COR/POL/041/2018-001

TRUST CORPORATE POLICY
ADVERSE INCIDENTS POLICY

APPROVING COMMITTEE(S)	Trust Policies Committee	Date approved:	26/07/18
EFFECTIVE FROM	Date of approval		
DISTRIBUTION	All Managers via Trust Bulletin		
RELATED DOCUMENTS	Duty of Candour COR/POL/075/2016-001 Whistleblowing Policy COR/POL/005/2018-001 Claims and Inquests Policy COR/POL/078/2015-001 Complaints Policy COR/POL/042/2016-001 Risk Management Policy COR/POL/004/2018-001 Responding to Deaths Policy COR/POL/224/2017-001 Prevention and Management of Needlestick, Sharp Injury and Exposure to Body Fluids Policy. Information Governance COR/POL/020/2014-001 Incident Management. Using Datix: How to manage incidents in Datix after they have been reported. Central Alerting System (CAS) Policy. Management of Medical Equipment Policy		
OWNER	Chief Nursing Officer		
AUTHOR/FURTHER INFORMATION	Patient Safety and Quality Advisor		
EXTERNAL REFERENCES	Serious Incident Framework March 2015 Never Events Policy Framework 2018. 7 Steps to Patient Safety. NPSA 2004. A Just Culture, NHSI 2018	Refer to: NHS Improvement	
SUPERCEDED DOCUMENTS	Adverse Incident Policy (COR/POL/041/2017-001)		
REVIEW DUE	3 years from approval		
KEYWORDS	Incident; Serious Incident; Datix; Reporting; Never Event; Duty of Candour, Just Culture, patient involvement, death, Inquest Hearing, Coroner, National Reporting and Learning System (NRLS), Serious Case Review, safeguarding, harm, near miss, StEIS		
CONSULTATION	Clinical Governance Group Site Medical Directors and Directors of Nursing Site Quality and Safety Leads CSS Director of Quality Performance		

	Education Academy Tissue Viability Team Medicines Safety Team Head of Health and Safety. Trust Risk Manager Trust Legal Team. Information Governance Medical Engineering Approved at Quality Board
INTRANET LOCATION	

	For the groups listed, compliance with this policy is a contractual requirement and failure to follow the policy may result in investigation and management action which may include formal action in line with the Trust's disciplinary or capability procedures for Trust employees, and other action in relation to organisations contracted to the Trust, which may result in the termination of a contract, assignment, placement, secondment or honorary arrangement.
	All individuals working in the Trust, in whatever capacity, including those employed by the Trust's private sector partners providing Facilities Management services and including those who have been seconded to work for its private sector partners under Retention of Employment (RoE) arrangements. CHL and its Service Providers are therefore expected to comply with this policy No staff groups working within the Trust are exempt from this policy.

WeConnect Digital Programme

In October 2019, every Trust clinical policy was reviewed to determine if it would be impacted due to the We Connect Digital Programme and the digital development of nursing documentation, electronic prescribing and physician documents.

<u>This policy is one such policy which has been changed accordingly.</u>

Therefore, please note that information regarding the patient will be entered into the individual electronic patient record on Millennium. In the event of downtime to Millennium, the Trust will revert to downtime procedures as defined in individual department business continuity plans.

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ADVERSE INCIDENT POLICY

1. INTRODUCTION AND AIMS

1.1. This policy relates to incidents that could have or did, lead to harm or loss to patients, staff, visitors, contractors or the Trust itself.

1.2. It describes the processes through which Trust employees are required to report incidents, serious incidents and near misses (prevented safety incidents), the management actions which must be taken when any such incident occurs, and the approach used by the Trust to investigate and learn from incidents and to disseminate this learning throughout the Trust and the wider health community

1.3. The purpose of this policy is to ensure that all incidents are appropriately reported, managed and investigated and that learning takes place after incidents occur to minimise risk of recurrence. This policy outlines the process by which incidents are managed, from the point of identification to the implementation of all recommendations from investigation reports. It:

- Defines an incident, near miss (prevented safety incident), and serious incident (SI).
- Outlines how incidents must be reported, managed and investigated and identifies mechanisms to ensure that all persons involved are appropriately supported.
- Outlines the procedures through which the Trust monitors the development and completion of action plans following incident investigation, and the other measures which the Trust takes to ensure learning as a result of incident investigation

2. DEFINITIONS

Incident	Any event occurring on Trust premises or in the course of work undertaken by Trust staff that could have, or did lead to harm or loss to patients, staff, visitors, contractors or the Trust itself.
Datix	Datix is a risk management system which is utilised by the Trust for the reporting and management of incidents, complaints and claims.
Serious Incident (As defined by the Serious Incident Framework 2015).	• 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.* ☐ Major loss of confidence in the service, including prolonged adverse media coverage or public concern about the quality of healthcare or an organisation. Additional detail regarding management of Serious Incidents can be found at: https://improvement.nhs.uk/resources/serious-incident-framework/
Serious harm	• Severe harm (patient safety incident that appears to have resulted in permanent harm to one or more persons receiving NHS-funded care); • Chronic pain (continuous, long-term pain lasting more than 12 weeks or beyond the time that healing post trauma or surgery should have occurred) or • Psychological harm; impairment to sensory, motor or intellectual function or impairment to normal working or personal life which is unlikely to be temporary (that is, has lasted or is likely to last for a continuous period of at least 28 days).

Near Miss (Prevented safety incident)	Any safety incident which had the potential to cause harm but was prevented, resulting in no harm to patients, staff, visitors or the Trust
Major Incident	A very serious incident in which there are multiple casualties or major risk affecting large numbers of people.
Never Event	Never Events are patient safety incidents that are wholly preventable where guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and have been implemented by healthcare providers. The complete list of never events and criteria can be found at: https://improvement.nhs.uk/resources/never-events-policy-and-framework/
Root Cause Analysis	A problem solving methodology utilised for incident investigation. It fosters a systems-based approach to the analysis process rather than a person centred approach.
StEIS *(Strategic Executive Information System)*	Electronic reporting system used for notification of serious incidents to the Clinical Commissioning Groups (CCGs), North East London Commissioning Support Unit (NELSCU) and NHS Improvement.
Human Factors	The science of enhancing clinical performance through an understanding of the effects of teamwork, tasks, equipment, workspace, culture and organisation on human behaviour and abilities and application of that knowledge in clinical settings Adapted from National Quality Board definition (2013)

* See Serious Incident Framework for additional detail regarding this category.

2.1. Level of harm:

2.1.1. The effects of patient safety incidents go beyond the impact of physical injury itself. Patients and their families may feel let down by those they trusted. The incident may also lead to unnecessary pain, additional therapy or operations and additional time being cared for in the hospital or community. Psychological injuries such as shock, anxiety, depression, fear of future treatment and disruption to work and family life can also occur. (NPSA 2004). These effects apply equally where staff or visitors are harmed through their interaction with the Trust.

2.1.2. The level of harm assigned to an incident should reflect the harm that the Trust itself was responsible for not just the outcome. For example, a patient may come into the Trust with a pressure ulcer but this would be a no harm incident as the patient was not under the care of the Trust at the time the harm occurred. However, if the patient developed a pressure ulcer within our care, this would be an incident with harm.

2.1.3. For the purposes of reporting within the Trust, level of harm is based upon the level of harm that actually occurred not on the level of harm that could have occurred.

2.2. Psychological harm:

2.2.1. Harm can be physical or psychological. For example, psychological distress that required a period of counselling would be moderate harm, and psychological distress that left the individual unable to return to work or resume their normal life would meet the definition of severe harm.

2.2.2. Where the ultimate outcome of an incident is not known at the time of the incident a best assessment should be carried out and if, at a later date, more information is received about the outcome, the incident's degree of harm can be updated.

Harm Categories:	
Death	Any incident that directly resulted in the death. The death must relate to the incident rather than the natural course of a patient's illness or underlying condition.
Severe Harm	The incident caused permanent or long term harm. A permanent or long term lessening of bodily functions, sensory, motor, physiologic or intellectual
Moderate Harm	The incident caused significant but not permanent harm and resulted in a moderate increase in treatment. Moderate increase is defined as: a return to surgery, an unplanned re-admission, a prolonged episode of care, extra time in hospital or additional treatment as an outpatient, cancelling of treatment or transfer to another area such as critical care as a result of the incident.

Low harm	The incident caused minimal harm and required extra observation or minor treatment. Minor treatment is defined as first aid, additional therapy or additional medication. It does not include any extra stay in hospital or any additional treatment as an outpatient, or continued treatment over and above the treatment already planned. Nor does it include a return to surgery or re-admission.
No harm	No harm has occurred and no extra measures (i.e. additional observations). Any safety incident which had the potential to cause harm but was prevented, resulting in no harm to patients, staff, visitors or the Trust. Where a patient presents to the Trust having sustained harm not caused by the Trust.

3. AN OPEN AND FAIR APPROACH

3.1. The Trust is committed to dealing openly and fairly with safety incidents, being transparent with affected parties and offering apologies and explanations if any action by Trust staff has led to harm.

3.2. There is a requirement for staff to ensure that there is clear communication with patients, their families or others involved in adverse incidents. The process for this is described in the Trust's Duty of Candour Policy.

3.3. All Trust staff are accountable to the Trust for their own actions and omissions. Professional staff are also accountable to their various professional bodies.

