Patient Safety Incident Response Policy
Incident Reporting and Management

Document Control:

For Use In:	Norfolk and Norwich University Hospitals NHS Foundation Trust		
Search Keywords	PSIRF, Safety, Incident, Investigation		
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Approved By:	Clinical Safety and Effectiveness Sub-Board (CSESB)		
Ratified By:	Quality and Safety Committee		
Approval Date:	16/08/2023	**Date to be reviewed by:** This document remains current after this date but will be under review	16/08/2024
Implementation Date:	The document will be live from 16/08/2023 to allow all to understand what is required ahead of implementation. The Patient Safety Incident Response Framework will commence 1st September 2023 within the Trust in which this policy will also be implemented from.		
Reference Number:	22799		

Version History:

Version	Date	Author	Reason/Change
V1.0	November 2022	Associate Director Quality and Safety, Patient Safety Specialist	New document

Previous Titles for this Document:

Previous Title/Amalgamated Titles	Date Revised
This document supersedes the Incident Management and Investigation Policy and Procedure Trustdocs ID:15736	Sept 2023

Distribution Control

Printed copies of this document should be considered out of date. The most up to date version is available from the Trust Intranet.

Consultation

The following were consulted during the development of this document:

- Chief Nurse
- Medical Director
- Associate Medical Director Quality and Safety, Trust Mortality Lead
- Deputy Chief Nurses
- Divisional Leadership Triumvirates
- Risk and Patient Safety Team
- Divisional Governance Managers
- Legal Services Team
- Associate Director Patient Engagement and Experience
- Associate Director Complex Health and Safeguarding
- Associate Director Quality Improvement, Nursing, Midwifery and Clinical Professional Excellence and Regulation
- Chief Pharmacist, Controlled Drug Accountable Officer
- Deputy Chief Pharmacist, Medication Safety Officer
- Medical Devices Safety Officer
- Lead Medical Examiner Officer
- Radiation Safety/Quality Assurance Lead
- Head of Information Governance Digital Health
- Lead Health and Safety Adviser
- Deputy Director Infection Prevention and Control
- Integrated Care Board
- Patient Safety Partner

Monitoring and Review of Procedural Document

The document owner is responsible for monitoring and reviewing the effectiveness of this Procedural Document. This review is continuous however as a minimum will be achieved at the point this procedural document requires a review e.g. changes in legislation, findings from incidents or document expiry.

Relationship of this document to other procedural documents

This document is a policy applicable to Norfolk and Norwich University Hospitals NHS Foundation Trust; please refer to the local Trust's procedural documents for further guidance, as noted in Section 10.

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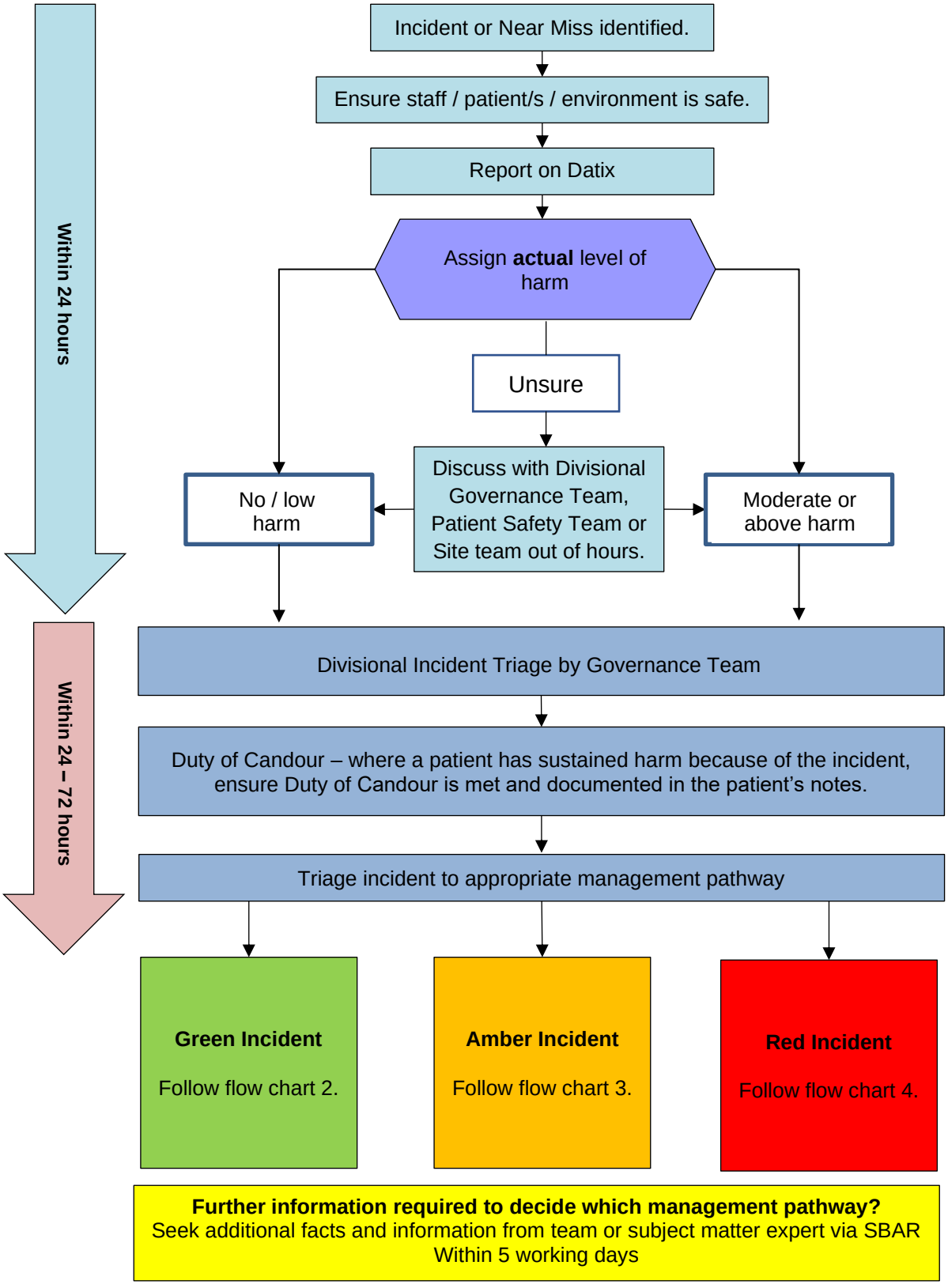
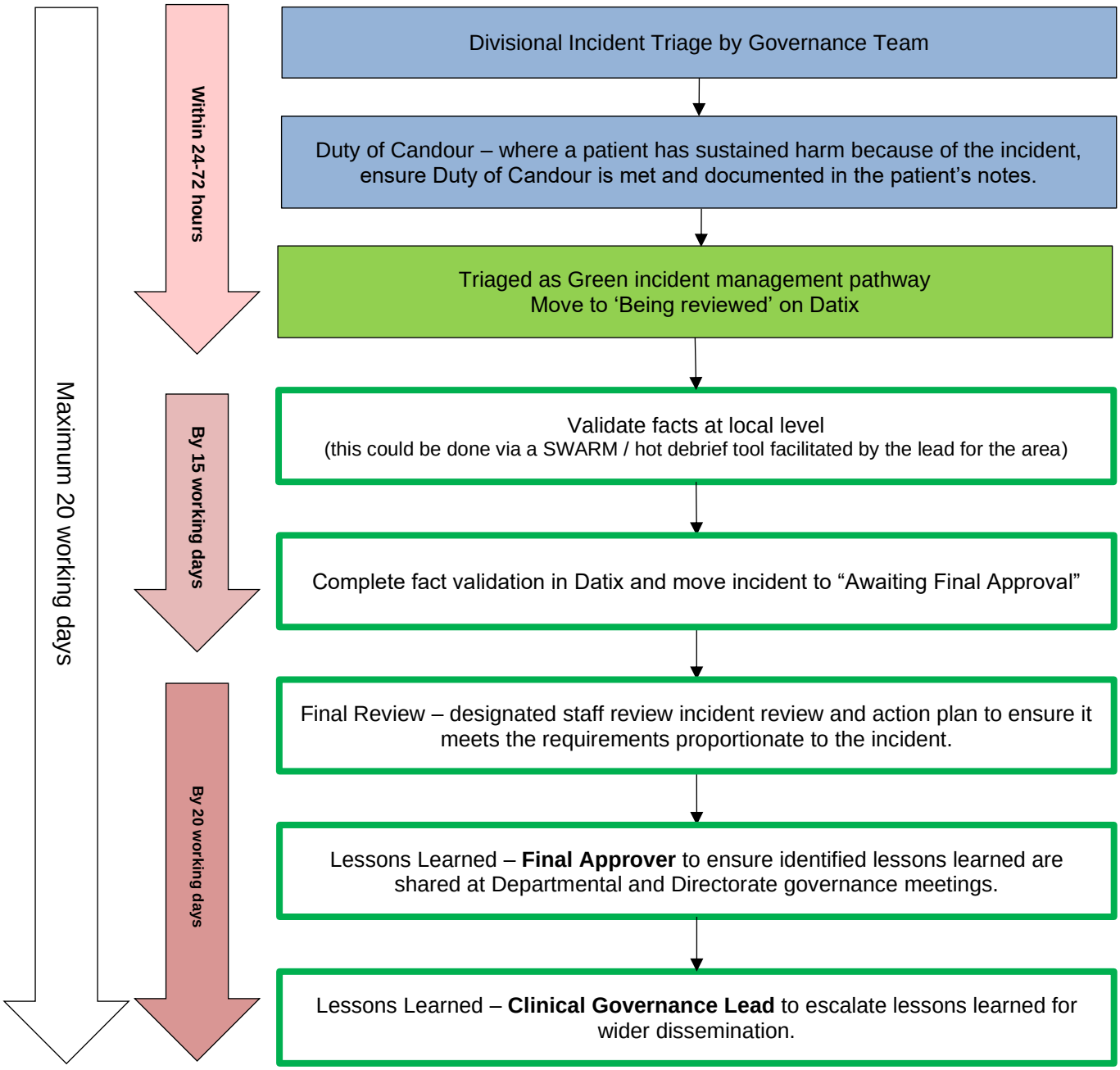


