West Hertfordshire Hospitals NHS Trust

Incident Reporting (Inc. Serious Incident) and Management Policy

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CONTRIBUTION LIST

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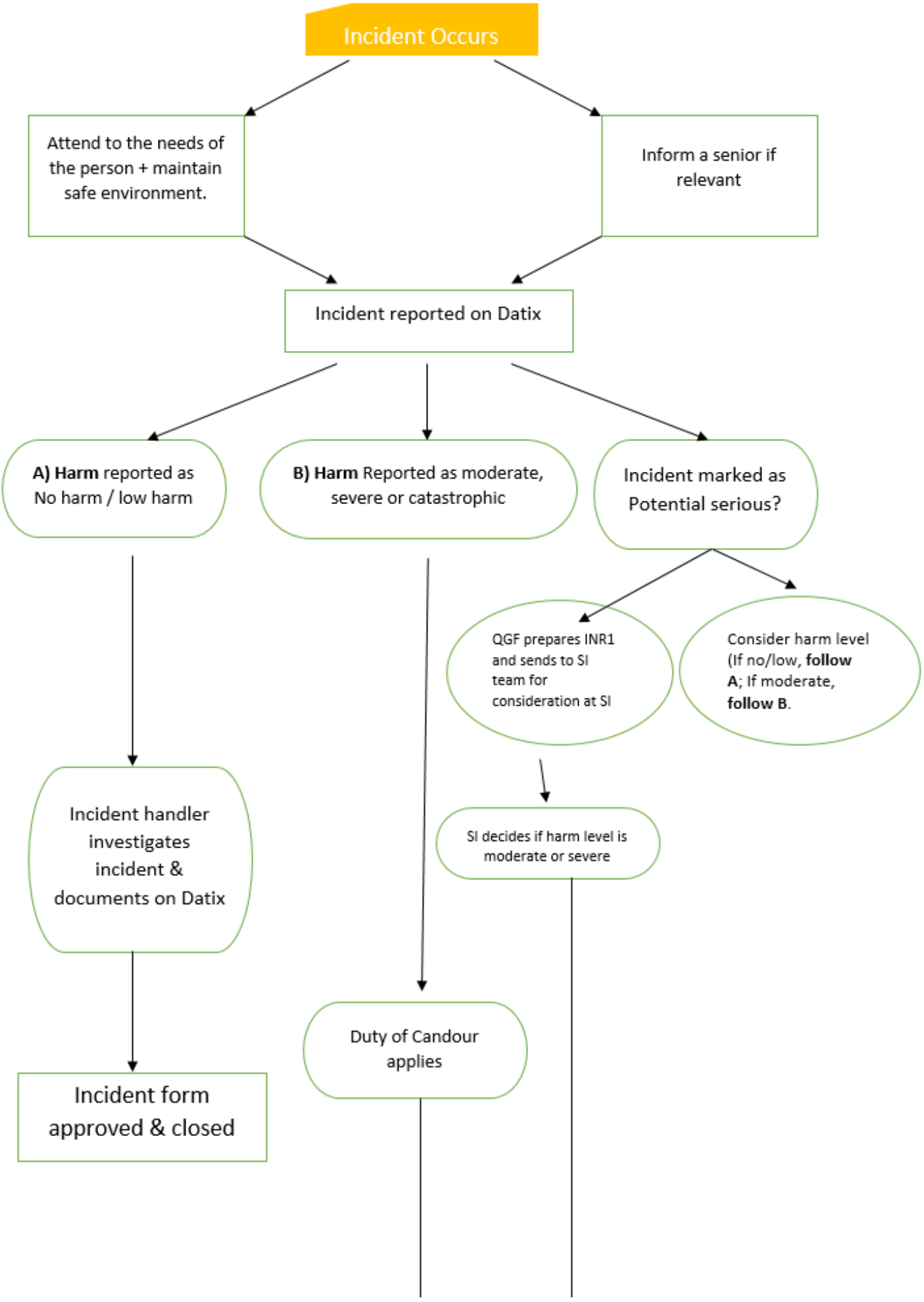
Change History

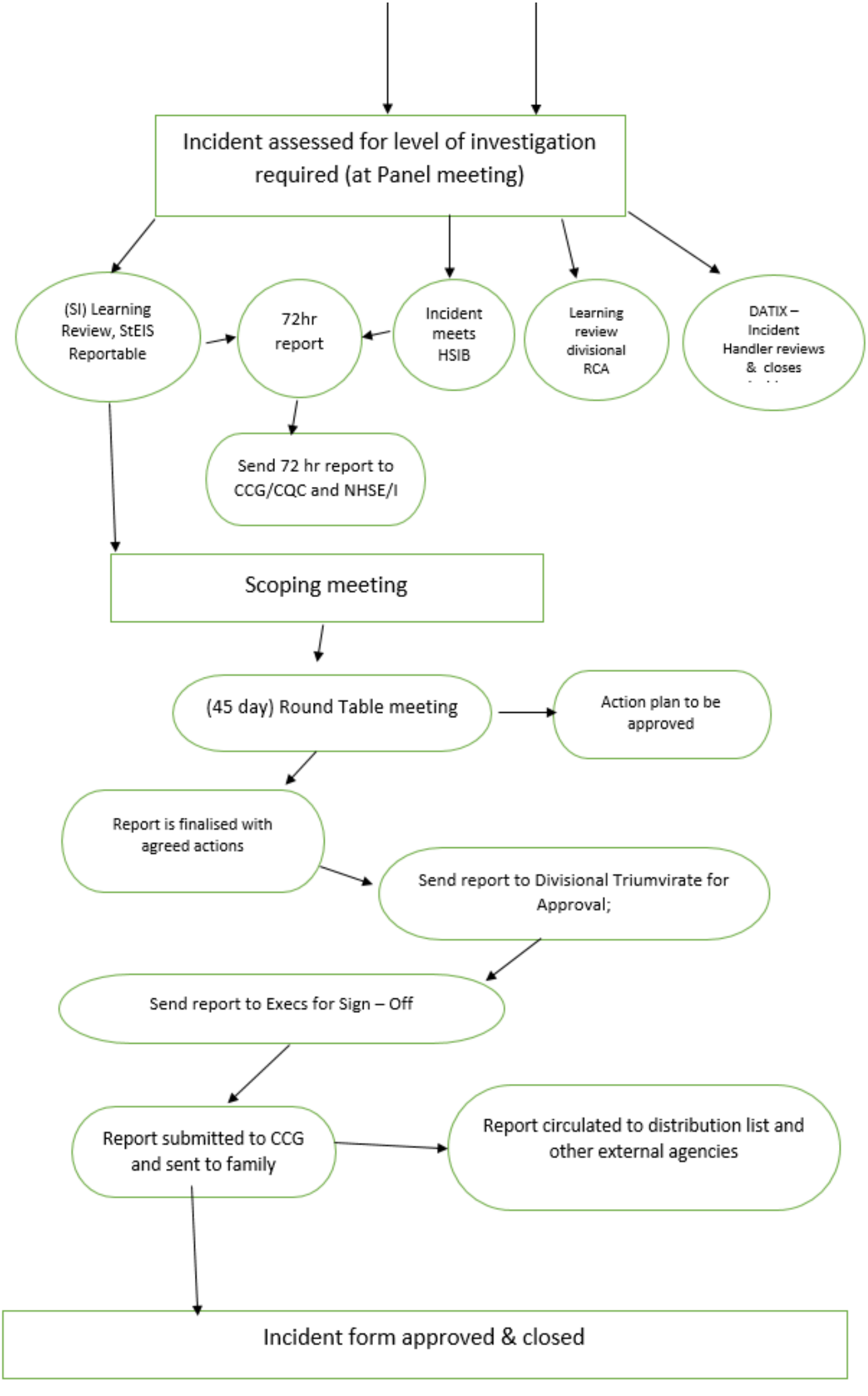
Version	Date	Author	Reason for change
12	Oct 2015	Mel Withero	Formal review
13	18 Feb 16	P Bircham	5.7 SIRG monthly not bi monthly 6.5.1 Divisional Incident RCAs 6.5.16 Root Cause Analysis Escalation of RCA content and changes.
13	5 April 16	P Bircham	3 Incidents Description of divisional incidents.
13	27 June 2016	J Smith	Frequency of reporting to the NRLS and reference to NHS Improvement
14	December 2017	L Gibson	Formal review
15	March 2021	M. Salami	Formal review
16	May 2022	C. Kamau M. Salami	Amendment and update of Trust Commissioned Services provided by Independent and 3rd Parties

CONTENTS

1 Incident management flow chart – overview.

The flow chart below is a simplified version of the process. For the full version please see the Quality Governance intranet page or follow this link.