3.4. When a safety incident occurs, managers are encouraged to evaluate the actions or omissions of individuals and to assess individual accountability. Managers must utilise NHSI's Just Culture Guide to aid decision making regarding the need for any disciplinary action and consult HR in the event that any formal action is considered appropriate. See appendix 5

3.5. Use of a disciplinary process should only be considered in cases where unequivocal circumstances indicate specific individual culpability. If necessary HR investigations can run concurrently with incident investigations

3.6. The Trust is vicariously liable for the acts/omissions of its employees, and as such takes full responsibility in the event of legal action arising from an adverse event. Personal liability only arises if criminal activity is suspected or the member of staff acts outside the course of their employment in the Trust.

4. SUPPORT TO STAFF MEMBERS FOLLOWING AN INCIDENT

4.1. Being involved in an incident may be distressing for staff. Managers are responsible for ensuring that their team is supported and that the support offered is suitable for the individual needs. This will include incidents where staff have:

- Witnessed distressing events;

- Experienced abuse or violence;
- Made errors or taken inappropriate actions resulting in management investigation under Human Resources policies;
- Been involved in treating a patient who died, including those subject to an inquest;
- Been required to contribute to an investigation;
- Been found through an investigation to have contributed, directly or indirectly to circumstances resulting in patient harm.

4.2. Staff are able to access counselling support to talk through any personal or work-related issues by calling the CiC Confidential Care Advice Line: 0800 085 1376. The advice line is open 24-hours a day, 365 days a year, and is staffed by fully trained, experienced and accredited counsellors.

4.3. If a staff member is injured as a result of an incident, then they should be referred to the A&E department or occupational health as appropriate. Staff who suffer an inoculation injury (needlestick, bite, splash or other exposure to body fluids) must follow the Trust Prevention and Management of Needlestick, Sharp Injury and Exposure to Body Fluids Policy.

5. COMMUNICATION OF CONCERNS BY STAFF

5.1. All staff have a duty to report via line management arrangements any concerns that they have about their own practice or that of colleagues, or about any aspect of the operation of the Trust which they feel may lead to adverse consequences. Any person who reports such concerns is entitled to management support in addressing the issues of concern.

5.2. The Trust's Whistleblowing Policy (Raising Concerns in the Workplace) sets out the process to follow if staff feel that they cannot complete an incident form or report an incident or concern to their manager without compromising their own position or that of other people.

6. MEDIA INVOLVEMENT

6.1. All media enquiries about incidents, or incidents which are likely to attract press attention, must be referred to Media Relations or Duty Press Officer out of hours, they will co-ordinate responses or a press release if appropriate. The issue of potential media interest will be discussed at any incident review meeting and Media Relations will be given information proactively where media interest is likely.

6.2. In all cases where information is given to the media, steps must be taken to ensure that any involved individuals (patient/relatives/staff/visitors/contractors) are advised and given information in advance of any public release

7. PROCESS

7.1. Incident reporting

7.1.1. All staff working in the Trust have a responsibility to report any incident that did or could have resulted in harm to patients, staff, visitors or the Trust.

7.1.2. Incidents must be verbally reported immediately to the most senior person on duty and a written report made on the Datix system as soon as is reasonably practicable.

7.1.3. The Datix report should be completed to the fullest extent possible in order to allow an accurate assessment of the report by the incident manager and other

incident reviewers. Where information is not available at the time of reporting, the initial reporter is responsible for responding in a timely fashion to requests for further information once the incident report is submitted.

7.1.4. The most senior person on duty must ensure that any immediate actions necessary to deal with the incident are undertaken. This includes providing information to patients and families as needed in line with the Trust Duty of Candour Policy, providing staff support and if needed, escalating the incident to a more senior member of staff. All such actions should be clearly documented on the Datix record and the patient's healthcare record as appropriate.

7.1.5. If the incident involves a piece of medical equipment the equipment must be removed from use and quarantined along with any associated peripherals and consumables - and ideally left switched on and settings/configuration unchanged. For further information refer to the Management of Medical Equipment Policy.

7.1.6. When a patient related incident is logged on Datix it is good practice to inform the patient and/ or next of kin about the incident and to apologise (as necessary) even if the harm suffered does not meet the threshold for Duty of Candour.

7.1.7. Anonymised patient related incident reports are shared outside the Trust with the National Reporting and Learning Service (NRLS) in order to support nationwide learning. Therefore, personally identifiable data (names etc.) should not be entered into the following sections: incident description or remedial action fields (by the reporter), the action taken or lessons learned fields (by the incident manager) as it is these sections that are shared.

7.2. Incident review

7.2.1. The allocated incident manager must ensure that incident reports are opened and reviewed within 5 calendar days of being reported. Service and divisional leadership teams must ensure that there is a process in place to ensure this occurs in the absence of the allocated incident manager.

7.2.2. Detailed guidance on incident management and the use of Datix is available in the Trust Incident Management Guide which is available on WeShare

7.2.3. Incidents with a harm rating of moderate, severe or death or those reported as Never Events will also be reviewed by the Trust Patient Safety Team and site/ trustwide division governance teams.

7.2.4. In addition specified incidents will be reviewed by specialist Trust advisors (for example medication incidents will be reviewed by the Lead Nurse for Medicines Safety).

7.2.5. Regardless of these specialist reviews the responsibility for review and escalation remains with the incident manager.

7.2.6. Where it is believed that an incident may be a potential serious incident (SI) then an SI proforma should be completed and submitted to: _BHSeriousIncidentsNotification email.

7.2.7. It is recognised that it is not always possible to be certain whether or not an incident meets the SI criteria. Where there is doubt advice can be sought from the site/ divisional governance teams or from the Trust Patient Safety Team. If uncertainty remains or it is not possible to access advice then an SI proforma should be completed and submitted for review.

7.2.8. Further detail on the management of serious incidents can be found in section 9 of this policy.

7.3. Incident Investigation

7.3.1. The incident manager should investigate the incident and then develop and implement any actions necessary to address the issues identified, in order to prevent or reduce the likelihood of re-occurrence.

7.3.2. The investigation findings and any actions taken or planned should be added to the Datix record and sent for final approval within 14 calendar days of the incident being reported.

7.3.3. The incident manager must provide regular feedback to the incident reporter and the other staff involved, of the investigation findings and subsequent actions.

7.4. Final approvals

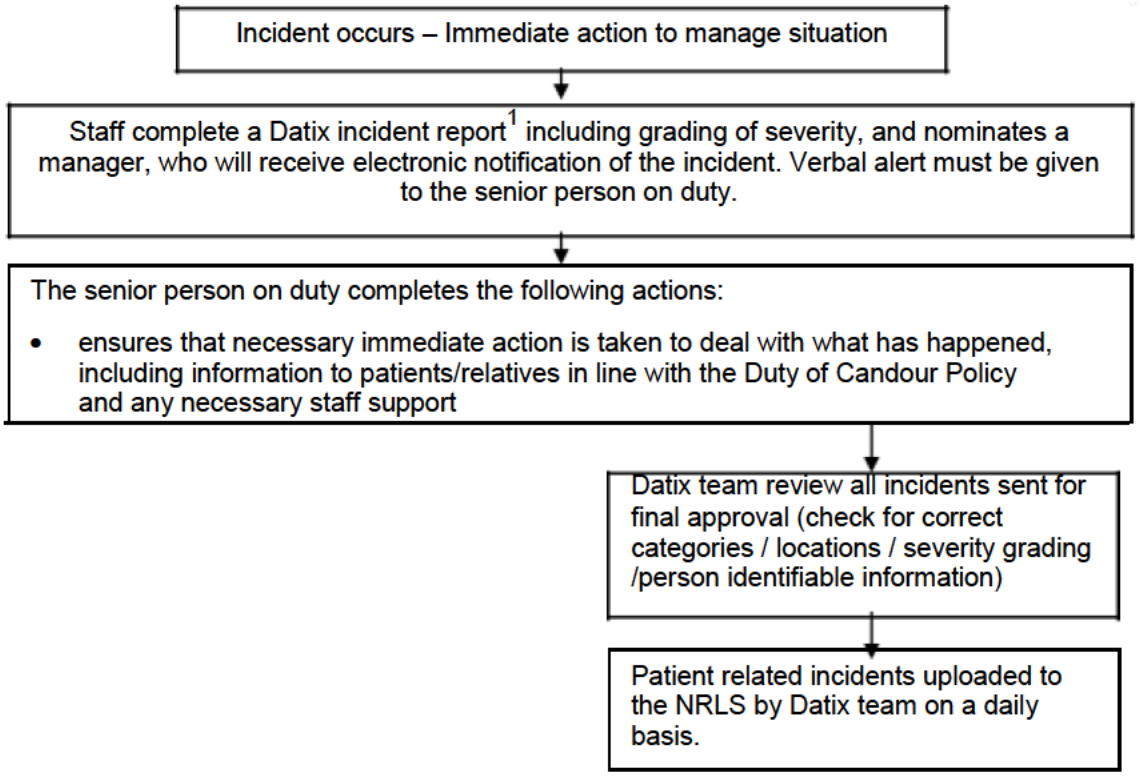
7.4.1. The Trust Datix team will review all incidents sent for final approval and ensure that record details are complete and correct. This will include ensuring that the correct categories, locations and severity grading have been selected and that no person identifiable data is entered into fields that will be shared with NRLS.

7.4.2. Where information is incorrect or incomplete (including if the duty of candour section has not been completed) the Trust Datix team will return the Datix record status to “Being Reviewed” and alert the incident manager to the required amendments.

7.4.3. Where incidents are being managed through other processes, such as the SI process, the incident manager should document the further escalation and submit the report for final approval.