Flow chart 2 – Green incident management pathway



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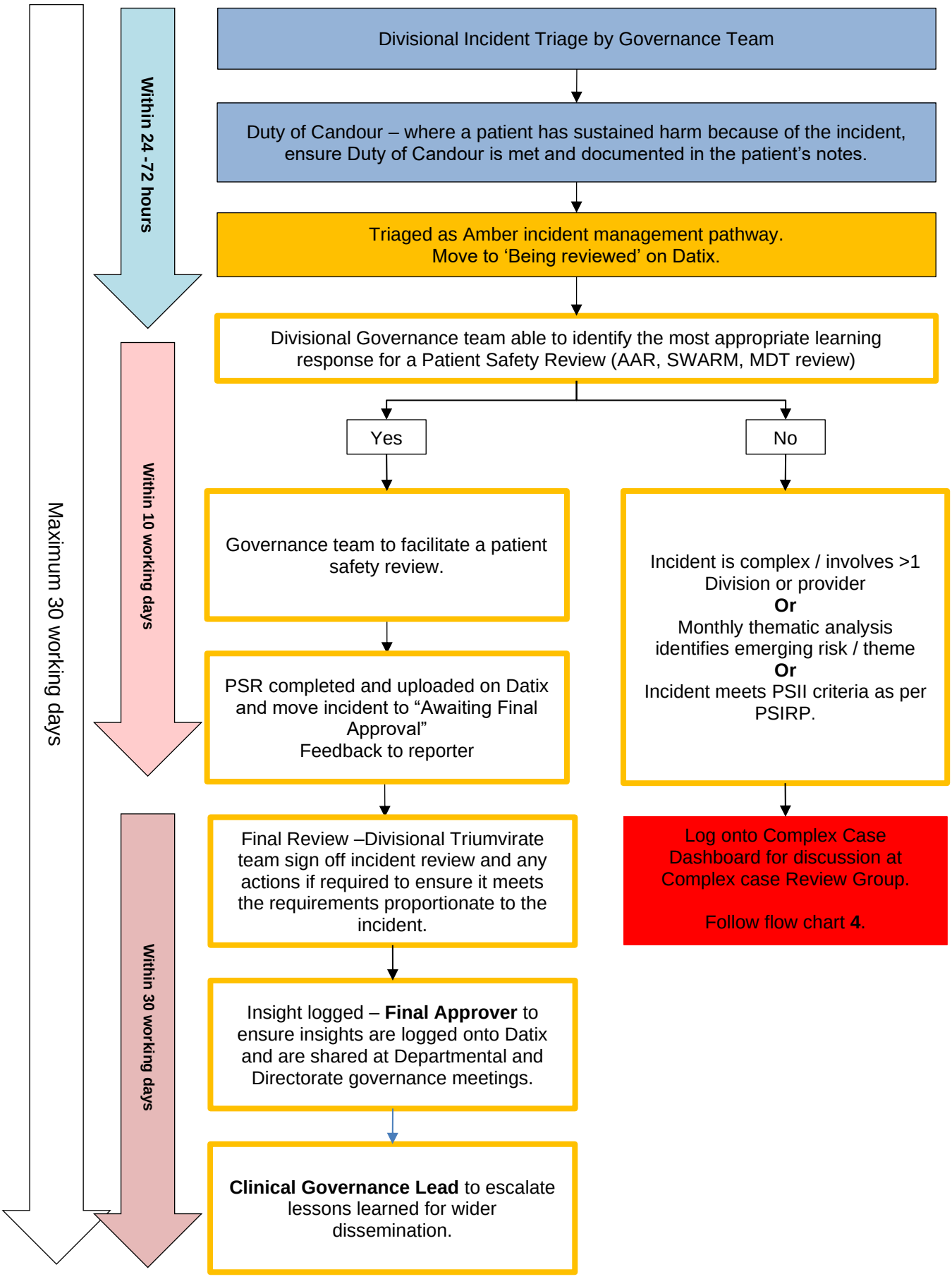
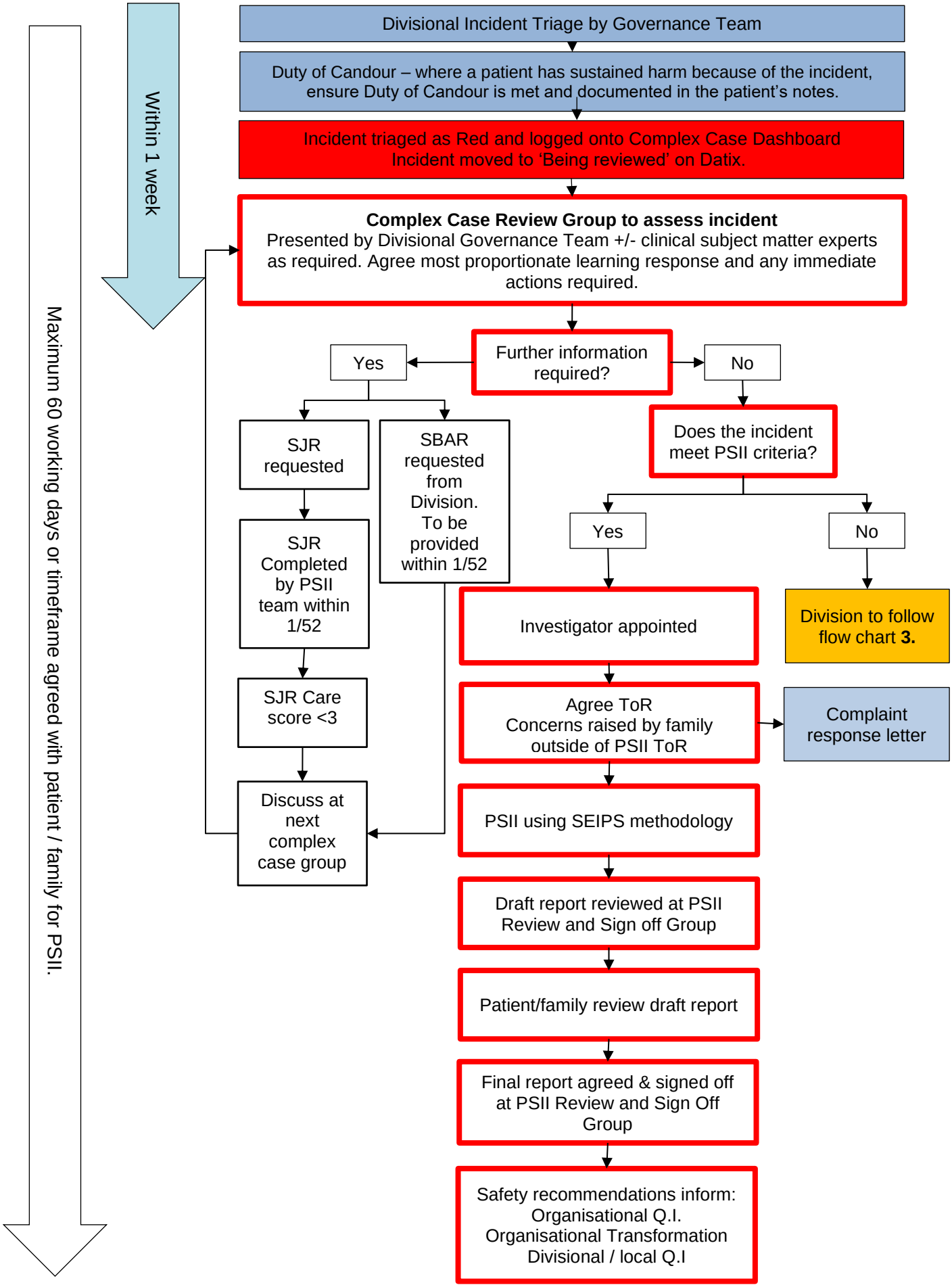
Flow chart 3 – Amber incident management pathway



Flow chart 4 – Red incident management pathway



1. Introduction

1.1. Rationale

This policy supports the requirements of the Patient Safety Incident Response Framework (PSIRF) and sets out Norfolk and Norwich University Hospitals NHS Foundation Trust's (hereafter referred to as 'the Trust') approach to developing and maintaining effective systems and processes for reporting and responding to patient safety incidents and issues for the purpose of learning and improving patient safety.

A patient safety incident or event is any unintended or unexpected incident or event which could have, or did, lead to harm for one or more patient's receiving healthcare, and can result in no harm or contribute to a fatal outcome. This policy requires all staff to take responsibility for reporting any incident or adverse event or near miss that they become aware of and review them as detailed within this policy.

The Trust acknowledges that adverse events usually reflect a breakdown in systems within the organisation and that people are trying to do their best to do their job safely and well. Experience shows that although staff actions may contribute to an adverse incident there are often underlying causes for these actions. Consequently, the Trust is committed to exploring how these system failures occurred and how they can be improved using a range of learning response tools.

The PSIRF advocates a co-ordinated and data-driven response to patient safety incidents. It embeds patient safety incident response within a wider system of improvement and prompts a significant cultural shift towards systematic patient safety management.

This policy supports development and maintenance of an effective patient safety incident response system that integrates the four key aims of the PSIRF:

- compassionate engagement and involvement of those affected by patient safety incidents.
- application of a range of system-based approaches to learning from patient safety incidents.
- considered and proportionate responses to patient safety incidents and safety issues.
- supportive oversight focused on strengthening response system functioning and improvement.

1.2. Objectives

The objectives of this policy are to ensure:

- An 'open, just and restorative' culture is promoted to assure staff that the Trust operates an open and honest environment where no groups or individuals will be unfairly blamed when things go wrong.
- Effective record keeping and reporting mechanisms are in place.
- That all incidents are managed in a timely and organised way.

- Clear lines of accountability and responsibility are identified for all elements of incident management.
- That all staff, including bank, locum, voluntary and agency staff are aware of the communication systems in place for the management of all types of incidents, via appropriate induction and training.
- Key communication mechanisms are established with family and/or carers in line with the Trust 'Being Open and Duty of Candour Policy' (Trust Docs ID: 977) and regulatory requirements of Duty of Candour.
- Lessons are learned from reported incidents, and appropriate action is taken to avoid recurrence, including making changes to practice, systems and process, and/or the environment to improve patient, staff and public safety.
- All appropriate levels of debrief and communication of lessons learned takes place following incidents.
- All relevant internal and external stakeholders, agencies and regulatory bodies are engaged, involved, and informed in line with national legislation and guidelines.

1.3. Scope

This policy is specific to patient safety incident responses conducted solely for the purpose of learning and improvement across all services, on all sites provided by the Trust.