Incident assessed for level of investigation required (at Panel meeting)
(SI) Learning Review, StEIS Reportable
72hr report
Incident meets HSIB
Learning review divisional RCA
DATIX – Incident Handler reviews & closes
Send 72 hr report to CCG/CQC and NHSE/I
Scoping meeting
(45 day) Round Table meeting
Action plan to be approved
Report is finalised with agreed actions
Send report to Divisional Triumvirate for Approval;
Send report to Execs for Sign – Off
Report submitted to CCG and sent to family
Report circulated to distribution list and other external agencies
Incident form approved & closed

2 Aim

Quality Commitment

WHHT is committed to:

- Sharing a commitment to quality of care and service
- Fostering a team working culture
- Building an organisation that drives quality

WHHT is committed to making safety a priority and doing its reasonable best to prevent injury, ill health and harm to patients, staff, visitors and to prevent the loss and damage to NHS assets, the Trust's reputation and to prevent breaches of patient confidentiality.

Reporting

Although incidents in health and social care are relatively uncommon, it is acknowledged that systems and processes have weaknesses and that errors will inevitably happen. A good organisation will recognise harm and the potential for harm and will undertake swift, thoughtful and practical action in response, without inappropriately blaming individuals.

The reporting and management of incidents is a critical tool in assisting the organisation to effectively manage risk. The reporting of incidents and near misses provides valuable data which can help improve safety, prevent the recurrence of incidents and facilitate wider organisational and cross-organisational learning.

Incident occurs

Investigation

Responding appropriately when things go wrong in healthcare is a key part of the way that the Trust can continually improve the safety of the services we provide to our patients. We know that healthcare systems and processes can have weaknesses that can lead to errors occurring and, tragically, these errors sometimes have serious consequences for our patients, staff, services users and/or the reputation of the organisations involved themselves. It is therefore essential that all staff continually strive to reduce the occurrence of avoidable harm.

Learning

Much can be learned from the prevented safety incidents (near miss), no or low harm incidents. Understanding why these incidents have happened may reduce the risk of more serious incidents happening and shared learning provides a significant opportunity to improve both the quality of care patients receive and the patient experience.

3 Objectives

3.1 It is the policy of the Trust to promote a positive approach to incident reporting throughout the organisation. Staff are encouraged, and supported, to be open and honest about events and issues that have or could cause damage to people, property or the organisation. The Trust operates an open and fair blame culture and will accept vicarious liability for the actions of staff as long as they were carrying out their duties in accordance with Trust policy, their professional standards, information, instruction, training and supervision they had received.

3.2 The Trust wishes to learn lessons and improve through the investigation of incidents. It is imperative that the Trust's electronic risk management system - DatixWeb - is used for reporting and recording all incidents to enable a proactive mechanism for risk management.

3.3 This policy is based on the "Serious Incident Framework Supporting learning to prevent recurrence: March 2015:" and the "Revised Never Events Policy and Framework: February 2018". These two Guidance documents replace all previous Guidance in relation to serious incidents (SIs) and Never Events.

3.4 The objectives of the policy are also consistent with the National Patient Safety Agency guidance on the Seven Steps to Patient Safety (2009) which are:

- Promoting a culture of learning through review and reflection of incidents and near misses,
- Ensuring a consistent approach across the organisation in the reporting and management of incidents,
- Enabling the effective reporting and provision of information on incident trends to ensure that lessons can be learnt and improvements made reducing re-occurrence of similar incidents,
- Improving the safety of service users, staff and visitors,
- Minimising the human, organisational and financial impacts of incidents through effective management,
- Enabling the identification and correction/ improvement of weaknesses in practices, systems or equipment,
- Ensuring the onward reporting of serious hazards and incidents to relevant stakeholders.

4 Definitions

Descriptor	Definition
Incident	An incident is described as “any event which has given rise to potential or actual harm or injury, to patient dissatisfaction or to damage/ loss of property” (Ref: NHS Executive). This definition includes patient/ service user injury, fire, theft, vandalism, assault and employee accident and near misses. It includes incidents resulting from negligent acts, deliberate or unforeseen.
Learning review (StEIS reportable) / Serious Incident (SI)	Learning review (StEIS reportable) (previously referred to as Serious Incident (SI) investigation) is defined when a patient, member of staff, or member of the public suffers serious harm or unexpected death on organisation premises, premises where health care is provided, including in a patient’s own home or anywhere in the community; where staff actions are likely to cause significant public concern; any event that might seriously impact upon the delivery of service plans and/or may attract media attention and/or result in a settlement following litigation and/or may reflect a serious breach of standards of service.
Learning review (divisional) / Divisional investigation (RCA)	Learning Review (divisional) (also known as a Divisional RCA) is an incident which does not meet the set criteria for a serious incident. However, it is considered that there is significant potential for learning and an investigation using the root cause analysis (RCA) technique is required to ensure that all aspects of the incident are reviewed and considered with a focus on systems and processes and the learning and actions address the root causes of the incident. The decision to conduct a Learning Review (divisional) can be made at divisional level for any incident which had caused no harm, low or moderate harm, or may be the outcome of an incident being discussed at the Serious Incident Panel meeting.
Near Miss	An incident that had the potential to cause harm but was prevented.

Never Event	Never events are a sub-set of Learning Review (STEIS reportable) (previously referred to as Serious Incident (SI)) 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’’. For a full list see Appendix 3.
Non-Clinical incidents	An unplanned or unexpected event in which a member of staff/contractor or the public has been, or could have been injured, killed, or suffer mental trauma, or led to loss or damage to equipment or property, or other financial loss
Patient Safety Incident	Any unintended or unexpected event that could have or did lead to harm on organisation premises where NHS funded care is provided, including a patient’s own home or anywhere in the community.
Divisional triumvirate	This consists of the Divisional Head of Nursing, Divisional Manager and Divisional Director.
Harm	Harm can be defined as:” *injury (physical or psychological), disease, suffering, disability or death”* In most instances, harm can be considered to be unexpected if it is not the result of the natural course of the patient’s illness or underlying condition. See appendix 5 to view the National Patient Safety Agency (NPSA) risk matrix.
Hazard	A hazard can be defined as*: “anything that can cause harm’’*. Hazards are situations with the potential to cause harm or damage and could include faulty equipment, worn or loose floor coverings, irritant chemicals etc. Incident reporting forms must be completed for all hazards. Individual responsibilities are not however discharged by the mere completion of an incident reporting form and all reasonable steps should be taken at the time to minimise the risk of injury arising from any identified hazard.

5 Scope

This Policy applies to all Trust staff and contractors working on Trust premises, including staff on interim or honorary contract, students and volunteers. It covers all types of incidents.

6 Responsibilities

Please see appendix 3 for a full list of staff responsibilities for the implementation of this policy.

7 Incident reporting and investigation process

7.1 Immediate response following an incident

The first priority for anyone who has witnessed, or was involved in an incident, is to ensure the needs of individual(s) affected are attended to, including any clinical care needs.

Environmental hazards must be recognised and managed. Once a safe environment has been established, any relevant equipment and / or medication must be securely retained and isolated and relevant documentation (such as patient notes) copied and secured to facilitate investigation and learning (originals to be retained if possible).

If there has been a death or serious injury, the most senior person on duty in the area must be informed immediately and, if a patient is affected, the patient's consultant must be contacted to advise on optimising immediate care.

If there is a suggestion that a criminal offence has been committed, this should be escalated immediately to the Divisional Management Team/On-call team who will make arrangements to contact the police, and the scene and evidence must be secured.