7.4.4. Patient related incidents will be uploaded to NRLS by the Datix team on a daily basis.

7.5. Incident reporting and management



8. SERIOUS INCIDENT MANAGEMENT

8.1. Serious incident identification

8.1.1. The Trust serious incident process is triggered through the submission of an SI proforma to the BHSeriousIncidentNotification email address. SI proformas can be submitted by any member of Trust staff.

Note 1	Staff must complete the electronic incident form found on the Barts Health Trust intranet. If for any reason the electronic system is not available staff must keep note of the incident and report as soon as the system is restored. The incident report should be completed within 24 hours of the incident occurring (if this cannot be done then as soon as possible thereafter). Guidance on completion of the incident form is available on the Trust Intranet
Note 2	Severity grading must indicate the ACTUAL harm that occurred as a result of the incident not the potential harm. Guidance is embedded in the Datix incident form.

8.1.2. When submitting an SI proforma to the BHSeriousIncidentNotification email only the SI proforma should be attached to the email, no other documents should be attached. Care should be taken to maintain confidentiality by entering only the specific biographical information requested in the first part of the form and not including patient, staff or other names in the remainder of the form.

8.1.3. The Trust Patient Safety Team review all incidents with harm rated as moderate, severe or death and those reported as Never Events against the SI criteria and may request that an SI proforma be submitted.

8.1.4. Sites and trustwide divisions (Clinical Support Services (CSS) and corporate divisions) should ensure that there is a process in place to monitor Datix to identify incidents that should be considered under the SI process and request the submission of an SI proforma as required.

8.1.5. Incidents with SI proformas submitted should be tabled for review via the site/ divisional review process.

8.1.6. Where incidents involve or have an impact upon external organisations such as Trust Partners or other health or social care providers they should be informed at the earliest possible opportunity and invited to contribute to the incident review and any subsequent investigation if appropriate.

8.2. Serious incident review

8.2.1. Each site or trustwide division should have in place a robust process for reviewing potential serious incidents. This process should be documented in a standard operating procedure (SOP) and as a minimum must include:

- A multidisciplinary review of the incident (membership of the MDT will depend upon the nature of the incident).
- Meetings scheduled weekly or per incident for sites/ divisions which have too few potential SIs to meet weekly.
- Consideration of any immediate safety actions necessary to prevent or reduce the risk of re-occurance whilst any investigation is ongoing.
- Consideration of whether the incident had or could have an impact on organisations external to the Trust such as other Trusts, GPs, Commissioners etc.
- Provision for a clear audit trail of the review and outcome decision.

8.2.2. The serious incident review outcome should be detailed in an SI briefing to the _SIBriefings email for approval by the Chief Nurse or Chief Medical Officer. The briefing should:

- be presented in an SBAR (Situation, Background, Assessment, Recommendation) format .
- Contain a clear recommendation for management of the incident.
- Record any necessary immediate or remedial actions required or undertaken to reduce the risk of recurrance.
- Detail how duty of candour requirements have been complied with.

8.2.3. The briefing will fulfil the requirements for initial review (usually termed the 72 hour review) unless the incident fulfils one of the criteria referenced in 8.4 where an additional report will be required.

8.2.4 Possible outcomes from the SI review are:

- Manage in Datix – incident is not felt to meet the criteria for a potential SI and should be managed via the usual incident management process.
- Manage via a specific process – (see 8.2.5)
- Internal SI for investigation – incident requires internal investigation but does not meet the criteria for external reporting.
- SI for external reporting via StEIS – meets the criteria for external reporting in the 2015 Serious Incident Framework.

8.2.5 Incidents with specific processes.

- Certain specific incidents have their own management pathway for investigation. These are: pressure ulcers, falls and VTEs. See appendix 1 for details of these pathways.
- Any request to establish a variation on the standard SI management pathway for specific incidents must first be presented to the Clinical Governance Group for review before being approved by Quality Board, in order to ensure a robust and consistent SI process.

8.2.6 The Chief Nurse or Chief Medical Officer should respond to the SI briefing within two working days.The response must be uploaded to the Datix record and the record updated.

8.3. External reporting

8.3.1 Where an incident has been approved for external reporting to Trust Commissioners the details of the incident must be uploaded to the StEIS system within two working days of approval from the Chief Nurse/ Chief Medical Officer.

8.3.2 Reporting on StEIS is completed by the Trust Patient Safety Team but can be delegated to site/ trustwide divisional governance teams with the approval of the Director of Quality Governance.

8.3.3 In the event of delegation of this role the Patient Safety Team is responsible for assuring the timeliness and quality of StEIS reporting by the site/ trustwide divisional governance teams.

8.3.4 Certain incidents have specific reporting requirements over and above reporting on StEIS. Senior staff in relevent services are expected to have an awareness of any specific reporting requirements relevent to that service. For a list of these requirements see appendix 4.

8.4. External communication regarding serious incidents

8.4.1 Some incidents require additional communication with Trust Commissioners and other stakeholders in addition to and prior to them being reported on StEIS. These include:

- Incidents which activate the NHS Trust or Commissioner Major Incident Plan.
- Incidents which will be of significant public concern.
- Incidents which will give rise to significant media interest or will be of significance to other agencies such as the police or other external agencies.
- Never Events (See appendix 2 for details).
- Incidents likely to have significant impact on primary care (accessing results, communication, patient referrals).
- Incidents likely to have a significant impact on Trust performance such as referral to treatment (RTT) times or cancer targets.
- Incidents likely to have an impact upon a large number of patients.
- Very unusual or extreme cases.

8.4.2 In the above instances communication with Commissioners and other external stakeholders should take place as soon as possible after the incident has been recognised and certainly prior to the incident being reported on StEIS.

- Responsibilty for communication of trustwide incidents sits with the Chief Medical Officer or Chief Nurse.
- Responsibilty for communication of site based or networked services incidents sits with the site (or CSS) Medical Director, Director of Nursing or Director of Quality Performance (CSS).

- Responsibilty for communication of corporate services incidents sits with the Director of Quality Governance.

The above responsibilities can be delegated, in the absence of the post holders, to an appropriate deputy.

8.4.3 Incidents that fall into the above categories should receive a more in depth individual review and a 72 hour report template should be completed and submitted to the Trust Commissioners as per the timeline in appendix 2.

8.4.4 The initial review report must be approved by a member of the Trust executive prior to sharing with the Commissioners and therefore sites should allow enough time for the approval process.

8.4.5 Sites and Trust wide divisions must have a process in place to review the above instances in a timely fashion if they occur outside of the timeframe of their usual SI management meetings.

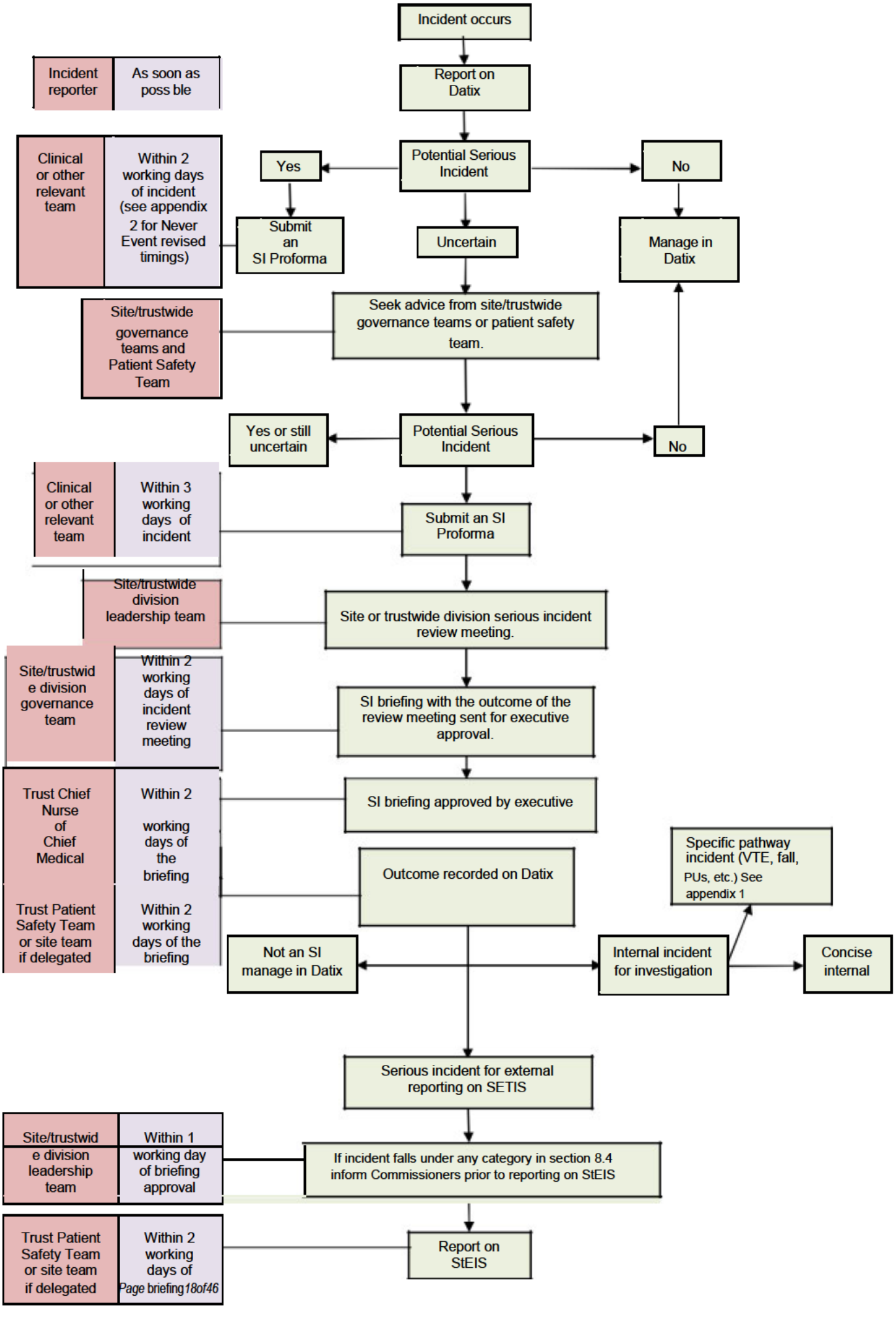
8.5. Personal data breaches

8.5.1 In accordance with the General Data Protection Regulations (GDPR) all breaches of personal data must be reported to the Information Commissioners Office within 72 hours (72 hours in total NOT 3 working days) of becoming aware of the breach, unless it is unlikely to result in a risk to the rights and freedoms of individuals. It is also a contractual requirement of the standard NHS contract to report incidents in accordance with this guidance.