The Patient Safety Incident Response Framework (PSIRF, 2020) provides the NHS with guidance on how to respond to patient safety incidents; with no distinction between incidents and 'serious incidents' for the purpose of learning. As such, it is relevant to all bodies involved in providing; commissioning, supporting, overseeing and regulating NHS-funded care.

Responses under this policy follow a systems-based approach. This recognises that patient safety is an emergent property of the healthcare system: that is, safety is provided by interactions between components and not from a single component. Responses do not take a 'person-focused' approach where the actions or inactions of people, or 'human error', are stated as the cause of an incident.

A patient safety incident is investigated or reviewed under this framework to understand the circumstances that led to it, for the purpose of system learning and improvement. There is no remit to apportion blame or determine liability, preventability or cause of death in a response conducted for the purpose of learning and improvement. Other processes, such as claims handling, invited external reviews, human resources investigations into employment concerns, professional standards investigations, coronial inquests and criminal investigations, exist for that purpose. The principle aims of each of these processes differ from those of a patient safety response and are outside the scope of this policy.

Where there are legitimate concerns about individual and/or organisational accountability including criminal or civil proceedings, disciplinary procedures, employment law, or professional standards and organisational or professional

regulators need to be involved, they must be informed, and their relevant protocols followed. Information from a patient safety response process can be shared with those leading other types of responses, but other processes should not influence the remit of a patient safety incident response.

This policy applies to all permanent and temporary staff employed, or those working under contract for services or under service level agreement, within the Trust. The policy also describes the arrangements for the management of incidents where more than one provider is involved.

1.4. Glossary

The following terms and abbreviations have been used within this document:

Term	Definition
AAR	After Action review
Accident	An unexpected event without apparent or deliberate cause that causes injury or damage
CDs	Controlled Drugs
CDAO	Controlled Drug Accountable Officer
CHIG	Clinical Harm Incident Group
Complex Case	An incident that involves several different causal factors that are linked in a close or complicated way. This could cross more than one division or provider, have an associate complaint or claim.
CSESB	Clinical Safety and Effectiveness Sub-Board
CQC	Care Quality Commission
Datix	Risk management database, central recording system of incidents, complaints, claims, actions, safety alerts, clinical audit and Risk Register
DH	The Department of Health
Dif 1	Datix incident and near miss reporting form.
Dif 2	Datix incident form to record the management of an incident.
External body	An organisation that has an official advisory or regulatory role that has been mandated to regulate the corporate and professional activities of the Trust.
HSE	Health and Safety Executive
HSIB	Healthcare Safety Investigation Branch
HTA	Human Tissue Authority
ICB	Integrated Care Board
ICS	Integrated Care System
Incident	An event or circumstance that could have resulted, or did result, in unnecessary damage, loss or harm such as physical or psychological distress to a patient, staff, visitors or members of the public
IPR	Integrated Performance Report
LFPSE	Learning from Patient Safety Events (LFPSE) service. A national database for the direct recording of incidents as they are reported. It collects data from all NHS funded providers. The

Term	Definition
	Integrated Care Board (ICB), NHS England and Care Quality Commission (CQC) have access to this database. This will eventually replace the National Reporting and Learning System (NRLS).
MBRRACE	Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries
MDT	Multi-Disciplinary Teams
MHRA	Medicines and Healthcare products Regulatory Agency. The government agency responsible for ensuring that medicines and medical devices work and are acceptably safe. The MHRA regulates a wide range of materials from medicines and medical devices to blood and therapeutic products/services that are derived from tissue engineering.
Near Miss	Any event that could have caused harm to patients, staff or the reputation of the Trust, had it been allowed to reach its natural conclusion.
Never Event	Never Events are incidents that are entirely preventable because guidance or safety recommendations providing strong systemic protective barriers are available at a national level and should have been implemented by all healthcare providers. A core list of never events is issued by NHS England.
Non-patient Safety Incident	Any unintended or unexpected incident which could have or did lead to harm or an undesired effect which was not as a direct result of patient intervention or the patients' clinical presentation.
PAF	Performance Assurance Framework
Patient Safety Incident	Any unintended or unexpected incident that could have led or did lead to harm or one or more patients receiving NHS-funded care.
PSII	Patient Safety Incident Investigation. Some incidents are classified as Patient Safety Incident Investigations (PSII). This is an incident identified which is investigated through a systematic process which includes systems-based analysis. The objective is to identify what happened, where, when, how, to whom and why. Using observation, listening and discussion for determining contributory/causal/ human factors and design recommendations/ improvements which address the underlying interconnected, system-based contributory and causal factors of patient safety incidents. PSII's are identified on an on-going basis based on the identification of areas of most significant risk, along with those categories for which a PSII is nationally mandated. The Trust publishes its' Patient Safety Incident Response Plan (PSIRP) on the Trust website, identifying those incidents requiring a PSII.
PSIRF	Patient Safety Incident Response Framework
PSIRP	Patient Safety Incident Response Plan. To support local improvement, the Trust must determine which categories of incident are priorities locally and require a Patient Safety Incident Investigation (PSII). In line with the PSIRF, the Trust will do this by reviewing past incident data (from the last three to five years

Term	Definition
	where available) to identify those incidents representing the most significant risks. This list must be set out in the PSIRP, reviewed and refreshed every 12 to 18 months adapted as new risks emerge or diminish locally.
PSP	Patient Safety Partner
PSR also known as a learning response	Patient Safety Response. Patient safety incidents which do not require PSII but may benefit from a different type of review to gain further insight or address queries from the patient, family, carers or staff. Different review techniques can be adopted, depending on the intended aim and required outcome and the Patient Safety Team will advise on the most appropriate technique.
Q.I	Quality Improvement
RIDDOR	Reporting of Injuries, Disease and Dangerous Occurrences Regulations 2013.
Risk	An uncertain event or set of events which, should it occur, will have an effect upon the achievement of objectives. It is measured in terms of likelihood and consequences.
SBAR	Situation, Background, Assessment, Recommendations communication tool
SEIPS	Systems Engineering Initiative for Patient Safety. Framework for understanding outcomes within complex socio-technical systems.
SJR	Structured Judgement Review
StEIS	Strategic Executive Information System**.** A national database for the recording of incidents. Different levels of controlled access are available to organisations e.g. the Trust can enter incidents and update on progress of investigation but cannot close a serious incident. The ICB, NHS England and the Care Quality Commission also have access to StEIS. This system will be phased out when all providers have transitioned to Learning from Patient Safety Events (LFPSE) service.
SWARM	Briefing huddle immediately after an adverse incident
The Trust	Norfolk and Norwich University Hospitals NHS Foundation Trust
TOR	Terms of Reference
Unexpected Death	Where natural causes are not suspected.