In the event that abuse or neglect is suspected the relevant child or adult safeguarding policy will be implemented.

All incidents and immediate responses must be reported on Datix.

Where the incident has resulted in moderate, severe harm or death, immediate consideration should be given initially by the incident reporter and incident manager as to how best to provide information and support to patients, relatives, carers and staff involved in incidents.

7.2 Reporting an incident by completing an incident form (Datix)

An electronic incident form must be completed via Datix as soon as possible after the event and before the person reporting the incident ends their work day/shift. Access to Datix is available on the Trust intranet on the home page and does not require a

password.

7.3 Definition of a patient safety incident.
An incident is an unintended or expected event, that could have, or has, resulted in unnecessary damage, loss or harm, including psychological/physical injury to any person (patient, visitors, member of the public or staff, etc.) or Trust premises or reputation

The list below shows examples of incidents which require reporting. **NB – this list is not exhaustive:**

- Medication errors
- Confidentiality breaches
- Surgical errors
- Unexpected death
- Treatment delays
- Slips/trips/falls
- Workplace accidents
- Inappropriate behaviour
- Unavailability of medical records when required

The incident record should contain known facts only not assumptions or opinions or comments on another staff member's performance or ability.

Any immediate remedial actions that have been completed should also be documented together with any conversations with the patient and /or their family (if the patient lacks capacity or is deceased), relevant to being open (for no or low harm) or duty of candour (for moderate harm, severe harm or death).

Incident forms must NOT:

- contain any person identifying details (staff or patients) in the text sections where this has been highlighted.
- be used for reporting grievances or concerns about another staff member's capability or performance, or
- be saved in the healthcare records.

The level of actual (not potential) harm that occurred as a result of the incident must be documented as this will provide the basis for the level of investigation required. The level of harm will be reviewed and may be amended by the incident handler or Quality Governance Facilitator (QGF) / Divisional Governance Lead following the outcome of SI panel meeting or an investigation.

Staff should record and briefly comment on all further actions taken or planned, and any lessons learned, including those with a Trust-wide implication.

All investigation reports should be uploaded to the relevant Datix record.

For further information on how to complete an incident form please refer to the Quality Governance intranet page by clicking here.

7.4 Incident harm grading and result

There are two drop down boxes on the Trust's incident reporting form in Datix for recording (1) the end result of the incident and (2) the incident harm grading sustained by the patient.

1.

2.

The result of an incident relates to whether ACTUAL harm was caused by the incident and is recorded as one of the following by the incident reporter:

- No harm sustained
- Harm sustained
- Near miss

It is good practice to record incidents that resulted in no harm, or are prevented, as this helps us to learn from them and identify trends that may result in actual harm in future.

The severity of an incident relates to the actual harm caused by the incident (actual impact) and is recorded by the incident reporter as one of the following:

- None
- Low
- Moderate
- Severe
- Death/catastrophic

Degree of Harm (Severity/Actual Impact on Patient)	
No Harm	No harm including Near misses
Low Harm	Minimal harm - patient(s) required extra observation or minor treatment)
Moderate Harm	(Short term harm - patient(s) required further treatment, or procedure) *Harm that requires a moderate increase in treatment and significant, but not permanent, harm.
Severe	Permanent or long-term harm. A permanent lessening of bodily, sensory, motor, physiologic or intellectual functions, including removal of the wrong limb or organ or brain damage, that is related directly to the incident and not related to the natural course of the service user's illness or underlying condition.
Death	Death (Caused by the Patient Safety Incident)

There is a drop down box on the (Datix) incident reporting form entitled " Is this incident potentially a Serious Incident?" This is for recording if the incident is a potential serious incident.

Any incident that has resulted in severe harm or death must be reported and marked on Datix as a potential serious incident immediately to the relevant management team including the patient's consultant, Quality governance facilitator. If the incident is

considered to be a moderate harm incident or above, this will be escalated to the Quality governance team as the duty of candour will need to be met.

For further guidance on scoring the harm resulting from an incident please see appendix 7.

7.5 Level of investigation

i. All incidents as defined in this policy must be investigated. However, the level of investigation needed will vary, depending on the nature, severity and potential risk of the incident.

ii. At Serious Incident Review Panel meeting, the level of investigation will be reviewed to identify those incidents that meet the serious incident criteria and will be investigated as serious incidents, or those which are a divisional investigation and managed within the division.

iii. Investigations must be carried out in an open and fair way to promote a learning environment, where emphasis is placed on the identification and, where possible, correction of inherent risk in systems and processes, and not on individual performance.

iv. The investigation process must not delay the immediate implementation of any action which would mitigate risk.

v. At a minimum, investigations must include staff informal discussion, formal interviews, or statements to determine “When, what, how, why and who was involved”. This information will be used to update Datix, along with any changes (actions) that have been made to prevent a reoccurrence.

vi. Incidents which occur frequently, such as patient falls and pressure ulcers may benefit from using a multi-incident thematic review. This allows one comprehensive action plan to be developed and monitored and, if used effectively, moves the focus from repeated investigation to learning and improvement. Thus if another similar incident occurs, resources can be focussed on quality improvement rather than repeated investigations.

vii. Incidents that are marked/reported on Datix as potential serious incidents or those are harm graded as moderate, severe of death/catastrophic are assessed for meeting SI criteria. Initial investigation will be carried out by the divisional governance team who will escalate to the incident to the SI team for review. Decisions are made whether to present the incident for consideration at the Serious Incident Panel meeting to determine the level of harm. The level of harm will be determined as one of the following

7.5.1 Near miss, no and low harm incidents (“Datix” level of investigation)

- These incidents should be managed locally by the ward/ department/matrons or Quality governance facilitator with the emphasis on minimising recurrence; and the outcome of the findings should be recorded on Datix.

- The Quality Governance personnel will re-grade the incident if felt necessary after reviewing all pertinent information. For future learning, trend analysis of these types of incidents may be undertaken by the QGF and presented to the Divisional Quality and Safety Meeting for review.

7.5.2 Moderate harm, causing significant (short term) but not permanent harm

- The divisional governance team will review all incidents in their Division on Datix on a daily basis and may re-grade the incident if felt necessary after reviewing all pertinent information and consulting with the ward/department and the head of department as necessary.

- Incidents with apparent moderate harm or those marked as potential serious incident must be presented to the SI team for consideration at the Serious incident review panel meeting as soon as possible via the Initial Notification Report form (INR)

- Moderate harm incidents that meet the Serious Incident Criteria are reported to StEIS and will follow the serious incident management process. An expert and a Duty of Candour (DoC Lead) will be identified to ensure that the DoC process is commenced. The investigation will be co-ordinated or conducted by the SI team as appropriate. Using the serious incident national framework methodology.

- Moderate harm incidents (which do not meet serious incidents criteria) are investigated by the division (known in the Trust as “Divisional RCA” not always following discussion at SI panel). The incident handler as named on Datix and may be supported by the Quality Governance team to identify causal factors, lessons learned and actions plans. DoC principle also applies.

- The divisional governance team and heads of nursing or management team are responsible for ensuring the duty of candour principle is met.

7.5.3 Severe harm, causing significant (long term) permanent harm, or Death/catastrophe

- The starting point is to consider all of the above as stated in moderate harm.

- For incidents which result in severe harm or death, a full root cause analysis must be carried out in consonance with the recommendations/outcome of the serious incident panel meeting held to discuss the details of the incident level of harm and level of investigation.

- Accounts of events from staff involved must be obtained as soon as possible after the event, most preferably by face to face interviews by the SI investigation team or the SI lead investigator.

- The final investigation report must be completed and reported within 60 days to the commissioners. Good practice dictates that an extension request must be made as soon as it is envisaged that the report will not be completed within the 60 days deadline and any subsequent deadline that may be breached.