8.5.2 The Security of Network and Information Systems Regulations 2018 (“NIS Regulations”) seek to ensure that essential services, including healthcare, have adequate data and cyber security measures in place to deal with the increasing volume of cyber threats. The Trust is required to inform the ICO of any network and information systems incidents which has ‘significant impact’ on the continuity of the essential service that we provide. Incidents must be reported without undue delay, and in any event within 72 hours of the Trust becoming aware of the incident.

8.5.3 This is in addition to the requirements of this policy. For further information please contact Information Governance or refer to the information Governance Pages on WeShare

8.6. Serious incident reporting process



8.7. Serious incident investigation

8.7.1 The depth of investigation required for a serious incident will be dependent on the severity of events, potential outcome and the opportunity for learning. There are three levels of investigation available:

Level	Application	Templates	Timeframes
Level 1 Concise Internal Investigation	For serious incidents that do not meet the criteria for external reporting under the serious incident framework (SIF). Less complex incidents that can be managed at a local level.	Concise internal Specific RCA templates for pressure ulcers, patient falls, VTE	Completed within 60 working days of executive approval of the SI briefing.
Level 2 Comprehensive Internal Investigation	For serious incidents that meet the criteria for external reporting under the SIF. The principes of objectivity must be upheld when identifying the investigation team. Investigators should not be drawn from the team/ area involved in the incident.	Comprehensive Internal Comprehensive internal (maternity) Specific RCA templates for pressure ulcers, patient falls, VTE.	Completed within 60 working days of reporting on StEIS.
Level 3 Independent Investigation	Required where the integrity of the investigation is likely to be challenged or where it will be difficult for an organisation to conduct an objective investigation internally. The investigator and **all** members of the investigation team must be independent of the provider.	To be agreed as part of the investigation commissioning.	Within 6 months.

8.7.2 Level 1 investigation can be investigated locally by the service concerned. Level 2 investigations should be undertaken by investigators removed from the incident and service concerned in order to maintain objectivity.

8.7.3 The statements in section 8 below relate to level 1 (internal) and level 2&3 (externally reported) serious incidents with the exception of 8.15 and 8.16 which apply only to externally reported serious incidents.

8.8. Involvement of patient and families

8.8.1 There is a legal requirement under the Duty of Candour regulations for the Trust to keep patients (or their next of kin where appropriate) fully informed in the event of the patient being harmed through their interactions with the Trust (see Trust Duty of Candour policy for further details).

8.8.2 In addition to the Trust's obligations under Duty of Candour the Serious Incident Framework (2015) requires NHS healthcare organisations to ensure that patients and their families:

- Are made aware, in person and in writing, as soon as possible of the process of the investigation to be held, the rationale for the investigation and the purpose of the investigation.
- Have the opportunity to express any concerns and questions. Often the patient or family offer invaluable insight into service and care delivery and can frequently ask the key questions.
- Have an opportunity to inform the terms of reference for investigations;
- Be provided with the terms of reference to ensure their questions are reflected.
- Know how they will be able to contribute to the process of investigation, for example by providing evidence.
- Be given access to the findings of any investigation, including interim findings.
- Have an opportunity to respond/comment on the findings and recommendations outlined in the final report and be assured that this will be considered as part of the quality assurance and closure process undertaken by the commissioner (for externally reported incidents).
- Be informed, with reasons, if there is a delay in starting the investigation, completing the investigation or in the publication of the final report; and be offered media advice, should the media make enquiries.

8.8.3 Some parts of these requirements will be met through the Duty of Candour process and as such do not need to be repeated but where they have not been met through Duty of Candour site and trustwide division governance teams must ensure that arrangements are in place to meet them.

8.9. Terms of Reference

8.9.1 The terms of reference for an investigation should be set by the site or trustwide division commissioning the investigation. They may be set at an SI review meeting or after the meeting, following consultation with the service involved, relevant subject matter experts and patient's and family members.

8.9.2 Specific terms of reference may also be requested by the Trust Commissioners, NHSI or other relevant external stakeholders.

8.9.3 Standard terms of reference are included in the Trust serious incident investigation templates. These should be supplemented by the incident specific terms of reference referred to above.

8.10. Commissioning serious incident investigations

8.10.1 Site and trustwide division governance teams are responsible for commissioning serious incident investigations for their areas of responsibility.

8.10.2 This includes:

- Providing the investigator(s) with the terms of reference and relevant template for the investigation.
- Assisting the investigator to identify and secure evidence relevant to the investigation. This includes patient medical records (paper and electronic), identifying staff to interview or request statements from, locating additional Trust records such as training records or audit results.
- Supporting the investigator(s) to identify and access any required subject matter experts.
- Ensuring investigators are aware of the report deadlines. This includes the final 60 working day deadline for submission to StEIS and internal deadlines for draft reports and internal quality assurance processes.
- Ensuring investigators are aware of the support available to them and how to access that support.

8.11. Investigation progress

8.11.1 Each site and trustwide division should have an agreed process for monitoring the progress and completion of serious incident investigations (both internal and externally reported). This should include intermediate deadlines for the investigators to submit draft reports and allow time for site/ trustwide divisional quality assurance processes.

8.11.2 Where an investigation is identified as being at risk of missing the submission deadline this should be escalated at the earliest opportunity to the site/ trustwide division leadership team so additional support can be provided.

8.11.3 Investigators are responsible for communicating with the site/ trustwide division governance teams on a regular basis regarding the progress of the investigation and informing the team if they experience difficulties in progressing the investigation or meeting the required deadlines.

8.12. Final report

8.12.1 The final report should be presented on a Trust approved template unless otherwise agreed with the Patient Safety Team.

8.12.2 It should be written in a way that is accessible and understandable to all readers, remembering that the report is likely to have at least three distinct audiences:

- The patient and/ or next of kin
- Trust colleagues
- Trust Commissioners and other external bodies

8.12.3 It should:

- Include evidence and details of the methodology used for the investigation.
- Identify the contributory factors, root cause(s) and recommendations.
- Ensure that conclusions are evidenced and reasoned and that recommendations are implementable.
- Include an action plan designed to deliver the report recommendations.
- Include a description of how patients and next of kin have been engaged with the investigation process.
- Detail the support provided to patients/next of kin and staff following the incident.

8.13. Action plans

8.13.1 The action plan is the vehicle through which the recommendations from the investigation are delivered. An effective action plan is essential to prevent or reduce the risk of recurrance of an incident.

8.13.2 Action plans should be written using the SMART approach and must:

- Be formulated by those who have responsibility for implementation and delivery of any actions.
- Ensure that every recommendation has a clearly articulated action that follows logically from the findings of the investigation.
- Include a responsible person (name and job title) to take responsibilty for implementation of each action point.
- Have clear deadlines for completion of actions.
- Include a description of the form of evidence that will be available to confirm completion.

8.13.3 Actions should be designed and targeted to significantly reduce the risk of recurrence of the incident. They must target the weaknesses in the system (i.e. the ‘root causes’ /most significant influencing factors) which resulted in the lapses/acts/omissions identified as causing or contributing towards the incident.

8.13.4 A monitoring committee must be identified to monitor the implementation of the actions and to consider the effectiveness of the actions on reducing the risk of recurrance.

8.13.5 Actions from externally reported serious incident investigations are entered onto the Datix action module by the central patient safety team following executive approval of the report. This role can be delegated to site/ trustwide division governance teams with the approval of the Director of Quality Governance. Where this role is delegated, the central patient safety team are responsible for assuring the timely and accurate recording of actions onto the action module.

8.13.6 Sites and trustwide divisions are strongly encouraged to use the action module to record actions from internal investigations in order to allow the monitoring of completion and the effectiveness of the actions. Where the action module is not utilised to record and monitor actions from internal investigations, sites and trustwide divisions must be able to demonstrate an equally robust process is in place.

8.14. Quality assurance and final approval.

8.14.1 Quality assurance processes are required to ensure completion of high quality investigation reports and action plans, to enable timely learning and closure of investigations and to prevent recurrence.

8.14.2 Each site and trustwide division is required to have in place a process of quality assurance prior to the report being sent for final approval.

8.14.3 Internal serious incident investigations (concise investigations) that were not declared externally can be given final approval by the site/ trustwide division leadership team. This could be the site director of nursing, medical director or operational director or their appointed deputies depending upon the type of incident.

8.14.4 Serious incidents that **were** declared externally must be reviewed and approved at site/ trustwide division level as described above prior to being sent to the Patient Safety Team for a final quality assurance.

8.14.5 The process of final quality assurance of externally reported serious incidents can be delegated to site/ trustwide division leadership with the approval of the Director of Quality Governance.