2. Responsibilities

The **Chief Executive** is accountable and responsible to the Board for ensuring that resources, policies, and procedures are in place to ensure the effective reporting, recording, investigation and treatment of incidents. In practice the Chief Executive may delegate the day-to-day responsibility for this to Executive Directors together with Divisional Directors or Departmental Heads. The Chief Executive has:

- Overall responsibility for ensuring the organisation has processes that support an appropriate response to patient safety incidents (including contribution to

cross-system/multi-agency reviews and/or patient safety incident investigations (PSII) where required).

- Overall responsibility for ensuring the development of a patient safety reporting, learning and improvement system.
- Ensures that systems and processes are adequately resourced: funding, management time, equipment, and training.
- Appoints executive lead for supporting and overseeing implementation of the PSIRF.
- Approves publication and ongoing review of the organisation's patient safety incident response plan (PSIRP).
- Ensures that the PSIRF, patient safety incident reporting data, patient safety incident investigation data, findings, improvement plans, and progress are discussed at the board's Quality and Safety Committee.
- Ensures that the organisation complies with internal and external reporting/ notification requirements.
- Acts as spokesperson in complex/high profile cases where the media/public is engaged.

The **Chief Nurse** is the nominated Director responsible for ensuring the Trust has appropriate arrangements in place for the management of incident reporting and associated investigation. The responsibility for defining and verifying an adverse event as a PSII rests with either the Chief Nurse or the Medical Director (or the Chief Executive in their absence) as part of the PSIRP. Through delegated responsibility, the Associate Director of Quality and Safety or their deputy will ensure the appropriate internal and external reporting is carried out and the investigation commences in accordance with this policy and procedure. Jointly with the Medical Director holds delegated responsibility from the Chief Executive for the sign off for PSII.

The Chief Nurse, with the Medical Director is the Trust's lead for clinical standards in relation to the quality and safety of patient care and providing clinical advice to the Board.

The **Medical Director** is responsible for ensuring that reporting and management of incidents including those involving doctors is undertaken in accordance with this policy. The Medical Director jointly with the Chief Nurse holds delegated responsibility from the Chief Executive for the sign off for PSII. The responsibility for defining and verifying an adverse event as a PSII rests with either the Chief Nurse or the Medical Director (or the Chief Executive in their absence) as part of the PSIRP.

The Medical Director, with the Chief Nurse is the Trust's lead for clinical standards in relation to the quality and safety of patient care and providing clinical advice to the Board.

Executive Directors/Executive Team
The principal accountability of all providers of care is to patients and their families/carers. In their fulfilment of the Trust's duty in this regard, the Board must

ensure that an appropriate incident management system is in place for the reporting of incidents and monitoring of incident trends, including PSII's and the recording of all Never Events in the annual reporting arrangements. The Board must ensure that the PSIRF is implemented from 'ward to board'. Provider organisations are also accountable for effective governance and learning through assurance of their PSIRP, and it is the duty of the Board to ensure appropriate arrangements are in place throughout the Trust to meet this expectation. The Board takes responsibility for leading the development of a just, open and learning culture within the organisation and for role modelling the behaviours required to achieve this.

The Board has overall responsibility for ensuring that risks are identified through the reporting and management of incidents, complaints, claims and Learning from Deaths reviews and that information from the trends and review / investigation of such are shared across the organisation. The Trust Board will receive reports from the Quality and Safety Committee on risks identified through incident reporting, complaints, claims and Learning from Deaths review.

All Executive Directors are responsible for ensuring incident reporting arrangements as described in this policy are implemented throughout their service areas.

The Executive Team ensures accountability from divisions regarding the implementation of actions and dissemination of learning following patient safety incidents, or other incident trends highlighting emerging issues. It receives assurance that the Trust's 'Being Open and Duty of Candour Policy' (Trust Docs ID: 977) is adhered to in terms of informing patients and/or relatives of incidents and the subsequent sharing of reports.

Non-Executive Director(s) are nominated to take a proactive interest in risk management and for seeking assurances on the implementation of this policy. Primarily this will be through membership and attendance at committee meetings and probity of reports on analysis of incidents at the Quality and Safety Committee.

Quality and Safety Committee, chaired by a Non-Executive Director has delegated responsibility on behalf of the Trust Board to oversee the management of clinical risks including those risks identified through incident reporting, complaints, learning from deaths and claims. The Committee will receive reports in accordance with its reporting schedule from sub-committees and from the divisions and services which will include information on the management of incidents, complaints and claims where appropriate.

Clinical Safety and Effectiveness Sub Board, chaired by the Medical Director, reviews incident, claims and Learning from Deaths activity and draws together lessons learnt from incidents and other sources of insight as part of its terms of reference. It advises the Quality and Safety Committee on the management of patient safety risks and priorities for action.

Risk Oversight Committee, chaired by the Chief Nurse, monitors the Trust risk register inclusive of those risks perceived as being significant risks, assessed directly at a local level which may include risks identified from the analysis of patterns and trends from the reporting of incidents, complaints, claims and Learning from Deaths.

In addition, the Committee will review each local risk register, according to a planned schedule, to ensure that appropriate risks are being identified regarding the provision of services and actions taken. It escalates the highest level of risks to the Hospital Management Board for discussion and oversight.

The **Complex Case Review Group** is a multidisciplinary group which will meet weekly to discuss all incidents logged on the complex case dashboard. They will oversee that the most effective proportionate learning response tool is selected and triangulate Incidents, Inquests and any complaints linked to these, to ensure they meet all statutory requirements and have clear key lines of enquiry for the review.

The **PSII Review and Sign Off Group,** chaired by the Chief Nurse, will review and comment on all draft PSII reports to ensure that they have met with the terms of reference, meet the national standards required and sign off completed PSII reports. By doing so will accept the safety recommendations made and ensure these inform the transformation and quality improvement work of the organisation.

The **Medical Examiner Service's** key role is to provide greater safeguards for the public by ensuring proper scrutiny of all non-coronial deaths and ensure the appropriate direction of deaths to the coroner. Whilst medical examiners employed by the Trust, they have a separate professional accountability and maintain their independence, which is vital to the scrutiny they provide, which is overseen by the national medical examiner. Medical examiners scrutinise all deaths to:

- provide advice on the proposed cause of death and ensure the overall accuracy of the Medical Certificate of Cause of Death (MCCD).
- identify problems in treatment or care and, as necessary, report to the trust's clinical governance process.
- discuss the cause of death with the bereaved and listen to any concerns.
- ensure the notification of deaths to the coroner as required by the law; this includes deaths where there are concerns that failure in care contributed to death or where the bereaved raise significant concerns about the care provided to their relative.
- liaise with, and assist, the coroner with medical information.
- educate and provide advice to other clinicians about death registration and the coronial process.

The **Medicines Management Incident Review Group**, chaired by the Chair of the Drug and Therapeutics and Medicines Management Committee (DTMM), is responsible for the monthly analysis of all medication incidents to identify themes for medication safety improvement. They will be responsible for identifying any emerging safety risks and reporting these onto the complex case dashboard for discussion at the weekly complex case group.