- The outcomes (i.e. actual harm) of Serious Incidents can cover all degrees of harm. For example, all Never Events are Serious Incidents but not all will result in severe harm or death. Therefore, the actual outcome that is reported to the NRLS may in fact be “no” or “low” harm, even though it’s declared as a Serious Incident. (The National Reporting and Learning System (NRLS) is a central database of patient safety incident reports.) Additionally some Serious Incidents may not involve actual or potential harm to any patient (e.g. an incident related to loss of confidential information affecting staff). Please refer to appendix 4 on “Never Events List, 2018 revised in 2021”.

7. 6 Likert Avoidability Assessment of Moderate, Severe harm and death incidents

When an incident has been confirmed as causing moderate, severe harm or death, the SI panel meeting may employ the Likert Avoidability scale to enhance its decision on the level of investigation to use. The level of avoidability of the incident/harm will be based on the presentation of the information available.

Avoidability is assessed using the avoidability judgement scoring system by the Royal College of Physicians (2016), developed from the Likert scoring described in the Hogan et al 2012, to determine those patient incidents considered likely to be avoidable.
Likert avoidability Scale:

1 Definitely avoidable
2 Strong evidence of avoidability
3 Probably avoidable, more than 50:50
4 Possibly avoidable, but not very likely, less than 50:50
5 Slight evidence of avoidability
6 Definitely not avoidable (unavoidable)

Likert scores of 1-3 indicate those incidents considered likely (ie over 50%) to be avoidable.
The SI panel will reach a consensus decision on which incidents are declared serious incident based on:

- Actual severity
- Risk of re-occurrence
- Likert avoidability
- Opportunity for learning
- Criteria set within the current NHSI/E safety investigations/serious incident framework or HSIB criteria.

Incidents deemed by the SI Panel (or Executive Team) to have high degree of unavoidability (Likert 4-6) are usually investigated and managed locally.

Limitation/Caution: Likert Avoidability scale is subjective and may not be used on its own.

7.7 Incident Investigation

Investigations must be carried out utilising Root Cause Analysis methodology and in an open and fair way to promote a learning culture, where emphasis is placed on the identification and, where possible, change/improvement of systems and processes, and not on individual performance.

The investigation process must not delay the immediate implementation of any action which would mitigate risk or further harm to the patient.

8.0 Harm Validation

It is part of the incident reporter's responsibilities to document the harm that has occurred as a result of the incident. There are times when the severity of incident is not known or can change as the incident is investigated and more information is available. Due to this an important part of the investigation process is for the harm entered; at the time the incident was reported; to be validated.

Incident harm validation must be completed by a member of the divisional governance team or the person investigating the incident.

If the incident is reviewed and evidence gained via the incident investigation shows that the harm recorded as a result of the incident is not accurate then a member of the divisional governance team or the person responsible for investigating the incident must amend the harm recorded and date the validation field.

If the incident is reviewed and evidence gained via the incident investigation shows that the harm recorded as a result of the incident is accurate then the Quality Governance Facilitator or the person responsible for investigating the incident must simply date the validation field.

8.1 Clinical Harm Review

At other times, a division may instigate a clinical harm review process on a periodic or ad-hoc basis. The review group may use the Likert avoidability scale (section 7.6 above) as an aid if appropriate. The review team will be constituted by a multi-professional team and the decision to change the harm or investigation level will be conveyed to, and ratified by the Chief Nurse and Chief Medical officer.

The Governance Facilitator or the person responsible for investigating the incident must amend the harm recorded and date the validation field.

9.0 Duty of Candour and Being Open

When a patient is harmed in the course of care being provided to them, the patient should receive an explanation and apology as soon as possible after the event occurred and staff should feel able to apologise and be supported by their immediate line manager.

The statutory duty of candour (applying to healthcare providers) applies to actual or suspected safety events which occur during the provision of care and result in moderate harm, moderate increase in treatment, severe harm or death, or prolonged psychological harm, or require treatment in order to prevent moderate harm, severe harm or death, or prolonged psychological harm. (CQC, 2015).

The Care Quality Commission has updated* its guidance on the duty of candour on 11th March 2021 to give a more specific explanation of what is defined as a notifiable safety incident.

A notifiable safety incident must meet all 3 of the following criteria:
1. It must have been unintended or unexpected.
2. It must have occurred during the provision of an activity we regulate.
3. In the reasonable opinion of a healthcare professional, already has, or might, result in death, or severe or moderate harm to the person receiving care. This element varies slightly depending on the type of provider.

A crucial part of the duty of candour is the apology. The CQC update of March 2021 re-emphasises that the apology required to fulfil the duty does not mean accepting liability'. As noted in the NHS Resolution - 'Saying Sorry' leaflet, apologising will not affect indemnity cover:

"Saying sorry is:

- always the right thing to do
- not an admission of liability
- acknowledges that something could have gone better
- the first step to learning from what happened and preventing it recurring."

Levels of Harm in Relation to Duty of Candour (Being Open)

The table below sets out the thresholds and details of harm levels for being open and duty of candour in relation to harm caused to a patient.

Harm assessment	Impact on patient
No harm	No impact

Minor harm	Requires additional monitoring, minor intervention or will require up to a week to heal the injury
Moderate harm	Harm that requires increase in treatment; prolonged pain or psychological harm. harm that requires a moderate increase in treatment (e.g. unplanned return to surgery, an unplanned re-admission, a prolonged episode of care, cancelling of treatment or transfer to another treatment area (e.g. ICU) significant but not permanent harm
Prolonged pain or psychological harm	pain or psychological harm which a patient has experienced or is likely to experience for a continuous period of at least 28 days
Severe harm	a permanent lessening of bodily, sensory, motor, physiological or intellectual functions, including removal of the wrong limb or organ or brain damage, that is related directly to the incident and not related to the natural course of the service user's illness or underlying condition.
Death	Death

For more details on the CQC 2021 update can be found in appendices 5 and 6.

For further guidance , please refer to the Duty of Candour Policy and the Incident Investigation tool kit on the Quality Governance Intranet page by clicking here. This policy includes clear guidance on timescales and a step by step guide on complying with the duty of candour legislation.

10.0 Process for Reporting to External Agencies

10.1 Strategic Executive Information System (StEIS)

All patient safety incidents (regardless of harm) are reported to the National Reporting and Learning System via the Datix System Administrator.

The Trust Incident Management Administrator will report all Learning review (STEIS reportable) incidents to the commissioners using the STEIS system.

10.2 Health Education England (Doctors in Training)

Directors of Education and Quality (DEC) in Health Education England (HEE) and its local Education and Training Boards are responsible for the quality of the education and training provided to the medical, nursing, dental and Allied Health Professionals (AHP) students and others, and training grade doctors. These students may be involved in serious incidents and HEE have a duty of care to them. Also they are an excellent source of feedback on the standard of patient care experienced in their placement.

Local education providers are required to send 'fitness to practice/ information (called an Exception Exit Report) to the local Health Education England office every 2-3

months. This includes trainees named and involved in unresolved serious incidents.

The Medical Director is responsible for this report, but it is completed on their behalf by the Medical Education team. This reporting is intended to ensure any trainees involved receive the appropriate support and that standards of training are appropriate. As well as support from their educational supervisor and departmental team, a referral to the Professional Support and Well-Being Service at HEE is usually made to be sure any additional needs are met.

10.3 Healthcare Safety Investigation Branch (HSIB)

The Healthcare Safety Investigation Branch (HSIB) is a part of NHS England, established in April 2017, to operate independently of other regulatory agencies. HSIB conducts independent investigations of patient safety concerns in NHS-funded care across England. It undertakes patient safety investigations through two programmes: National Investigations and maternity investigations.

National Investigations – HSIB's national investigations encompasses any patient safety concern that occurred within NHS-funded care in England after 1 April 2017. It considers the requirement to investigate potential incidents or issues based on wide sources of information. These include the scale of risk and harm, the impact on individuals involved and on public confidence in the healthcare system, as well as the potential for learning to prevent future harm.

Maternity investigations - From 1 April 2018, HSIB became responsible for all patient safety investigations of maternity incidents occurring in the NHS which meet criteria for the "Each Baby Counts programme" and the MBRRACE criteria for maternal deaths. (Mothers and Babies—Reducing Risk through Audits and Confidential Enquiries across the UK (MBRRACE-UK).

