processes.
- Participate in weekly Divisional Serious Incident Review and Learning meetings to review each SI report and agree which require escalation to the Trust Serious Incident Review and Learning Group.
- Ensure that action plans generated from incidents within the Division are followed through to completion.

4.6 Patient Safety Team /Health & Safety Manager

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

- Train staff in the use of Datix and other tools to support risk management.
- Monitor incidents and raise any potential SI's with Divisions and the Serious Incident Review and Learning Meeting where these have not been raised by a Division and undertake further enquiries as required.
- Once an incident has been confirmed as a SI or ICR, the Patient Safety Team / Health & Safety Manager will notify relevant staff both internally and externally.
- Quality control data and sample the completeness and accuracy of incidents reported.
- Export data as required to the National Reporting & Learning System.
- Notification of incidents in accordance with CQC requirements in regulations 16, 17 & 18 of the CQC (registration) regulations 2009.
- The Patient Safety Team / Health & Safety Manager will 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 Safer Care Group or Health & Safety Committee.

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 serious incidents outside normal working hours, review incident and inform Executive Director on call of potential SIs as appropriate.
- Executive Director - determines whether incidents reported to them is an SI (see appendix 1) and if so, inform the On Call Manager for Worcestershire CCGs via WAHT switchboard as necessary.
- Inform The Patient Safety Team / Health & Safety Manager as soon as practicable.

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

Clinical Governance Group (CGG)

- Receive reports on the management of SIs and outcomes / learning from investigations from the Serious Incident Group.
- Receive reports from each Division in relation to incidents, investigations, actions and learning that can be shared with other Divisions.
- Receive analysis of clinical 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 investigation process and 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 incident reporting with in the division
- Discuss completed SI investigation reports and monitor action plans

Serious Incident Review and Learning Meeting (SIR&LG)

- Review and provide final 'sign off' for SIs and ICRs previously designated as complete by the Divisions.
- Report concerns and analysis to the CGG for consideration and action.

Divisional Serious Incident Review and Learning Meeting

- Review all SIs or discuss potential SIs to determine which require escalation to the Trust SIRLG.
- Review progress with investigations and provide support if the investigation team require it.
- Review completed investigations and be satisfied they are robust before taking them to the Trust SIR&LG for final approval

Trust Infection Prevention and Control Committee (TIPCC)

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

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 an adverse event 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:

- Definition of serious incidents (SI) (Appendix 1)
- Reportable Work Related Incidents and III-health and events which must be reported to the Health and Safety Executive. (Appendix 2)
- Incident Reporting Examples (Appendix 3)
- Incident Grading & 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.

5.2 Incident Management

Incidents are responded to in proportion to their severity. The most serious events will be rated as having a consequence that is severe harm or death (or a risk that is high in the case of near miss events) (see Appendix 5). These must be responded to immediately and refer to the Investigating Serious Incidents Policy.

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 several departments and specialist staff

5.3 Serial 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 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 National Learning & Reporting System (NRLS) 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.

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 / Health & Safety Manager

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 within three working days of receipt.

On behalf of the Chief Nursing Officer, the Patient Safety Team will report patient safety incidents to the National Reporting and Learning System. All incidents reported to the NRLS will be provided in a format, which does not include any personal identifying details of staff, patients, visitors or contractors.

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.

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.

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 an 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.

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.
- Individual staff involved in SIs and ICRs should record their own factual notes.

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 SIs and ICRs as required (Refer to Appendix 6 for list of stakeholders).

The following staff and stakeholders will receive notification of a SI 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

If an incident is identified as a SI as defined by the CCG, the following will also be notified:

- Non-Executive Directors
- Clinical Commissioning Groups
- Others will be informed as required, depending on the nature of the incident.

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 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 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 provide 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 Clinical risk and governance lead 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 National Reporting and Learning System (NRLS).

8. Policy Review

This policy will be reviewed 1 year following approval.

9. References

Serious Incident Framework, DH, March 2015
Revised Never Events Policy and Framework, DH, March 2015
Serious Incident (SI) Management Policy & Procedure, Worcestershire CCGs March 2016
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
The Never Events list 2015/16, DH March 2015
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.