The **Clinical Harm Incident Group (CHIG)** reviews all incidents regardless of harm level in patients on an elective waiting list. If a theme or trend is identified through CHIG this can be logged onto the complex case dashboard for discussion at the Complex Case Review Group.

Divisional Governance Boards are responsible for reviewing reported incidents, applicable to their service, monitoring of associated action plans, identifying trends and where possible taking action to improve practice. They are also responsible for reporting to Divisional Board and Clinical Safety and Effectiveness Sub Board. They should ensure this information is communicated widely to all staff particularly if those staff are pivotal to the implementation of change.

Divisional Triumvirates have following responsibility to:

- Ensure all incidents are acted upon in a timely manner and to the level commensurate with this policy and associated policies. Moderate harm and above grade incidents that are cascaded via Datix should be acted upon immediately.
- Ensure the development of an action plan to address any local issues and present to the relevant forum.
- Ensure patients, relatives or carers are informed of when things have gone wrong or have not had the desired outcome in line with the Trust 'Being Open and Duty of Candour Policy' (Trust Docs ID: 977).
- Ensure staff who may have been involved in a significant incident are supported.
- Undertake departmental review of incidents, carrying out risk assessments and adding risks to the risk register for further action and monitoring as necessary.
- Quality assure and sign off all Patient Safety Reviews (PSR).

It is the **Ward Managers / Operational Managers / Head of Departments / Line Managers/ Matrons** responsibility to:

- Ensure that incidents, including Near Miss incidents are reported via the Datix system as soon as possible following the incident.
- Ensure all incidents are assigned a harm level.
- Ensure that severe harm and above incidents/Never Events are reported immediately and escalated in accordance with this policy and that the appropriate Divisional Director and the Patient Safety Team are notified.
- Engage with and participate in PSR approaches when required.
- For incidents with lower harm levels, ensure that the facts are captured and validated thoroughly and timely.
- Ensure that any procedures within their area take account of incidents which have been brought to their attention.
- Make safe any area or equipment following an accident and retain equipment for inspection where required.
- That patients, relatives or carers are informed when things have gone wrong or have not had the desired outcome in line with the Trust's 'Being Open and Duty of Candour Policy' (Trust Docs ID: 977).

- Ensure recommendations and actions are disseminated and carried out as a result of any PSR.
- Ensure that all staff involved in an incident are supported through the process and to always maintain confidentiality.
- Ensure lessons learned are cascaded to relevant staff through discussion at team meetings, training and education sessions, newsletters, and posters.
- Ensure that aggregated quantitative and qualitative data on types, numbers and themes from incidents are produced and reviewed through local governance groups.

Divisional Governance Managers are responsible for ensuring:

- All incidents reported are reviewed through a daily incident triage within the Division and allocated to the most appropriate review and management route and if required seeking further information from clinical teams.
- In all incidents where Moderate or above harm has occurred, duty of candour has been carried out in accordance with the Trust's 'Being Open and Duty of Candour Policy' (Trust Docs ID: 977) and escalated where needed.
- For incidents requiring a proportionate review using a learning response tool, ensure that the most appropriate method is used and facilitate the review.
- For more complex incidents that span across Divisions or for incidents that the team is unsure about which review method to use, to log the incident onto the complex case dashboard.
- Identify a named patient / family contact for non PSII incidents where required to undertake meaningful engagement about the incident.
- Identify a named staff contact for those involved in non PSII incidents where required to undertake meaningful engagement and signpost them to support.
- Track incidents to ensure review within required timescales and management; escalating any concerns as required.
- Logging and tracking actions associated with an incident or PSR / Learning Response.
- Monthly analysis of no and low harm incidents to identify trends and potential clinical risk and report on the Complex Case dashboard for discussion at the weekly complex case group.
- Maintaining records of reported incidents using the Datix incident management system.
- Monitoring the appropriate reporting and grading of reported incidents and seeking clarification from relevant managers should grading be inconsistent with trends.
- Divisions are accountable for the timely delivery of the learning response and agreed actions and learning following a patient safety review.

The **Associate Director of Quality and Safety** is responsible for:

- Developing strategies, designing and implementing systems to raise awareness of incident reporting, risk assessment, risk registers, investigation processes including training in learning response tools and implementing the 'Being Open and Duty of Candour Policy' (Trust Docs ID: 977).
- Managing the Trust's central risk management database 'Datix' to ensure access to timely and accurate information on the Trust risk profile and in mandatory reporting to external agencies e.g Learning from Patient Safety Events Service (LFPSE).
- Oversight of the development and management of the PSIRP within the Trust. Along with the Chief Nurse and Medical Director, they are also responsible for advising the Care Quality Commission and NHS England about incidents where applicable.
- In conjunction with Human Resources and Organisational Development colleagues, for creating and providing an appropriate just and restorative learning culture and support infrastructure for staff involved in incidents.

The **Head of Patient Safety** is responsible for

- Oversight and management of the Trust compliance with PSIRF ensuring that the required investigation standards are met.
- Ensuring relevant patient safety training programmes are available for staff.
- Organisation wide trend analysis to identify cross cutting themes including the identification of health inequalities.
- Ensuring that learning from adverse events and incidents is shared across the Trust and where relevant the health system.
- Ensuring appropriate notification of incidents to relevant internal and external stakeholders, agencies and regulatory bodies.
- Notifying the Chief Executive, Executive Directors, Non-Executive Directors and all other relevant stakeholders, of unexpected deaths or other serious incidents that may attract media attention.
- Liaising with the Trust's Communications Team on any incidents that may result in media interest.
- Providing appropriate advice and support to the Chief Nurse and Medical Director to enable the accurate identification, reporting and investigation of incidents.
- Ensuring an effective quality assurance process is in place to monitor the quality of investigations, associated reports and action plans.
- Ensuring an effective tracking system is in place so that investigation and learning response data and progress against action plans can be monitored and reported on to the Trust Board and Sub Committees
- Ensuring that evidence is collected and appropriately stored to validate the implementation of recommendations and actions arising from PSII's.
- Ensuring assurance evidence can be retrieved in a timely way when required by the Trust Board or other internal or external stakeholders, as appropriate.

- In conjunction with Workplace Health and Wellbeing support staff training in recognising the signs of stress and post-traumatic stress disorder in themselves and others and how to access help and support.

The **Patient Safety Incident Investigators** must have been trained over a minimum of two days in systems based PSII. In the event of an incident meeting the criteria for a PSII or identified on the PSIRP, a named investigator will be allocated and responsible for:

- Ensuring that they are competent to undertake the PSII assigned to them and if not or there is a conflict of interest, request it is reassigned.
- Developing clear terms of reference in conjunction with the Chief Nurse, Medical Director, clinical teams, patients/relatives (those affected).
- Ensure that they undertake PSIIs in line with the national PSII standards.
- Undertake PSIIs and PSII-related duties in line with latest national guidance and training.
- Identify those affected by patient safety incidents, both patients, families, carers and staff and support their needs, including signposting to support services.
- Provide them with timely and accessible information and advice.
- Provide documentary evidence in support of the investigation findings and conclusions for safekeeping by the Patient Safety Team. This will include copies of evidence, statements and completed analysis tools.
- Following executive approval of the report, the report findings will be fed back to the Divisional Triumvirate and Governance Team, and the Patient Safety Learning Coordinator groups to maximize the opportunities for learning.