The purpose of this programme is to achieve rapid learning and improvement in maternity services, and to identify common themes that offer opportunity for system-wide change. HSIB's defined criteria:

- Current HSIB investigation criteria align closely with expectations of the Serious incident framework.
- All maternity incidents investigated by HSIB should also be reported on the strategic Executive Information System (StEIS) – this will ensure CCGs and NHS England and NHS Improvement remain fully informed of ongoing investigations.
- Organisations should continue to undertake an immediate review (72- hour report) to identify urgent safety concerns.

For these incidents, HSIB's investigation replaces the local investigation, although the NHS trust remains responsible for Duty of Candour and for referring the incident to us. For more information please visit : https://www.hsib.org.uk/about-us/

10.4 The Reporting of Injuries Diseases and Dangerous Occurrences Regulations (RIDDOR)

The Reporting of Injuries Diseases and Dangerous Occurrences Regulations (RIDDOR) 1995 (amended 2013) requires employers to report certain types of injury, some occupational diseases and dangerous occurrences that 'arise out of or in connection with work' to the Health and Safety Executive (HSE).

The scope of these regulations cover:

- Accidents which result in death of any person
- Accidents which result in an employee or self-employed person suffering from a major injury
- Accidents which result in an employee or self-employed person being absent from work or unable to undertaken normal duties for more than seven days
- Accidents which result in a person not at work (e.g. patient, service user, visitor) suffering an injury and being taken to hospital; or, if the accident happens at a hospital, suffering a major injury which would otherwise have required hospital treatment
- An employee or self-employed person suffering from a work related disease
- Specific dangerous occurrences, which may not result in a reportable injury, but have the potential to do significant harm such as a needle stick injury exposing staff to a known biological hazard (e.g. Hepatitis).

Please see the Health and Safety intranet page for more information by clicking here .

10.5 Police investigations

Where an incident is subject to a criminal police investigation the Trust must be in full liaison with the investigation police officer assigned to the case. This must be undertaken by a member of the Serious Incident team.

Any incident which is subject to a criminal police investigation must **not** be investigated unless explicit permission has been provided from the investigation police officer. This must be provided in writing.

11 Analysis of collated incident data

Having a trust wide repository for incident data (Datix), enables staff to analysis this data to help them understand how well their specialty, department, division or site is functioning and where to focus resources to improve safety.

Incident and other risk management data are collated divisionally for the Quality and Safety Group and bi-monthly for the Quality and Safety Integrated Performance Report which is presented to the Board.

Dashboards are available via the Datix team to all staff who have a Datix account which enables them to view a bespoke breakdown of areas that require monitoring or regular reviews. This can be applied to all modules within Datix such as incidents, complaints, safety alerts and risk registers.

12 Approving and Closing incident on Datix

Incident handler/managers are responsible for ensuring information relating to incidents is accurate and comprehensive

Quality Governance Facilitators / Divisional Governance Leads are responsible for monitoring that an accurate and up-to-date record of incidents is reported and investigated within their area of responsibility and maintained on Datix.

Incidents must be processed within the following time scales:

Incident status on Datix	Timescale
Incidents awaiting acknowledgement	10 days
Incidents with open investigation	30 days
Incidents awaiting sign off / closure	15 days

12.1 The divisional governance team and divisional/department manager may approve and close incidents when they are satisfied that:

- The incident has been recorded accurately on Datix including incident description, location, categorisation, details of any equipment/medication involved and the details of the person(s) affected and staff involved (and their role i.e. participant/person reporting the incident);
- There is no person identifiable information within the free text fields
- Key incident documentation has been uploaded (including statements, completed analysis tools, investigation reports/action plans, etc.).
- The incident harm has been accurately recorded
- In approving an incident, staff should be satisfied that root causes have been clearly identified and documented, learning should be articulated clearly and shared appropriately and any changes to practice should be evaluated to confirm the risk of repetition has been minimised and no other hazards have been created or existing controls weakened.

On closing the incident email notifications will be sent to the incident reporter providing feedback

13 Staff Support for those involved in the incident

It is essential that all investigations are conducted in a manner that is demonstrably

supportive to those involved. The process must be about listening, learning and improving.

This will include:

- Providing those who are involved in the investigation with a full account of the reasons for the investigation,
- Giving staff involved in an incident an opportunity to talk to the lead investigator and ensuring that they are kept informed of progress
- Any findings of the investigation and response to third parties must be shared with those who were involved in the investigation.

The welfare of any staff involved in an incident must be considered particularly in relation to psychological trauma or stress.

Such support may take different forms depending on the type of incident and the level of involvement of the staff member or the personal injury (physical or mental) suffered by the individual. Support may include:

13.1 Personal Debrief

The personal debrief is where the manager and the staff member involved sit in private and discuss the incident in an uncritical atmosphere.

13.2 Confidential care

All staff should be made aware of the Confidential Care service available. If staff require further support line managers can refer the individual for counselling (via Occupational Health) if it is appropriate.

Please see the Work Related Stress Management, Staff Mental Wellbeing and Resilience Policy and Procedure for further guidance

13.3 Doctors in training who are involved in an SI

Any serious incident reported to the SI Team which involves a doctor in postgraduate training (trainee) at any level must also be reported to the Medical Director, Director of Medical Education (DME) and Medical Education manager. The Medical Education team can ensure the educational and clinical supervisors of the trainee are informed and can start to put in place appropriate support to the trainee as soon as possible. It is likely the relevant educational and clinical supervisors working in the department or division will be aware of the incident and any trainee's involvement.

A discussion with the Medical Director, with the DME, educational supervisor and Clinical Director and/or Divisional Manager about whether the trainee can continue to work or needs time off should happen soon after the incident is declared.

14 Communication with many affected individuals

It is acknowledged that on occasions, particularly where many patients have been involved or the incident has come to light some months later, it may not be possible to inform the individuals affected, although it will be the responsibility of the Divisional Management Triumvirate to ensure every effort to do has been demonstrated. Please refer to the Duty of Candour (Being Open) policy for further information.

There may be circumstances where there are multiple enquiries needing to be responded to, or a complex, high profile incident needing well-coordinated action planning and implementation. In these events hotline arrangements will be implemented.

15 Training

Risk Management training is incorporated in the Trust mandatory training programme as part of the Health and Safety module. This includes incident reporting and management. Additional training regarding incident reporting and management is available to all staff and training sessions are held regularly on all sites.

A Root Cause Analysis training programme is in place for all staff that is responsible for investigating incidents.

16 Serious Incident Review Group (SIRG)

It is the responsibility of the divisional management team to take ownership of the action plan(s) resulting from a Learning Review (STEIS Reportable) and ensure the implementation is closely monitored. For cross Divisional issues, the action plans will be disseminated to the Divisional Management Teams with specific reference to the actions to be taken within each Division and what action is being taken at a Corporate level.

For all Learning Review (STEIS Reportable) investigations the Divisional Management Team, where the incident occurred, will be responsible for presenting the action plan at Serious Incident Review Group.

The Divisional Management Teams are responsible for ensuring the actions are developed to address the issues identified in collaboration with the staff members responsible for the implementation of the actions. The plans must be SMART (specific, measurable, achievable, relevant and timed) indicate the actions to be taken, the timescale for the actions to be completed, the relevant leads for the actions and any update on progress.

The Divisional Management Teams must identify a named individual in the Division with overall responsibility for monitoring the action plan and ensuring that the actions

are completed within the agreed timescales.

The action plans should also indicate who has given over-all divisional sign off, and which divisional group the action plan will be monitored at.

Effective and timely implementation of actions is required to ensure that lessons are learned following a serious incident requiring.

17 WHHT Commissioned Services provided by independent and third parties

Where a serious incident (SI) or Never Event (NE) has been identified by an independent provider or third party and notified to the Trust, the process will be to agree (the investigation) through their internal process and cross-referenced with WHHT's Serious Incident review panel process.