Related Trust Documents .

Investigating Serious Incidents Policy
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 Meeting, Members of the Clinical Governance Group, Medicines Safety Officer and Health & Safety Manager This policy will be approved at the Trust Leadership Group. .

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

Definition of a Serious Incident, reportable to Clinical Commissioning Groups

The revised Serious Incident Framework (March 2015) determined there is no definitive list of events/incidents that constitute a serious incident 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.

Serious Incidents 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.

- 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.

Serious Incidents are recorded on the Strategic Executive Information System (STEIS) which is part of the 'UNIFY' system, and is the source of Performance Management information for the Department of Health and the NHS. The UNIFY system allows users to report and view Serious Incidents.

Serious Incidents are to be reported onto STEIS and within two working days of detection of the incident.

Initial Case Reviews

When a Serious Incident is reported, an Initial Case Review is required by the Trust within 72 hours. The CCG may also request the Initial Case Review report.

The relevant Division is responsible for providing the Initial Case Review report and the Patient Safety Team will co-ordinate this process.

Monitoring and closure of a Serious Incident will be through the CCG.

This is to be achieved within 60 working days of the incident being reported.

These timescales may be extended on a case by case basis. On occasions where the provider is not able to progress the investigation due to external factors, the Trust can request that the CCG 'stop the clock' until such a time that the internal investigation can continue.

Further details can be found within the CCGs Serious Incident (SI) Management Policy and Procedure:

Appendix 2

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 day' 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 3
Incident Reporting Examples

This list is not exhaustive and is provided as a guide to which events should be reported.

Communication	**Documentation**
Communication failure with patient/within team/ others	Missing/unavailable medical notes
Bleep not answered	Results/ information not in notes
Consent incorrect/ inadequate details	Results incorrect/delayed/unavailable
Inadequate or no consent obtain	Duplicate registration numbers
Lack of clinical assessment	Specimen missing/labelling error
Breach of confidentiality	X-rays unavailable
Inadequate handover of care	Record illegible
Policy or guideline not followed correctly	Theatre list details incorrect
Medication	**Radiology**
Incorrect prescription/preparation/administration	Wrong patient/site
Adverse reaction	Incorrect / insufficient information on request card
Delay in availability/administration	No nurse escort if one was required
Security/safe handling issue	Report delayed/not reported
Incorrect advice	Not acted upon by referring clinician
Patient initiated incident	Repeated due to unavailable images film
Admission	**Infection Control**
Delay in admission/failure to admit	Outbreaks/beds blocked as a result
Failure of follow up arrangements	Failure to follow Trust policy
Unexpected admission to ITU/specialist care unit	Clostridium difficile / MRSA
Discharge delays / poor discharge planning	Disposal of clinical waste
Absconder/ missing patient/self discharge	Inappropriate placement of potentially infectious patients
Accidents	**Bed Management**
Falls	Inappropriate admission or transfer
Faint/collapse	No in-patient beds available
Contact with sharp/blunt objects	Lack of availability of specialist beds/A&E trolleys
Contact with hot /cold liquid or surface	Extra patients/overspill area opened
Needlestick injuries	Same sex accommodation
Aggression	**Diagnosis**
Verbal abuse	Incorrect diagnosis
Physical abuse	Failure/delay in diagnosis
Self harm	Complication following diagnostic procedure
Transfusion	**Equipment**
Incorrect details on request	Failure/broken/defective/unavailable
Reaction to transfusion	Decontamination/sterilisation
Incorrect blood group	Injury whilst using device
Delay in receiving product/unavailable	Misuse/lack of training
Storage/transportation of product	Connected incorrectly/not connected
Administration errors	**Staff**
Tissue Viability	Lack of availability(all staff groups)
Extravastion	Staff training issues
Pressure sore	**Transport**
Laceration/skin tear/abrasion/burn	Delay in arrival
Dehiscence of surgical wound	No appropriate escort
Bruising	Inappropriate mode of transport
Treatment	**Treatment**