The **Head of Risk Management** is responsible for

- Ensuring the Trust Risk Management system supports the requirements of PSIRF and is compliant with LFPSE standards.
- Providing training to relevant staff on the use of the web based Datix system in relation to incident reporting, investigating and management.
- Supporting the development of the Datix system to meet the needs of the organisation.
- Providing regular and ad-hoc reports to Executive Sub-Boards, Divisions, Directorates and individuals as required, to support the monitoring and analysis of incident reporting trends.

The **Patient Safety Team** is responsible for

- Identifying and reporting to Executive Leads (Chief Nurse or Medical Director) any potential PSII or Never Events.
- Convening the weekly complex case review group in a timely manner for all incidents logged on the complex case dashboard, and those with the potential

to be declared as a PSII and ensure contemporaneous action notes are recorded of these meetings.

- Reporting confirmed PSII's onto the Strategic Executive Information System (StEIS) and the national system that will eventually replace StEIS.
- Maintaining the Trust PSII and PSR Log and ensuring that all reports are submitted within the scheduled time frames.
- Ensuring final PSII Reports are submitted to relevant Governance and Clinical Leads and final reports, and any associated documents are attached to the relevant Datix incident report.
- Informing, via email, the following Trust staff whenever a PSII is reported/identified:
    - Chief of Division
    - Divisional Nurse / Midwifery Director
    - Divisional Operational Director
    - Divisional Governance Manager
    - Chief Nurse
    - Medical Director
- The Patient Safety Team will lead the PSII, working with subject matter experts and clinical teams to oversee the completion and submission of reports, create an action log and develop the safety recommendations.

The **Associate Medical Director – Quality & Safety and Mortality Lead** will lead on specific workstreams related to the clinical strategy, as directed by the Medical Director. Initiatives will be derived from areas where incidents or other adverse events indicate that improvements in clinical standards in relation to the quality and safety of patient care are required.

All **named contacts for patients, families and carers** following patient safety incidents:

- As a minimum should have experience of and been trained in 'being open' and Duty of Candour. Training is available via ESR – 234 Duty of Candour Training
- be able to establish a relationship with those affected (and become known to and trusted by the patient, their family and carers).
- be able to offer a meaningful apology, reassurance and feedback to patients, their families and carers.
- have a good grasp of the facts relevant to the incident but be sufficiently removed from the incident itself.
- be senior enough or have sufficient experience of and expertise in the type of patient safety incident to be credible to the patient, their family and carers, and colleagues.

- have excellent interpersonal skills, including being able to communicate with the patient, their family and carers in a way they can understand, without excessive use of medical jargon.
- have a good understanding of how the incident will be responded to and ensure realistic expectations are set.
- be able to liaise with several different individuals and be prepared to help those affected navigate complex systems/processes.
- actively listen to patient, family and carer queries/concerns and engage with other staff to ensure these are responded to openly and honestly.
- facilitate and signpost to relevant support services (including independent advocacy services as required).
- be able to maintain a short to medium term relationship with the patient, their family and carers where possible, and to provide continued support and information whilst an incident is reviewed.
- be culturally aware and informed about the specific needs of the patient, their family and carers and adjustments that might be required.

For continuity and consistency of communication, a co-contact should be assigned to support the lead contact and to act as lead contact during times when the first named contact is absent.

Named contacts for staff

- Facilitate private and confidential conversations with staff affected by a patient safety incident.
- Work with line managers to provide advice and support to these staff.
- Signpost and facilitate their access to additional support services as required.
- Liaise between these staff and review/PSII teams as required.

Associate Director for Complex Health and Safeguarding / Named Professionals for Safeguarding Adults / Named Professionals for Safeguarding Children are responsible for ensuring the reporting framework for Safeguarding operates and supports the incident reporting policy. All Safeguarding incidents must be reviewed and escalated in accordance with external Safeguarding procedures. This includes ensuring that any completed Safeguarding referral has an associated incident form. The post holder maintains the Safeguarding adult database providing reports to relevant groups, internal and external, as required and takes part in any investigation where Safeguarding is believed to be a factor.

Radiation Safety / Quality Assurance Lead will support the Trust in complying with the relevant statutory legislation for the use of radiation in healthcare.

Ionising Radiation Regulations 2017
Ionising Radiation (Medical Exposure) Regulations 2017
Control of Electro Magnetic Fields at Work Regulations 2016
Control of Artificial Optical Radiation at Work Regulations 2010

Environmental Permitting Regulations 2016
Radiation (Emergency Preparedness and Public Information) Regulations 2019
The Carriage of Dangerous Goods (Amendment) Regulations 2019

They will ensure the relevant external Trust Radiation Protection Advisor is informed and consulted regarding radiation incidents.

All Radiation Protection Advisors to the Trust must be appointed in writing and be consulted regarding matters as detailed in the legislation.

They will advise and ensure reporting of radiation incidents to the Health and Safety Executive, Care Quality Commission, Environment Agency, Officer for Nuclear Regulation and the Medicines and Healthcare products Regulatory Agency as appropriate.

The **Laser Safety Officer** must have appropriate scientific background and knowledge of laser safety and will be appointed by the Trust in writing. The Laser Safety Officer will advise the Trust to comply Control of Artificial Optical Radiation at Work Regulations 2010, and national guidance and standards; the MHRA Guidance, Lasers, intense light sources systems and LEDs – guidance for safe use in medical, surgical, dental and aesthetic practices.

The Laser Safety Officer will advise and report any laser incidents reportable to the Medicines and Healthcare products Regulatory Agency.

Controlled Drug Accountable Officer
The Controlled Drug Accountable Officer (CDAO) of the Trust is the Chief Pharmacist who is responsible for all aspects of the safe and secure management of Controlled Drugs (CDs) within the Trust. This includes ensuring that safe systems are in place for the management and use of CDs, monitoring and auditing the management systems and investigation of concerns and incidents related to CDs. The CDAO also liaises with other CDAOs and members of the Local Intelligence Network and police.

Any concerns regarding CDs can be raised with the CDAO (the Chief Pharmacist.

The **Medication Safety Officer** is responsible for reviewing all reported medication incidents in the Trust and using the relevant information to promote safe practice.

The **Medical Devices Safety Officer** is responsible for reviewing all reported incidents related to medical equipment in the Trust and using the relevant information to promote safe practice.

The **Head of Information Governance Digital Health** is responsible for reviewing all incidents related to information governance in line with the Data Security and Protection toolkit and report any significant breaches to the Information Commissioners Office. Any serious breach involving staff will be managed via Human Resources processes.

The **Lead Health and Safety Adviser** is responsible for reviewing all work-related accidents or injury incidents involving members of the public or staff and where applicable reporting these to the Health and Safety Executive under Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013 (RIDDOR).