8.14.6 In the event of delegation of this role the Patient Safety Team is responsible for establishing a process to allow the monitoring of the quality of final serious incident investigation reports submitted by the site/ trustwide divisions.

8.14.7 All externally reported serious incident investigation reports must be given final approval at Trust Executive level prior to submission to the Commissioners. Final approval will usually be given by the Chief Nurse, Chief Medical Officer or their appointed deputies.

8.15. Extensions

8.15.1 Externally reported serious incident investigations must be completed and submitted to the Trust's Commissioners within 60 working days. Extensions (maximum 20 working days) can be applied for if they meet the criteria outlined in the 2015 Serious Incident Framework.

8.15.2 The Trust can request extensions to the report submission deadline, but there must be compelling reasons for doing so; for example, new information coming to light which requires further investigation. This must be agreed and confirmed by the appropriate commissioner in advance of the original deadline. Extensions are effective from the day on which the serious incident report was due for submission.

8.15.3 Applications for extensions must be approved by the Chief Medical Officer/Chief Nursing officer. A briefing must be sent to the _SI Briefings email address outlining the following information:

- Datix ID/StEIS ID
- Brief Incident description
- Reason for extension (with reference to the criteria above)

8.16. De-escalations

8.16.1 In some cases a serious incident is reported externally on StEIS but on further review, it transpires that the incident does not meet Serious Incident Framework reporting criteria. In these cases a de-escalation form should be completed and submitted for approval to the Chief Medical Officer/Chief Nursing Officer using the _SI Briefings email address. The Patient Safety Team then submit the form to our Commissioners for approval, the process can take up to 10 working days.

8.16.2 De-escalations should also be considered for any investigation where the final conclusions indicate the incident was not related to Barts Health care/service delivery issues. In these cases, the final report will be submitted to our commissioners and the request will be made at that time.

8.17. Clock stops

8.17.1 There is no automatic bar on investigating incidents where criminal proceedings are underway. Wherever possible, serious incident investigations should continue alongside criminal proceedings. This should be considered in discussion with the police. Following a formal request by the police, a coroner or a judge, the investigation may be put on hold, as it may potentially prejudice a criminal investigation and subsequent proceedings (if any).

8.17.2 Where such a request has been received an email should be sent by the site/ trust wide division governance team to the Chief Nurse and Chief Medical Officer, copying in Patient Safety, to seek their approval to request a clock stop from the Commissioners. Once approved, the request for a clock stop should be sent to the Commissioners.

8.17.3 Once approval is received from the Commissioners, Datix should be updated and the StEIS submission due date removed from the record.

8.17.4 It is the responsibilty of the site/ trustwide division governance teams to ensure that they have a process in place to track clock stopped investigations in order to ensure that the investigation is re-commenced at the earliest opportunity.

8.17.5 Site and trust wide division governance teams are responsible for liaising with the police and the Trust legal team is responsible for liaising with coronors/ judges in order to ensure that the Trust is updated on the progress of the external

proceedings and any significant developments of which the Trust needs to be aware. Any such developments should be shared with the Chief Nurse and Chief Medical Officer.

8.17.6 Once the clock stop has been lifted the Commissioners should be informed and a new submission date agreed. The revised date should be entered into the StEIS deadline date field on Datix.

8.18. Documentation

8.17.1 The Datix record should be the primary repository for communication and documentation related to a serious incident investigation. This allows trustwide access for all staff with the requirement to view the record.

8.17.2 All relevant communcation related to the serious incident should either be attached to the document record or recorded on the serious incident notepad. This includes the SI briefing, executive response and record of external reporting as well as draft reports and evidence of their approval.

8.17.3 The Datix record should provide a clearly auditable record of the process of management of the serious incident.

8.17.4 The responsibilty for ensuring the completeness of the record lies with the site/ trustwide division governance teams and the central patient safety team with each being responsible for recording their parts of the process.

9. LEARNING AND ANALYSIS

9.1. The primary reason for undertaking an incident investigation is to learn from what went wrong so the risk of recurrance can be reduced or eliminated. The Trust has many routes by which it learns from incidents and disseminates that learning.

9.2. The Central Patient Safety Team will produce quarterly reports for Quality Board and the Quality Assurance Committee detailing trustwide trends and will advise on their management.

9.3. Each service, division, network, clinical board, site/ truswide division is expected to include within it's governance remit a review of incidents on a quarterly basis to identify areas of concern. This could relate to numbers of incidents, levels of harm or increasing trends that require exploration.

9.4. Specific trustwide committees, for example the Transfusion, Medicines Safety and Screening committees, are expected to review incidents related to their sphere of practice to identify themes, trends or areas of concern that require action to address them. They are also expected to monitor the completion and impact of the actions identified.

9.5. The Education Academy should use learning from serious incident reports as well as incident, complaints and claims data to review the Trust education offer on a yearly basis. This includes mandatory training as well as other clinical

education. This review will be supported with input from the Patient Safety Team and Sites/ trustwide divisions.

9.6. Central Patient Safety team in partnership with site/ trustwide division governance teams will develop a strategy to disseminate learning from incidents across the Trust.

9.7. Learning from specific incidents

The terms of reference for the site/ trustwide division serious incident review meetings should include consideration of immediate learning or action required to reduce the risk of incidents recurring and its dissemination. Appropriate routes of dissemination include site and departmental safety huddles and safety alerts (site/service specific or trust wide).

Learning from serious incidents (internal as well as external) should be shared with the staff and teams directly involved with the incident. It is preferable for this to be done face to face if at all possible to support personal and team reflection.

9.7.3 The final report should be shared with staff and teams involved and disseminated to other relevant site or service leads to consider if the lessons learned are relevant to them.

9.7.4 Each site/ trustwide division should agree an approach to sharing learning from specific incidents to ensure that the learning is made available to all relavant staff groups. This could be include newletters, learning vignettes or events related to specific incidents or incident trends.

9.7.5 The effectiveness of actions taken is assessed through ongoing monitoring of adverse event trends, and in some cases by local or Trust wide audit.

9.7.6 Where a specific type of incident gives rise to particular concern, it will be referred to a relevant committee / dedicated working group which will be charged with establishing an overarching programme of work to address the risks involved and to ensure that improvements are made. These workstreams will be monitored by the Patient Safety Team (or other specialist team if more appropriate) and included in the annual report on improvement projects.

10. DUTIES AND RESPONSIBILITIES

The Chief Executive	Chief Executive has overall responsibility for ensuring a risk management system is in place and the Trust is managing incidents safely. The Chief Executive will demonstrate commitment to a safety culture and to the Trust's Open and Fair approach. Ensure that all Directors demonstrate the same commitment through their own actions.
Chief Nursing Officer **Chief Medical Officer**	The Chief Nursing Officer /Chief Medical Officer will give approval, following discussion with the PST and relevant Site Leads incidents to be reported externally as an SI The Chief Nursing Officer /Chief Medical Officer (or their nominated deputies) will give final approval for all SI investigation reports.

The Trust Board and the Quality Assurance Committee.	Obtain assurance that the organisation manages incidents appropriately, learns from investigations, minimises harm and seeks to avoid recurrence. Receive and review regular reports on Serious Incidents and associated risk reduction actions.
	Obtain assurance that the Trust is appropriately meeting its responsibilities for patient safety and for providing appropriate care, support and information to persons involved in incidents.
Director Quality Governance	Accountable for the overall effectiveness of the incident process and management of Serious Incidents. Provide support and advice to the Chief Nurse and Medical Director with regard to the SI process.
Patient Safety and Quality Advisor	Provide advice and support to the Director of Quality Governance, Chief Nurse, and Medical Director with regards to the SI process. Provide advice and support to the sites to ensure learning, implementation of change and improvement to enhance safety.
All staff working in the Trust	Protect the safety of patients, visitors, staff members and contractors following any incident Report incidents as set out in this policy and alert the senior person on duty when an incident occurs Contribute to incident investigations when requested to do so.
Site Based Directors	When notified of potential SI: Liaise with Senior Manager / Site Manager and site Governance team to ensure immediate incident management is completed Appoint investigatory team where required Chair initial SI review meeting Provide site approval for report and action plan prior to submission of report for Executive approval Give consideration to whether the actions of any staff members should be reported to a professional body Oversee the monitoring of incidents within the site and ensure that trends or serious incidents are investigated by the site. Participate in the review if SI investigations and reports as part of the SI panel.
Senior Managers/Site Manager	When notified of a potential SI: Assess the situation to ensure that all immediate safety actions have been taken and are documented Liaise between the area in which the incident occurs and the bronze rota manager/site lead as appropriate, documenting all action taken. In the case of incidents involving estates, facilities or equipment, liaise with the appropriate on call team (will vary dependent on hospital site). Where a crime may have occurred, report incident to the