Contracts:

The process for reporting incidents and complaints must be stated in the contract between WHHT as commissioner and the service provider. In addition, clarity in above regarding roles and responsibilities as follows:

Following the outcome of the SI panel meeting, the provider as commissioned will be expected to follow their internal governance arrangements for investigation and reporting. This includes:

1. Provider notifies WHHT regarding possible SI or Never Event

2. Submission of the 72-hour report of the incident to the Trust.

3. Report on STEIS where applicable

4. Actions taken and key lead and duty of candour lead candour to ensure that the patient or relative/family have been fully informed and any other information as appropriate

5. Make official request for information where that patient had contact with Trust after treatment.

6. The process for investigation and report submission will align with the providers governance arrangements. However, the Trust will expect the report to be submitted within the national framework timescales.

7. A review will be undertaken by the trust, and as appropriate, any further clarification or discussion will take place.

As the commissioner WHHT will:

- Review the process and go back to the provider should further information be required
- The action plan will be monitored through SIRG

The Quality Facilitator for Outsourcing and Contracts will have centralised oversight of this process and ensure liaison between all departments involved.

To close a never event and SI, it is anticipated that all action plan evidence be submitted to the trust for review at SIRG meeting.

18 Liaison with other interested parties

18.1 Official bodies

It is the responsibility of the Chief Nurse / Medical Director to determine whether external bodies are to be involved in the investigation, based on the detail of the incident itself. It will be the responsibility of the Lead Investigator to inform and involve any organisation as appropriate; this may include one or more of the following:

- Professional body, e.g. NMC, GMC, HCPC
- Health and Safety Executive
- Healthcare Safety and Investigation Branch (HSIB)
- GPs (particularly if the incident involves many patients), NHS England, CCG, other NHS Trusts and DH where applicable.
- NHS Resolution/ Trust legal Advisors
- Police/ Coroner/ Social Services
- Medicines and Healthcare products Regulatory Agency
- Public Health Bodies (e.g. SHOT, MHRA)
- Local Supervising Authorities for a maternal death
- Child Protection Agency
- The Clinical Commissioning Group
- The NHSE/I and Integrated Care System ICS

N.B: This list is not exhaustive

19 Communications with Media

In circumstances where there is actual or anticipated media interest in an incident, then the Serious Incident Lead Investigation Officer is responsible for informing the Director of Communications.

The Director of Communications will be responsible for dealing with the Trust's response to the media, in conjunction with the Chief Executive and the Communications team.

It will be the responsibility of the Director of Communications to make every effort to ensure staff are briefed on how to deal with the media if they should be approached.

20 Evaluation measures

20.1 Monitoring- **Monitoring & Compliance**

What key element(s) need(s) monitoring as per local approved policy or guidance?	Who will lead on this aspect of monitoring? Name the lead and what is the role of the multidisciplinary team or others be if any.	Which tool will be used to monitor/ check/ observe/ Assess/ inspect/ authenticate that everything is working according to this key element from the approved policy?	How often is the need to monitor each element? How often is the need complete a report? How often is the need to share the report?	What committee will the completed report go to?
Element to be monitored	**Lead**	**Tool**	**Frequency**	**Reporting arrangements**
Monitoring of continuous and improved incident reporting, harm resulting from incidents and learning from incident investigation.	Head of Patient Safety/Serious Incident Investigation Lead	Month Integrated Performance Report	Monthly	Trust Board
	Head of Patient Safety /Assurance and Compliance Lead	Quality and Safety Integrated Performance Report	Bi-monthly	Safety and Compliance Committee
	Risk Lead and Datix Manager	National Reporting and Learning System uploads and feedback reports	Weekly	Quality and Safety Group
	Divisional Management Triumvirate	Divisional Quality Governance reports	Monthly	Quality and Safety Group
Monitoring of serious incidents required a learning review (STEIS reportable) or a learning review (divisional) being escalated appropriately, thorough and timely investigation completion, learning identified, implemented and evidenced	Head of Patient Safety/Serious Incident Investigation Lead	Annual Report SIs and Never Events	Annual	Quality and Safety Group
	SI Investigation Lead	Serious Incident Review Group	Bi-monthly	Quality and Safety Group (included in Annual Report SIs and Never Events)

20.2 Review

This policy will be update in accordance with changes to external guidance or following internal process change in response to audit results/recommendations or self-assessment of the process.

21 Equality Impact Assessment Statement

West Herts Hospitals NHS Trust has made every effort to ensure this policy does not have the effect of discriminating, directly or indirectly, against employees, patients, contractors, or visitors on the grounds of race, colour, age, nationality, ethnic (or national) origin, gender, sexual orientation, marital status, religious belief or disability. This policy will apply equally to full and part time employees.

22 References

- Care Quality Commission - Updated guidance on meeting the duty of candour, Published: 11 March 2021, https://www.cqc.org.uk/news/stories/updated-guidance-meeting-duty-candour, accessed 19 August 2021
- Health and Safety Executive: RIDDOR - Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013
- National Framework for Serious Incidents Requiring Investigation (2010)
- National Patient Safety Agency: Being Open: Communicating patient safety incidents with patients and their carers (2005)
- NHS England Revised Never Events policy and Framework 2018
- NHS England Serious Incident Framework 2015
- NPSA Information Resource to support the reporting of Serious Incidents (2010)
- Root Cause Analysis Toolkit National Patient Safety Agency (2004)
- Seven Steps to Patient Safety National Patient Safety Agency (2004)

23 Related Policies

- Duty of Candour Policy
- Health and Safety Policy
- Safeguarding Adults from Abuse Policy
- Safeguarding Children, Young People and Unborn Babies Policy
- Work Related Stress Management, Staff Mental Wellbeing and Resilience
- Policy and Procedure
- Information Governance Management Framework

24 Equality Impact Assessment

		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	
	Disability - learning disabilities, physical disability, sensory impairment and mental health problems	No	
	Marriage & Civil partnership	No	
	Pregnancy & maternity	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?	NA	
4.	Is the impact of the policy/guidance likely to be negative?	No	
5.	If so can the impact be avoided?	NA	
6.	What alternatives are there to achieving the policy/guidance without the impact?	NA	
7.	Can we reduce the impact by taking different action?	NA	

If you have identified a potential discriminatory impact of this procedural document, please refer it to the Associate Chief Nurse, Quality Assurance, 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 the Associate Chief Nurse, Quality Assurance.

25 Policy and Procedure Sign-off Sheet

Policy Name and Number: Incident Reporting (Inc. Serious Incidents) and Management Policy **Version Number and Date:** February 2021 **No:** 15 **Service Location: Corporate Services** **All staff members must sign to confirm they have read and understood this policy.**			
Name	**Signature**	**Name**	**Signature**

26. Policy Ratification Form

Name of Document: Incident Reporting (Inc. Serious Incidents) and Management Policy

Ratification Date: tbc

Name of Persons	Job Title	Date
Divisional Support (Direct Line Manager / Matron / Consultant / Divisional Manager)		
Consultation Process (list of stakeholders consulted / staff groups presented to)		
Executive Team Divisional Directors Divisional Managers Heads of Nursing Quality Governance Facilitators Quality Governance Team Information Governance Team Health and Safety Manager Safeguarding Team		
Endorsement By Panel/Group		
Name of Committee	**Chair of Committee**	**Date**

Document Checklist		Yes / No
1.	Style & Format	
	Is the title clear and unambiguous?	Yes
	Is the font in Arial?	Yes
	Is the format for the front sheet as per Appendix 1 of the policy framework	Yes
	Has the Trust Logo been added to the Front sheet of the policy?	Yes
	Is it clear whether the document is a guideline, policy, protocol or standard operating procedure?	Yes
2.	Rationale	

Document Checklist		Yes / No
	Are reasons for development of the document stated?	Yes
3.	Content	
	Is there an introduction?	Yes
	Is the objective of the document clear?	Yes
	Does the policy describe how it will be implemented?	Yes
	Are the statements clear and unambiguous?	Yes
	Are definitions included?	Yes
	Are the responsibilities of individuals outlined?	Yes
4.	Evidence Base	
	Is the type of evidence to support the document identified explicitly?	Yes
	Are key references cited?	Yes
	Are supporting documents referenced?	Yes
5.	Approval	
	Does the document identify which committee/group will approve it?	Yes
6.	Review Date	
	Is the review date identified?	Yes
	Is the frequency of review identified? If so is it acceptable?	Yes
7.	Process to Monitor Compliance and Effectiveness	
	Are there measurable standards or Key Performance Indicators to support the monitoring of compliance with and effectiveness of the document?	Yes
	Is there a plan to review or audit compliance with the document?	Yes