Delay/incorrect treatment	Difficulty/delay in obtaining clinical assistance
Delay in assessment/review	Delay or failure to monitor
Operation or procedure delayed/cancelled	Unexpected death
Complication following/during operation/procedure	Death of anyone under 18 years old (expected & unexpected)
Unplanned return to theatre	Complication following/during operation/procedure
In-hospital cardiac arrest	Wrong site surgery
Retained instrument / swab	

Appendix 4 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 2015/16 applicable to WAHT

1. Wrong site surgery
2. Wrong implant/prosthesis
3. Retained foreign object post-operation
4. Mis-selection of a strong potassium-containing solution
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)
6. Maladministration Overdose of Insulin due to abbreviations or incorrect device
7. Overdose of methotrexate for non-cancer treatment
8. Mis-selection of high strength midazolam during conscious sedation
10. Falls from poorly restricted windows
11. Chest or neck entrapment in bedrails
12. Transfusion or transplantation of ABO-incompatible blood components or organs
13. Misplaced naso or oro-gastric tubes
14. Scalding of patients

Appendix 5

Incident Grading Duty of Candour

The National Learning & Reporting System (NRLS) definitions of harm are used.

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** <u>Within 10 working days of the incident</u>: 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. <u>Within 10 working days</u> 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	

Appendix 6

Key Stakeholders Requiring Information on Selected Incidents

Worcestershire Clinical Commissioning Groups (CCGs)

Worcestershire CCGs are to be informed of all serious incidents as described in appendix 1. 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).

National Reporting & Learning System (NRLS)

All patient incidents, accidents and near miss events are reported to the NRLS. 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 SPC

The Worcestershire SPC General Manager is to be informed of any events that occur at Worcestershire Royal Hospital where services they provide may be implicated.
NHS Estates/PFI team are the external body requiring reports on defects and failures relating to non-medical equipment, engineering plant, installed services, buildings and building fabric. The Patient Safety Team / Health & Safety Manager are responsible for liaising closely with the Trust Estates Department/PFI team.

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

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

Supporting Document 3 – Checklist for review and approval of key documents
This checklist is designed to be completed whilst a key document is being developed / reviewed.

A completed checklist will need to be returned with the document before it can be published on the intranet.

For documents that are being reviewed and reissued without change, this checklist will still need to be completed, to ensure that the document is in the correct format, has any new documentation included.

1	Type of document	Policy
2	Title of document	Incident Reporting Policy
3	Is this a new document?	Yes ☐ No ☒ If no, what is the reference number CG-008
4	For existing documents, have you included and completed the key amendments box?	Yes ☐ No ☐
5	Owning department	Clinical Governance & Risk Management
6	Clinical lead/s	Chief Nursing Officer
7	Pharmacist name (required if medication is involved)	N/A
8	Has all mandatory content been included (see relevant document template)	Yes ☐ No ☐
9	If this is a new document have properly completed Equality Impact and Financial Assessments been included?	Yes ☐ No ☐ Not a new document
10	Please describe the consultation that has been carried out for this document	Key individuals involved in incident reporting have been consulted during the development of this policy.
11	Please state how you want the title of this document to appear on the intranet, for search purposes and which specialty this document relates to.	Incident Reporting Policy
Once the document has been developed and is ready for approval, send to the Clinical Governance Department, along with this partially completed checklist, for them to check format, mandatory content etc. Once checked, the document and checklist will be submitted to relevant committee for approval.		

Implementation

Briefly describe the steps that will be taken to ensure that this key document is implemented

Action	Person responsible	Timescale
See 6.1		

Plan for dissemination

Disseminated to	Date
See 6.2	

1	**Step 1 To be completed by Clinical Governance Department** Is the document in the correct format? Has all mandatory content been included? Date form returned	 Yes ☐ No ☐ Yes ☐ No ☐
2	Name of the approving body (person or committee/s)	
	Step 2 To be completed by Committee Chair/ Accountable Director	
3	Approved by (Name of Chair/ Accountable Director):	
4	Approval date	_____/_____/_____

Please return an electronic version of the approved document and completed checklist to the Clinical Governance Department, and ensure that a copy of the committee minutes is also provided.

Office use only	Reference Number	Date form received	Date document published	Version No.
			01/08/12	8.2