	police. Liaise with site lead and site Governance team to ensure immediate incident management is completed
Senior person on duty	The most senior person on duty at the time an incident occurs is responsible for ensuring that the incident is correctly managed, reported and escalated. They must also ensure the actions taken are clearly documented.
Departmental Managers	Ensure that all managed staff know the correct procedures for incident reporting Discuss incidents reported in their ward/department with their staff. Following any incident report: - Ensure that any necessary immediate safety actions are taken. Ensure that anyone harmed or directly affected by the incident is offered appropriate support, and given information in line with the Trust's Duty of Candour policy. - When nominated as an "Incident Manager", review, grade, update and approve Datix records within 14 days and ensure feedback to the reporter - To undertake an investigation, utilising the RCA methodology and tools available as appropriate, to determine the underlying causes of the incident and to take necessary action to reduce the risk of reoccurrence. - Escalate Serious Incidents as set out in this policy
Patient Safety Team	Provide leadership in relation to incident management and learning Provide training to all levels of staff with regards to incident management and investigation Monitor clinical incidents, provide trend data and analysis. Ensure learning from incidents is identified and shared across the organisation to staff, managers and the Trust Board Provide advice to the sites regarding level of escalation required for incidents Maintain an overview of all reported SIs, to provide updates to the Trust Board, Quality and Safety Committee and Executive leads as required Be the external liaison for all SIs (including reporting SIs on the STEIS database, distribute completed SI reports to NELCSU, liaise with other organisations where there are cross organisation SIs) Provide advice and support to SI investigations as required (including taking on role of lead investigator where appropriate) Liaise with Patient Safety and Quality Advisor , Director of Quality Governance , Chief Nurse, Chief Medical Officer for final approval of SI reports
Site / trust wide division governance	Monitor incidents within their site – ensure appropriate escalation of incidents identified as moderate/severe harm or

teams	death Provide support to the site senior managers and Directors when an SI is suspected with regards to initial management and onward escalation. Administration of telephone conferences and meetings within the SI pathway (including organising and minute taking) Manage the serious incident pathway for SIs originating within their site Ensure investigatory documentation (e.g. statements) are added to the incident record on Datix Provide support to the site senior manager and Leads with regards to the duty of candour process during and following SI investigations Ensure learning from incidents within the site is shared with the PST for onward distribution
Datix management team	Provide support, training and advice regarding the Datix system. Undertake updates to the system as required Provide final approval for Datix incident reports to ensure that information governance requirements are met prior to external reporting of incidents. Liaise with the Patient Safety Team and/or site/ trustwide division governance teams where concerns are identified about incident management. Provide feedback to incident reporters/handlers as appropriate Ensure all patient safety incidents are reported to the National Reporting and Learning System in a timely manner Provide statistical and other reports as required
Health and Safety team	Monitor non-clinical incidents ensuring appropriate escalation to the Health and Safety Executive when required under RIDDOR reporting requirements Provide specialist advice for incident handlers, investigators and SI process as required.
Information Governance Manager	Monitor data security and protection incidents ensuring appropriate escalation to the Information commissioner as required Liaise with the Caldicott Guardian, SIRO and Data Protection Officer as appropriate in relation to any serious incidents which involve information governance issues Provide specialist advice for incident handlers, investigators and SI process as required.
Specialist advisory teams (e.g. medicines safety; infection control; blood	Monitor incidents relevant to specialist area; provide trend data and analysis as required. Offer support to the incident investigation pathway and ensure any necessary reports are made to external

transfusion; clinical physics etc)	organisations Offer specialist advice to Serious Incident investigations, participating in the investigatory process as required.
External contractors / agency staff / students / staff employed by other organisations	Report on the BH Datix system any incident on BH premises or affecting BH patients/staff OR Copy to the BH Datix team any external agency incident report completed in relation to the incident
Public Affairs Officer	Receive and act upon reports in relation to SIs which have an obvious external consequence or are likely to result in media interest. Handle media enquiries in line with the Trust's Media Protocol, preparing media holding statements or briefings where required. Brief press office counterparts and CCGs, NELSCU, NHSE, the DoH, and the press offices of other external agencies where appropriate.
Bronze on call	Provide advice for the site manager when SIs occur out of hours ensuring that all initial incident management actions have been completed. Liaise with Senior Manager on Call/Executive on Call as indicated If the incident is likely to attract media attention, notify the on-call member of the press office Brief site Leads on any out of hours SI
Senior Manager on Call/Executive on Call	Out of Hours only: Immediate notification of NHS England where an SI of particular gravity has occurred. Provide support and advice to Bronze on call as necessary

11. MONITORING THE EFFECTIVENESS OF THIS POLICY

Issue being monitored	Monitoring method	Responsibility	Frequency	Reviewed by and actions arising followed up by
Completeness of incident reporting	Analysis of reporting levels and types of incident reported	Risk Systems Team	Monthly	Site Quality and Safety Committees
Reporting to External agencies	Audit of external agency reporting	NELSCU	Monthly	Trust QB

SI themes; volume; compliance with investigation time limits; completion of action plans	SI performance and issues report	Patient Safety and Quality Advisor	Quarterly	Trust QB
Completion of action plans arising from incident investigation	Report to Site Q&SC (or equivalent board)	Site Governance Managers	Monthly	Site Q&SC
Training	(as set out in Statutory and Mandatory Training Policy)			

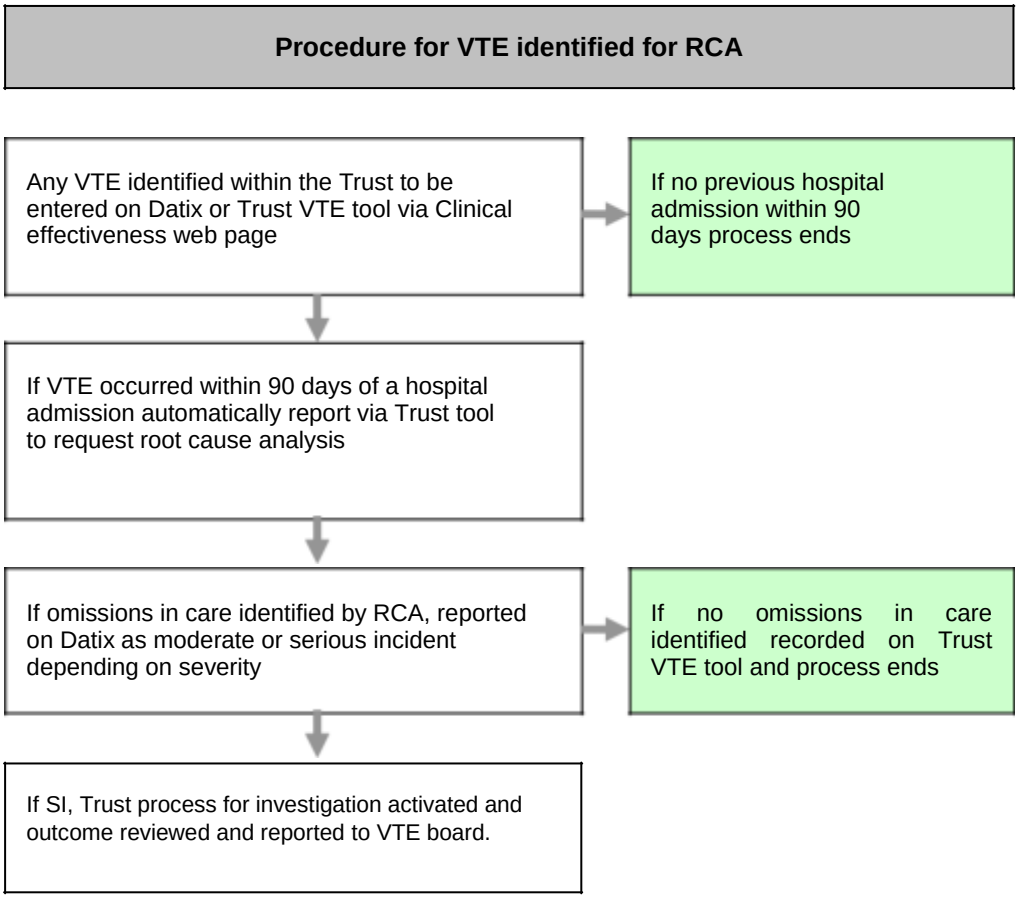
Change Log – Access and Management – Referral to Treatment		
Substantive changes since previous version	**Reason for Change**	**Author & Group(s) approving change(s)**
Standard paragraph inserted at start of policy on 23 October 2019.	All Trust clinical policies have been reviewed by the Interim Trust Policies Manager and Head of Quality Standards in relation to electronic records relevant to We Connect Go Live. Of the Trust's 250+ policies, a total of 74 clinical policies were identified as referring to clinical record keeping. These policies require minor amendment to reflect recording details into the Millennium system rather than into paper documentation.	Trust Policies Committee under Chairs Action.

APPENDIX 1 - INCIDENTS WITH SPECIFIC INVESTIGATION PATHWAYS

Some incidents have specific pathways/ processes for investigation. These are venous thromboembolism (VTE) MRSA bacteraemias, patient falls and Trust aquired pressure ulcers.

Venous thromboembolism (VTE)

All VTEs (deep vein thrombosis (DVT) or pulmonary embolism (PE)) occuring in adult (over 16) patients should follow the process below.



It is the responsibilty of the clinical team caring for the patient to complete the initial VTE root cause analysis and escalate to the potential SI pathway by submitting an SI proforma if omissions in care are identified. Further detail can be found in the Venous Thromboembolism (VTE) Prophylaxis in Adult Inpatients policy.

Patient falls

Any patient slip, trip or fall (hereafter referred to as falls) must be reported on Datix as per the Preventing Patient Slips, Trips and Falls Clinical Policy.

An SI proforma must be submitted for any fall resulting in a moderate or above level of harm.

Where a site has an established Harm Free Care review panel (or equivalent) falls with a moderate level of harm can be reviewed through the panel for consideration of the appropriate level of investigation and whether or not the fall meets the criteria for external reporting.

For falls occuring on sites without an estabished Harm Free Care panel the incident must be reviewed through the usual site serious incident review process.

All falls incidents which result in the patient dying within 28 days (where the fall was the direct cause or a significant contributing factor) or the level of harm was severe MUST be reviewed through the site/ trustwide division serious incident review process.