Name of Person completing Ratification Form	**Job Title**	**Date**

Ratification Group/Committee	**Chair**	**Signature**	**Date**
Quality & Safety Group			

27. List of appendices available on the Quality Governance intranet page:

Appendix 1: Incident / Serious Incident process flow chart

Appendix 2 Levels of Harm in Relation to Duty of Candour (Being Open)

Appendix 3 Full list of staff responsibilities

Appendix 4 Never Events List 2018 (updated February 2021)

Appendix 5 Flow Chart for Notifiable Safety Incidents, CQC Duty of Candour Notifiable Safety Incidents April 2021

Appendix 6 Notifiable Safety Incidents Examples

Appendix 7 Scoring the harm resulting from an incident flow chart

Appendix 8 Incident investigation tool kit

28. Appendices

Appendix 1 – Incident / Serious Incident process flow chart

A simplified version of the flow chart is available on page 4 of this policy, for the full version please see the Quality Governance intranet page or follow this link.

Appendix 2 - Levels of Harm in Relation to Duty of Candour (Being Open)

The table below sets out the thresholds and details of harm levels for being open and duty of candour in relation to harm caused to a patient.

Harm assessment	Impact on patient	Communication process
No harm	No impact	Being Open Record conversation on patient records
Minor harm	Requires additional monitoring, minor intervention or will require up to a week to heal the injury	Being Open Record conversation on patient records
Moderate harm	Harm that requires increase in treatment; prolonged pain or psychological harm. harm that requires a moderate increase in treatment (e.g. unplanned return to surgery, an unplanned re-admission, a prolonged episode of care, cancelling of treatment or transfer to another treatment area (e.g. ICU) significant but not permanent harm	Duty of Candour
Prolonged pain or psychological harm	pain or psychological harm which a patient has experienced or is likely to experience for a continuous period of at least 28 days	Duty of Candour
Severe harm	a permanent lessening of bodily, sensory, motor, physiological or intellectual functions, including removal of the wrong limb or organ or brain damage, that is related directly to the incident and not related to the natural course of the service user's illness or underlying condition.	Duty of Candour
Death	Death	Duty of Candour

For more details on the Duty of candour process, please refer to Duty of Candour Policy WHHT: G003 version 5

Appendix 3 – Full list of staff responsibilities

Responsible staff/group	Description
All staff	Employees' responsibilities: each employee has a duty to report an accident, incident or near miss involving a patient, visitor or staff member to their manager as soon as is reasonably practicable after the incident.
Chief Nurse	The Chief Nurse has Executive responsibility for Quality Governance and as such reports directly to the Board and the Chief Executive on all matters relating to this.
Medical Director	The Medical Director has Executive responsibility for Risk Management and Serious Incidents and as such reports directly to the Board and the Chief Executive on all matters relating to this.
Head of Patient Safety	The Head of Patient Safety is responsible for ensuring that systems and processes relating to incident reporting and investigation are fit for purpose and are implemented in practice. Where they are not, to make recommendations as appropriate to the Quality and Safety Group, Safety and Compliance Committee and the Board.
Managers	Promoting an open and fair culture of incident reporting and investigation.
Quality Governance Facilitators	Oversee and review general incident handling as well as the management of individual incidents to ensure they are appropriately reported, investigated and actions are closed in a timely manner on a weekly basis. Advise, assist and support all staff in their division to manage incidents and determine severity and risk scores appropriately. Provide final approval/closure to incidents on Datix (in conjunction with Matrons and divisional triumvirate management), ensuring that quality checks are undertaken including: the severity, risk score, duty of candour, and categorisation of incidents and the removal of patient identifiable in the description field. To ensure duty of candour compliance is documented on Datix as required. To facilitate (in conjunction with Matrons and divisional triumvirate management) the provision of feedback to staff regarding all incident themes, actions and learning, to support continuous and measurable improvement in the

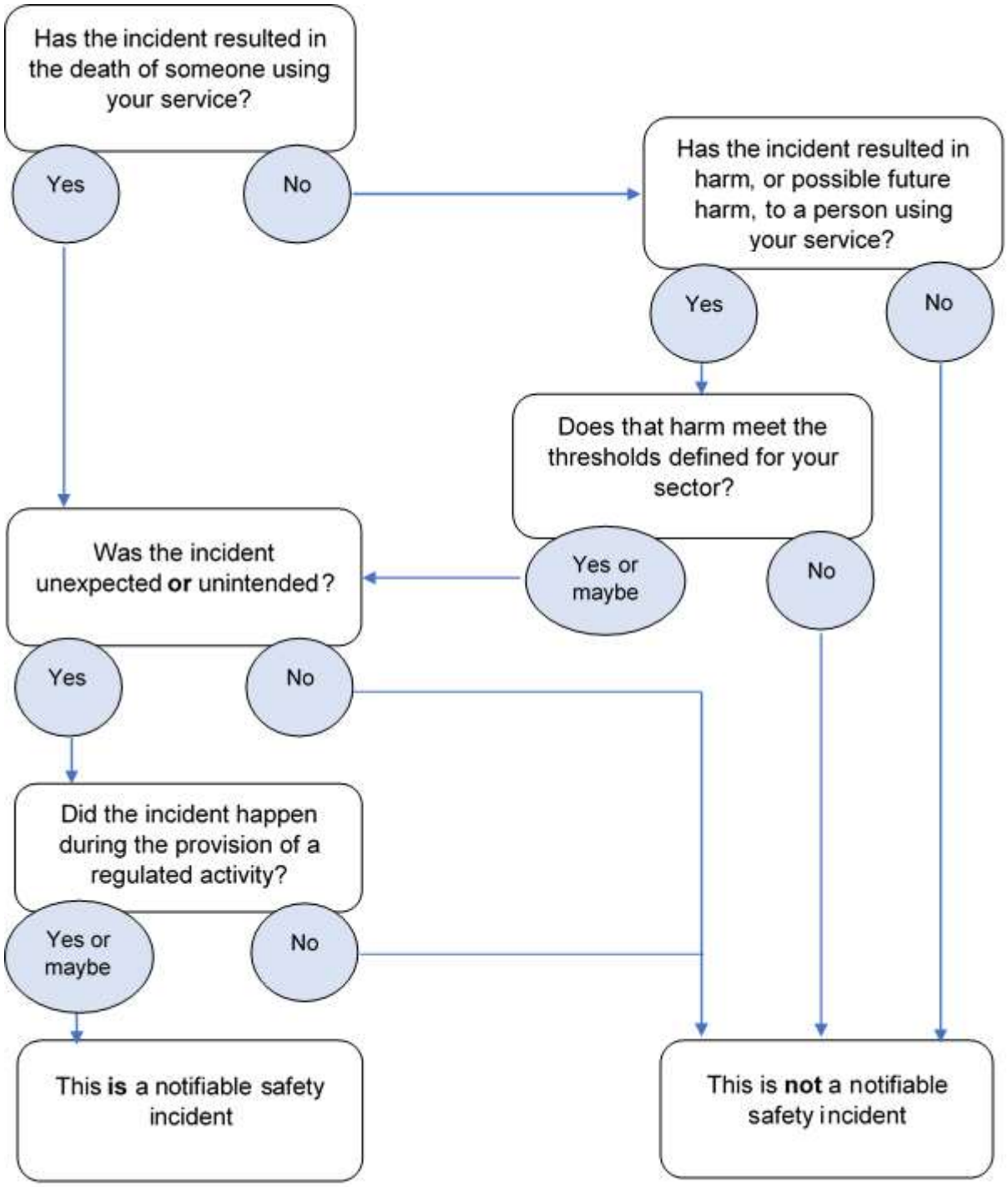
	quality of services provided.
Incident investigator	Any member of staff (not exclusive to clinical staff) may be appointed to an incident handler/investigator. Incident handler/investigators are responsible for reviewing all incidents allocated to them within 2 working days and when required ensuring they are re-assigned to an alternative relevant Incident handler/investigator from the drop down list on the incident form. Incident handler/investigator will review the harm and categorisation of each incident, to determine the accuracy and the potential need to escalate further if felt the incident potentially meets SI/never event criteria. An Incident handler/investigator is responsible for carrying out an investigation into an incident adhering to this policy and ensuring that recommendations are provided to the appropriate individuals and forums. To provide feedback or learning across their area of responsibility.
Serious Incidents Lead/ Investigator	The Serious Incident Investigation Lead and Investigators are responsible for the day to day practice of reviewing all incidents raised on Datix as Potential SIs, applying the serious incident criteria to determine whether a discussion at the learning review (SI) panel is required, for ensuring that the process for declaring, investigating and reporting of learning reviews (StEIS reportable) is reflective of local the policy and meets the expectations of the Trust, and the national Serious Incident framework.