Where a site has an established Harm Free Care panel the panel must meet frequently enough to ensure that falls incidents are reviewed in a timely fashion so undue delays in external reporting and monitoring the investigation process do not occur. Weekly is suggested as a suitable timescale.

A patient over the age of 65 sustaining a fractured neck of femur should automatically be considered severe harm due to the potential long term consequences.

A hip fracture is one of the most serious consequences of falls in the elderly, with a mortality of 10% at one month and 30% at one year.There is also significant morbidity associated with hip fractures, with only 50% returning to their previous level of mobility and 10 to 20% of patients being discharged to a residential or nursing care placement (Radclife & Keefai 2014).

Falls incidents (internal and external) should be investigated using the Trust Falls Root Cause Analysis template. This template is designed to guide the investigator to consider all factors that may be relevant to the fall.

Where an externally reported falls incident is very complex, involves multiple falls or mutiple environments of care it may be more appropriate to use the Trust comprehensive investigation template for the report, utilising the falls RCA template to guide the investigation. In this event advice should be sought from the Central Patient Safety Team.

Radcliffe L. & Keefai Y (2014) Reducing mortality from hip fractures: a systematic quality improvement programme. BMJ Quality Improvement Reports. DOI: 10.1136/bmjquality.u205006.w2103

Pressure Ulcers

Any pressure ulcer must be reported on Datix as per the Trust Adult Pressure Ulcer Prevention Policy.

Any pressure ulcers graded 2, 3 or 4 should be reported as moderate harm and an SI proforma submitted.

Where a site has an established Harm Free Care review panel (or equivalent) pressure ulcers with a moderate level of harm can be reviewed through the panel for consideration of the appropriate level of investigation and whether or not the pressure ulcer(s) meets the criteria for external reporting.

For pressure ulcers occuring on sites without an estabished Harm Free Care panel the incident must be reviewed through the usual site serious incident review process.

Where a site has an established Harm Free Care panel the panel must meet frequently enough to ensure that pressure ulcer incidents are reviewed in a timely fashion so undue delays in external reporting and monitoring the investigation process do not occur. Weekly is suggested as a suitable timescale.

External reporting criteria for pressure ulcers:

1. Patients sustaining multiple (more than 3 over varying body sites) pressure ulcers should be considered to have sustained severe harm. These incidents should be reported externally.

2. Grade 3 or 4 pressure ulcers where a safeguarding alert has been raised. A safeguarding alert should be raised by the Trust where there is evidence of ommissions of care that contributed to the development of the pressure ulcer(s) for a vulnerable adult. This includes a lack of, poor quality or innacurate documentation of skin assessment, risk assessment (Waterlow score) and completion of the SSKIN bundle.

It is recognised that criteria 2 may not be clearly understood until the initial RCA has been completed. In this case it is the responsibilty of the site Director of Nursing to ensure that a system exists to ensure that consideration is given as to whether a pressure ulcer incident now meets the criteria for external reporting once the RCA is completed.

Pressure ulcer incidents (internal and external) should be investigated using the Trust pressure ulcer Root Cause Analysis template. This template is designed to guide the investigator to consider all factors that may be relevant to the pressure ulcer.

Where an externally reported pressure ulcer incident is very complex, involves multiple pressure ulcers or mutiple environments of care it may be more appropriate to use the Trust comprehensive investigation template for the report, utilising the pressure ulcer RCA template to guide the investigation. In this event advice should be sought from the Central Patient Safety Team.

APPENDIX 2 - NEVER EVENT (NE) COMMUNICATION/ NOTIFICATION TIMELINE

Timeline (working days)	Action required	Responsibility	Comments	If not a NE.
Day 0	Potential NE occurs/ is identified			
Day 0	Potential NE is reported on Datix	Incident Reporter		
Day 0	Inform the patient/ next of kin of the incident and apologise	Consultant responsible for the patient or Senior Nurse/ Midwife for the area as appropriate.	Refer to the Trust Duty of Candour policy for further detail	
Day 0	Begin to gather information re: NE If likely NE follow below Note: Certainty is NOT required to follow the process below. The principle should be to escalate *potential* NEs early and de-escalate as necessary.	Site/ Women's/ CSS governance team. ***Relevant Service Lead.***	Liaise with reporter and clinical team. Seek advice from Patient Safety Team (PST)/ subject experts as needed	Assess level of harm and manage via Adverse Incidents Policy.
Day 0	Inform the site medical director/ director of nursing of the potential NE (preferably face to face or by phone)	Consultant responsible for the patient or Senior Nurse/ Midwife for the area as appropriate.		
Day 0	The support needs for staff involved in the incident must be considered. They should be invited to the review meeting.	Line managers. Site/ CSS/ Women's governance team		
Day 1	Complete and submit SI proforma.	Site/ Women's/ CSS governance team.		

	Notification via email of potential NE sent to: Chief Nurse (CN) Chief Medical Officer (CMO) Site/ Women's/ CSS leadership (MD, medical director, DoN, DoM) Relevant Service Lead Patient Safety It is preferable, if at all possible, to inform the CN/ CMO verbally prior to the notification email being sent.	Site/ Women's/ CSS governance team. Site medical director/ director of nursing (DoN) or midwifery (DoM) as appropriate.	Include headline Potential Never Event in subject heading	
Day 1	Make arrangements for urgent review meeting.	Site/ CSS/ Women's governance team.		
Day 1/2	An early, preliminary conversation should occur with Commissioners to alert them to a potential NE.	Site medical director/ DoN/ DoM		
By day 3.	Urgent review meeting takes place.	Attendance: Service representatives. Site/CSS/ Women's governance team. Site/CSS medical director/ DoN or appointed deputy. Subject experts as appropriate/ possible.	If significant uncertainty remains about NE status following review meeting and expert advice the site/CSS medical director or DoN can seek input from relevant	Assess level of harm and manage via Adverse Incidents Policy.

	If confirmed or probable NE follow below.		Clinical Commissioning Group Quality and Safety Lead (CCG Q&S). The overriding principle should be that a potential NE should be reported and then de-escalated as needed if consensus cannot be reached.	
Day 3	Complete and submit SI briefing for exec approval	Site/ CSS/ Women's governance team		
Day 3	Inform: Relevant CCG Q&S lead (if not done previously) NHS Improvement (NHSI) CQC Inspection manager Site CQC relationship manager	Site/ CSS medical director/ DoN Site/ CSS medical director/ DoN PST Site/ CSS medical director/ DoN	It is preferable that these stakeholders are informed prior to the external reporting of a NE on StEIS.	
Day 4 or within 1 working day of the review meeting if sooner.	72 hour report completed and submitted for exec approval.	Site/ CSS/ Women's governance team	If not sent to PST for forwarding for exec approval then copy PST in.	
Day 4	Exec approval for external reporting	Chief Nurse/ Medical Officer		
Day 4	Exec approval for 72 hour report	Chief Nurse/ Medical Officer		

Day 4	Report NE on StEIS	PST		
Day 4	Submit 72 hour report to: CCG Q&S leads and deputies for: Newham Tower Hamlets Waltham Forest North East London Commissioning Support Unit (NELCSU) [redacted] (NHSI)	Site/ CSS/ Women's governance team	Please copy in PST	

APPENDIX 3 - SUGGESTED SERIOUS INCIDENT INVESTIGATION TIMESCALES

Serious incidents reported on StEIS have a deadline of 60 working days for submission. Serious incident investigations are complex processes that can easily run over time if close attention is not paid to progress and to resolving delays in a timely fashion. This document provides a suggested timescale for the various parts of the process to allow sites and trustwide divisions to establish monitoring processes for their serious incident investigations.

Prioritising resources at the beginning of the process: timely identification of investigators, effective commissioning, identifying and securing evidence is likely to pay significant dividends at the end of the investigation in terms of the completeness and quality of the final report. All times below refer to number of working days.

Before day 0. Consideration can be given to the identification of investigators, identification and securing of key evidence and preliminary terms of reference (ToR) either during the SI review meeting or as an out of meeting discussion with relevant parties.

Day 0: Incident reported on StEIS.

Day 0 to 5: If not completed prior to StEIS reporting:

- Identify investigator(s)
- Agree terms of reference with service involved.
- Contact patient/ family (if not done previously) and invite them to contribute to ToR.
- Secure key evidence
- Write commissioning letter to investigator(s) outlining terms of reference and arranging to meet with them

Day 5 to 10:

- Meet with investigator(s) and ensure that they fully understand the ToRs, the process of the SI investigation and assist in identifying and securing key evidence. This includes patient records, access to staff for interviews or provision of staff statements, relevant policies, guidelines or best practice documents and other sources of evidence such as audits.
- Ensure Investigator(s) are aware of the support available and the timescales for 1st and subsequent drafts.

Day 10 to 30:

- Investigator(s) undertake investigation and produce 1st draft of investigation report including recommendations.

Day 20:

- Governance team check in with the investigators to ensure investigation is on target to meet 1st draft deadline and identify any support needs.

Day 30 to 35:

- Draft report is reviewed for quality assurance (QA) by the site/ trustwide division governance team.
- Following governance team QA the report is shared with the service concerned and the service designs an action plan to meet the recommendations.

Day 35 to 40:

- Early findings, recommendations and if appropriate the 1st draft are shared with the patient/ family for their input.

Day 40 to 45:

- Draft returned to investigator for any revisions following input from service and patient/ family.

Day 45 to 50:

- Second draft report submitted to site medical director, director of nursing, head of midwifery or equivalent in trustwide divisions.

Day 50 to 53:

- Maternity reports go for QA to the Trust director of midwifery
- Reports involving safeguarding go for QA to the safeguarding team.

Day 53 to 56

- Report to PST for final QA.

Day 56 to 59:

- Report sent for executive approval.

Day 59:

- Executive approval and report closed on StEIS.

APPENDIX 4 - A JUST CULTURE GUIDE

NHS Improvement

A just culture guide

Supporting consistent, constructive and fair evaluation of the actions of staff involved in patient safety incidents

This guide supports a conversation between managers about whether a staff member involved in a patient safety incident requires specific individual support or intervention to work safely. Action singling out an individual is rarely appropriate - most patient safety issues have deeper causes and require wider action.

The actions of staff involved in an incident should **not** automatically be examined using this *just culture guide*, but it can be useful if the investigation of an incident begins to suggest a concern about an individual action. The guide highlights important principles that need to be considered before formal management action is directed at an individual staff member.

An important part of a just culture is being able to explain the approach that will be taken if an incident occurs. A just culture guide can be used by all parties to explain how they will respond to incidents, as a reference point for organisational HR and incident reporting policies, and as a communication tool to help staff, patients and families understand how the appropriate response to a member of staff involved in an incident can and should differ according to the circumstances in which an error was made. As well as protecting staff from unfair targeting, using the guide helps protect patients by removing the tendency to treat wider patient safety issues as individual issues.

Please note:

- **A just culture guide** is not a replacement for an investigation of a patient safety incident. Only a full investigation can identify the underlying causes that need to be acted on to reduce the risk of future incidents.
- **A just culture guide** can be used at any point of an investigation, but the guide may need to be revisited as more information becomes available.
- **A just culture guide** does not replace HR advice and should be used in conjunction with organisational policy.
- **The guide** can only be used to take one action (or failure to act) through the guide at a time. If multiple actions are involved in an incident they must be considered separately.

Start here - Q1. deliberate harm test

1a. **Was there any intention to cause harm?**

Yes → **Recommendation:** Follow organisational guidance for appropriate management action. This could involve: contact relevant regulatory bodies, suspension of staff, and referral to police and disciplinary processes. Wider investigation is still needed to understand how and why patients were not protected from the actions of the individual. END HERE

No go to next question - **Q2. health test**

2a. **Are there indications of substance abuse?**

Yes → **Recommendation:** Follow organisational substance abuse at work guidance. Wider investigation is still needed to understand if substance abuse could have been recognised and addressed earlier. END HERE

2b. **Are there indications of physical ill health?**

2c. **Are there indications of mental ill health?**

Yes → **Recommendation:** Follow organisational guidance for health issues affecting work, which is likely to include occupational health referral. Wider investigation is still needed to understand if health issues could have been recognised and addressed earlier. END HERE

if **No to all** go to next question - **Q3. foresight test**

3a. **Are there agreed protocols/accepted practice in place that apply to the action/omission in question?**

3b. **Were the protocols/accepted practice workable and in routine use?**

3c. **Did the individual knowingly depart from these protocols?**

If No to any → **Recommendation:** Action singling out the individual is unlikely to be appropriate; the patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. These actions may include, but not be limited to, the individual. END HERE

if **Yes to all** go to next question - **Q4. substitution test**

4a. **Are there indications that other individuals from the same peer group, with comparable experience and qualifications, would behave in the same way in similar circumstances?**

4b. **Was the individual missed out when relevant training was provided to their peer group?**

4c. **Did more senior members of the team fail to provide supervision that normally should be provided?**

If Yes to any → **Recommendation:** Action singling out the individual is unlikely to be appropriate; the patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. These actions may include, but not be limited to, the individual. END HERE

if **No to all** go to next question - **Q5. mitigating circumstances**

5a. **Were there any significant mitigating circumstances?**

Yes → **Recommendation:** Action directed at the individual may not be appropriate; follow organisational guidance, which is likely to include senior HR advice on what degree of mitigation applies. The patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. END HERE

if **No**

Recommendation: Follow organisational guidance for appropriate management action. This could involve individual training, performance management, competency assessments, changes to role or increased supervision, and may require relevant regulatory bodies to be contacted, staff suspension and disciplinary processes. The patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. END HERE

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Based on the work of Professor James Reason and the National Patient Safety Agency's Incident Decision Tree

Supported by: Academy of Medical Royal Colleges; avma; CareQuality Commission; General Medical Council; National Guardian Freedom to Speak Up; NMC Nursing & Midwifery Council; NHS England; Royal College of Nursing

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APPENDIX 5 - EXTERNAL REPORTING REQUIREMENTS

External Stakeholder	Type of Incident	Responsible person	Comments
External PFI partner	External PFI staff involved in an SI	Site Governance Manager	Check local information for contact details as PFI partners vary across the organisation For SBH, RLH the SI proforma and review meeting invite should be sent to the following email address: **NHPPCO-SUI@bartshealth.nhs.uk**
Public Health England	Any incident where there is a risk to public health e.g. tuberculosis, sexually transmitted diseases as a result of failed/delayed diganosis	Site Governance Manager	
Public Health England, Screening Quality Assurance Service (London) and NHS England (London).	NHS breast screening programme NHS cervical screening programme NHS bowel cancer screening programme NHS diabetic eye screening programme programme NHS abdominal aortic aneurysm screening programme NHS fetal anomaly screening programme	Manager of the relevant screening service	https://www.gov.uk/government/publications/managing-safety-incidents-in-nhs-screening-programmes

External Stakeholder	Type of Incident	Responsible person	Comments
	NHS infectious diseases in pregnancy programme NHS sickle cell and thalassaemia programme NHS newborn blood spot programme NHS Newborn hearing screening programme NHS newborn and infant physical examination programme		
National Reporting and Learning System	All clinical incidents and near misses are uploaded via the National Reporting and Learning System (NRLS)	Datix Manager via National Reporting and Learning System (NRLS) reporting	This information does not contain personal details of patients or staff involved and is reported on a weekly basis. The NPSA use this data to make recommendations to the NHS with regard to improving patient safety. The NPSA also produce regular reports comparing similar Trusts, based on this information.
Health and Safety Executive	The Trust has a legal duty to formally notify the Health and Safety Executive (HSE) with details of injuries, diseases and dangerous occurrences that occur in the course of work activities under The Reporting of Injuries, diseases and Dangerous Occurrences Regulations (1995).	Health and Safety Manager	Reporting must be done Immediately for serious injuries and dangerous occurrences; and Within 10 days for over three-day absence from work for staff injured in a work-related incident

External Stakeholder	Type of Incident	Responsible person	Comments
NHS Improvement	Any incident declared as a Serious Incident	Patient Safety Team	
Clinical Commissioning Groups	Any SIs Any incident involving CCG service/staff	Patient Safety Team	Contact is via email to NELSCU
NHS Digital/ Information Commissioner's Office (ICO)	Any major breech of confidentiality / information security	Information governance manager	
Human Tissue Authority	Any adverse incident in relation to the post mortem sector (storage, removal and disposal of bodies and post mortem tissues).	Designated Individual for Barts Health HTA licence 12187	https://www.hta.gov.uk/policies/post-mortem-hta-reportable-incidents
London Fire Brigade / NHS London (estates division)	Actual fire or suspected arson	Fire safety advisor	
Other NHS Trusts	If an incident involves care the patient received at another Trust or if a patient from that Trust was involved in an incident whilst receiving care from Barts Health NHS Trust.	Patient Safety Team	Contact will be made with the clinical risk advisor / patient safety manager at the other trust
Local Safeguarding Children Board	Incidents involving the safety and security of children where there is suspicion they may have been the subject of	Trust Child Protection Officer	

External Stakeholder	Type of Incident	Responsible person	Comments
	physical/emotional/sexual abuse either at home or whilst in hospital		
Social Services (adult protection)	Any incident which may involve a Safeguarding Vulnerable Adults (safeguarding alert to be raised)	Senior Nurse Safeguarding	This report should be made before an incident review meeting and an invite to participate in that meeting issued to Adult protection social worker Also consider notification to local learning disability boards where appropriate
Medicines and Healthcare products Regulatory Agency – Medical Devices	Any incident where medical equipment is involved and there has been or is the potential for harm to occur the patient or the user of the equipment, the MHRA must be notified before any repairs/modifications are made to the medical device	Clinical Engineering dept	
Medicines and Healthcare products Regulatory Agency – medicines	Reports on suspected adverse drug reactions are submitted to the MHRA using the yellow card system that is available at the back of the British National Formulary or the online equivalent	Chief Pharmacist / individual clinicians	A Trust adverse incident report should also be completed
Health Protection Agency	Adverse incidents relating to food and infectious diseases	Infection Control Team	

External Stakeholder	Type of Incident	Responsible person	Comments
Serious Hazards of Transfusion (SHOT)	Major adverse events surrounding the transfusion of blood products (excluding coagulation factors, albumin and immunoglobulin)	Transfusion Nurse Specialist	
CQC – Radiation Incidents	Incidents that must be reported under the Ionising Radiation (Medical Exposure) Regulations 2000 (IRR17 & IRMER 18)	Radiation Protection Officer	
Counter Fraud and Security Management Service	All incidents of physical violence against staff	Trust Local Security Management Specialist	See the Trust Securities Policy for further details
Police	Incidents involving security, threatening behaviour/assault or any other involving criminal behaviour. Safety incidents where gross negligence / recklessness are suspected	Trust Local Security Management Specialist	
Coroner	Patient Death as a result of a safety incident	Consultant (or designated junior doctor)	Staff must refer to guidance from local Coroner's court for details on referral method and further criteria