- **Appendix 4 - Never Events List 2018 (updated February 2021)**

  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. For a full list of Never Events please follow this link.

Appendix 5 Flow Chart for Notifiable Safety Incidents

CQC Duty of Candour Notifiable Safety Incidents April 2021



Appendix 6 Notifiable Safety Incidents Examples

(CQC Notifiable Safety Incidents March 2021)

MATERNITY

What happened?

A woman in an NHS hospital experienced pain during an elective caesarean section. She found this experience traumatic and subsequently had an acute episode of severe anxiety and depression that lasted more than 28 days. It was discovered that she had been not receiving enough anaesthesia from an epidural line.

Does this qualify as a notifiable safety incident?

Was the incident unexpected or unintended?

Yes. The incident was both unexpected and unintended.

Did it occur during provision of a regulated activity?

Yes. The incident occurred while the woman was receiving care under the regulated activity 'maternity and midwifery services'.

Has it resulted in death or severe or moderate harm?

Yes. The incident has resulted in “prolonged psychological harm” (psychological harm lasting more than 28 days).

The woman was receiving care in an NHS hospital so the harm definitions in Regulation 20(8) apply. If the maternity care had been delivered in an independent hospital, Regulation 20(9) would apply instead.

Conclusion

The answers to all three questions are 'yes'. So this qualifies as a notifiable safety incident. And all steps outlined in the duty of candour (Regulation 20) should be carried out.

SURGERY

What happened?

An elderly woman undergoes a coronary artery bypass operation. She has given appropriate consent for the risks of the operation, including for stroke and death. Unfortunately, the woman suffers a large stroke during the operation and dies as a result.

Does this qualify as a notifiable safety incident?

Was the incident unexpected or unintended?

Yes. The incident was a possible risk of the operation, and as such her consent was sought; however the incident was still unintended.

Did it occur during provision of a regulated activity?

Yes. The incident occurred during provision of the regulated activity 'Surgical procedures'.

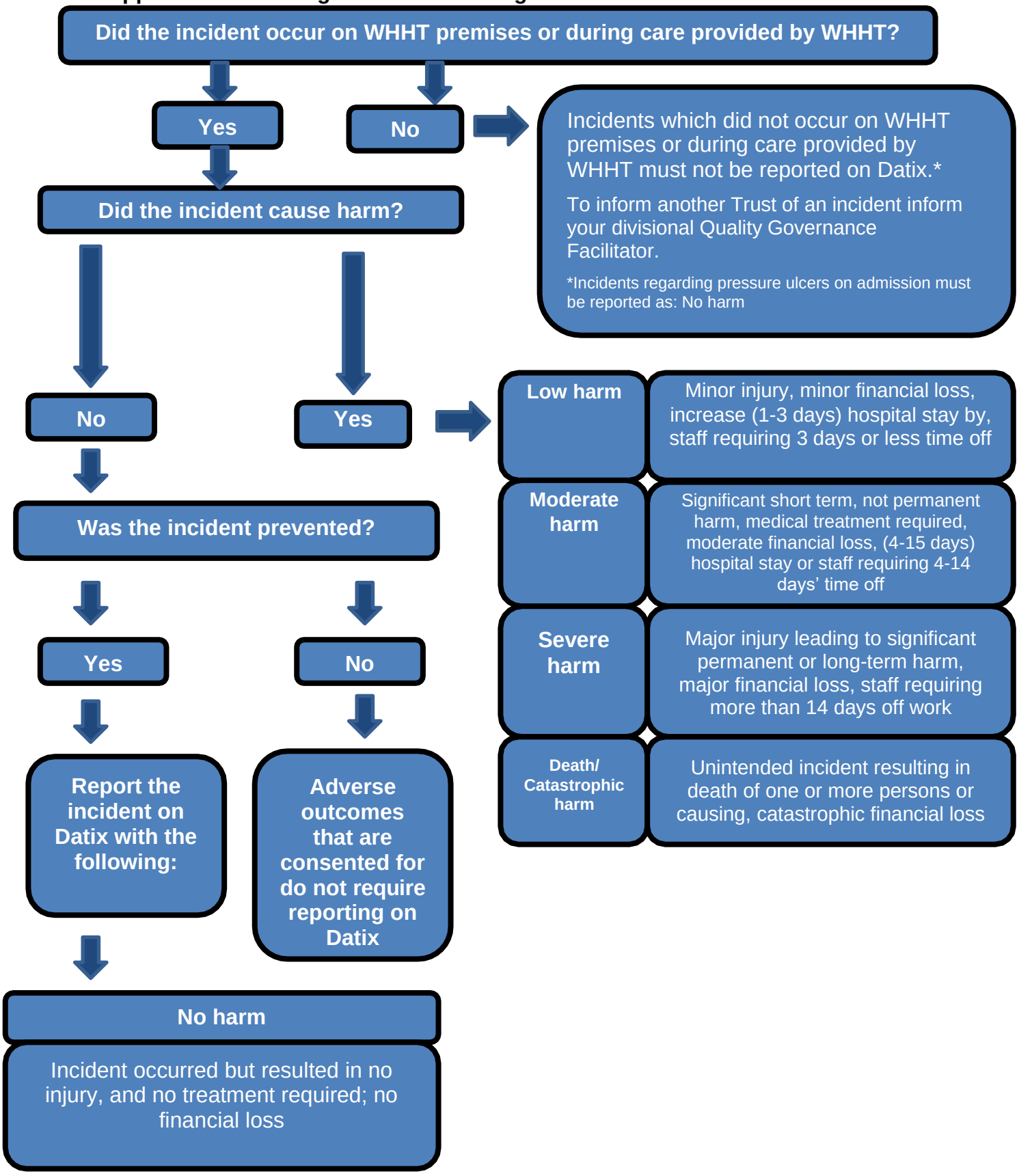
Has it resulted in death or severe or moderate harm?

Yes. The incident resulted in death. The woman was receiving care in an NHS hospital so the definitions in Regulation 20(8) apply. The incident resulted in death.

Conclusion

The answers to all three questions are 'yes'. So this qualifies as a notifiable safety incident. And all steps outlined in the duty of candour (Regulation 20) should be carried out. Note that on the facts provided in this example, there is no suggestion of error or fault on the part of the provider. But neither is required for something to qualify as a notifiable safety incident.

Appendix 7 – Scoring the harm resulting from an incident flow chart



- **Appendix 8 – Incident investigation tool kit (available on the Quality Governance intranet page):**
    - Incident Management flow chart (full version)
    - NPSA Risk Matrix
    - Duty of Candour Leaflet
    - Duty of Candour handout
    - Duty of Candour letter template – initial letter
    - Duty of Candour letter template – report letter
    - Investigation report template
    - Guidance for requesting factual accounts
    - Factual account template
    - General advice for staff on writing factual accounts
    - Guidance on investigative interviews
    - Time line template
    - Five why's tool
    - Fishbone diagram
    - Contributory factors framework
    - Guidance to RCA Investigative report writing