All Managers at all levels within the Trust
All managers, regardless of their level within the Trust, are responsible for:

- Encouraging an 'open, just and restorative' culture within their service area.
- Ensuring all staff who report incidents receive an acknowledgement that encourages a positive reporting and risk management culture.
- Ensuring incident reporting arrangements are implemented within their service areas.
- Following an incident, take immediate action within the scope of their remit to prevent recurrence and/or eliminate or reduce any identified risks i.e. make the individual or environment safe.
- Provide immediate and appropriate support to staff, patients and families following incidents, using the principles of Being Open and Duty of Candour as per the Trust's 'Being Open and Duty of Candour Policy' (Trust Docs ID: 977), where required.
- Conduct local review into all reported incidents at the appropriate and proportionate level.
- Update Datix with the actions requiring completion, action owners and due date, ensuring owners are aware of their responsibilities.
- In conjunction with the Patient Safety Team, make arrangements to notify any other regulatory body of any incident as appropriate to their service area or function.
- Conduct a risk assessment and notify their line manager of identified risks highlighted by an incident or near miss, where risks cannot be reduced to an acceptable level (please refer to the Risk Management Policy – Trust Docs ID 1041 for further guidance).
- Complete and close incident forms within their service area, via the Datix system, and/or nominate a staff member to do this on their behalf, ensuring that all mandatory sections are completed with appropriate information and evidence of appropriate investigation.
- Adhere to the Trust's key performance measures for investigation and closure of incidents (20 working day standard) reported to the Trust's Performance and Accountability Framework.
- Use information from reported incidents, including analyses of themes and trends, to inform the undertaking and review of risk assessments for their service areas.
- Ensure an appropriate individual(s) within their service area is nominated to sign off incident forms in their absence.

All staff

- Report all incidents and near misses (where intervention has prevented harm to patients or staff) via the Trust's electronic incident management system, Datix.
- Ensure the details of any incident are contemporaneously and objectively reported in the patient's clinical record.
- Raise any concerns about situations that led to, or could lead to, an incident or a near miss with their line manager or the Patient Safety Team.
- Actively participate in any subsequent incident investigation such as: providing a written account of the incident; attending multidisciplinary fact-finding and feedback meetings such as After Action Review or Debrief activities
- Attend a Coroner's inquest on behalf of the Trust if called to do so.

The Trust will make available appropriate support to those staff involved in an incident, where this is required as defined in the PSIRP.

3. Our patient safety culture

The Trust aims to create a restorative just and learning culture of openness, in which staff do not feel afraid of reporting adverse events or feel blamed when they are involved in an incident. In this way learning can take place and improvements made locally and which can be shared across other services. The Trust will ensure that, apart from the exceptions below, incident reporting is not associated with blame or disciplinary action. The Trust may only consider using disciplinary or legal action against individuals in untoward events when there is:

- Alleged gross or repeated misconduct,
- Alleged professional mal-practice or criminal behaviour,
- An incident which results in a police investigation.

The Trust is committed to promoting and improving the quality and safety of care and treatment all patients receive, as well as preserving the safety of its staff, visitors, and others. To achieve this, it is important to support and embed a positive reporting culture throughout the organisation to enable learning when things do not go as expected. A safety conscious organisation is one which is receptive to adverse incidents so it can learn, develop, and change practice. We have embedded these principles into our procedures for the review of incidents.
In accordance with the Equality Act 2010 and the Francis Report (2013), this policy will support the Trust to ensure that learning responses and investigations are reviewed with fairness and transparency ensuring that all staff regardless of their protected characteristics are supported and listened to when raising a concern or reporting an incident relating to the quality of care and patient safety.

The Trust recognises the significant impact being involved in a patient safety incident can have on staff and will ensure staff receive the support they need to positively contribute to the review of the incident and continue working whilst this takes place.

There is a range of support and information available:

- The Patient Safety Team will advise, and signpost staff involved in patient safety incidents to the most appropriate information about the patient safety incident review process and further support functions.
- The Trust employee assistance scheme, Vivup which has a 24/7 support line 0330 380 0658.
- Workplace Health and Wellbeing
- Mental Health First Aiders
- Schwartz Rounds. Sessions are themed and provide a structured forum and safe space where staff come together to discuss the emotional and social impact of working in healthcare. You can join the conversation, share your experience or simply listen to their stories.
- Freedom To Speak Up Guardian - A confidential service for staff if they have concerns about the organisation's response to a patient safety incident.
- Support from Patient Safety Incident Investigators for those involved in a Patient Safety Incident Investigation
- Professional Nurse/Midwifery Advocates
- Complex Health Hub
- Chaplaincy

All staff with knowledge of the events being reviewed are encouraged to actively participate in the learning response. That may be through submitting written information, joining an After Action Review or debrief meeting as part of a learning response or a one-to-one conversation with the Patient Safety Incident Investigator.

All contact with staff will involve the collection of their account of the events and their views and opinions on how systems can be improved. Whomever is leading the review will agree with staff the timescales for feedback of progress and findings in accordance with the type of review method being utilised.

4. Patient safety partners

As part of our commitment to working with members of the public we have embarked on a Patient Safety Partner (PSP) programme. This is where members of the public support our Quality and Safety Improvement work. Initially starting with one PSP and building up to a maximum of six PSPs by 2026, those who support us in Safety and Quality Improvement have expectations as part of their contribution to the PSIRF to:

- Undertake the training required to the national standard for their role as specified in the National Patient Safety Syllabus as well as other relevant training.
- Be active members in the Trusts Safety oversight committees and groups; Quality and Safety Committee and Patient Safety and Effectiveness Sub-Board.
- Participate in investigation oversight groups.

- Be active members of the Quality Programme Board, QI Collaboratives and other work streams with the aim of helping us design safer systems of care and prioritise risk.
- Co-design information material for patients and the public.
- Encourage Patients, Families and Carers to play an active role in their safety.
- Contribute to safety recommendations following investigation, particularly around actions that address the needs of patients.
- Contribute to staff patient safety training as required.

5. Engaging and involving patients, families and staff following a patient safety incident

The PSIRF recognises that learning and improvement following a patient safety incident can only be achieved if supportive systems and processes are in place. It supports the development of an effective patient safety incident response system that prioritises compassionate engagement and involvement of those affected by patient safety incidents (including patients, families, and staff). This involves working with those affected by patient safety incidents to understand and answer any questions they have in relation to the incident and signpost them to support as required. See NHS England's 'Engaging and involving, patients, families and staff following a patient safety, incident' supporting guidance.

The Trust is committed to creating a culture of openness with patients, families and carers particularly when clinical outcomes are not as expected or planned. There is a responsibility as well as a statutory requirement under CQC Regulation 20, Duty of Candour for all healthcare organisations to be open and transparent with patients and their families when things go wrong with treatment or care delivery. Registered professionals should also refer to their professional guidance with reference to Duty of Candour requirements. This forms the basic principle of the Trust's 'Being Open and Duty of Candour Policy' (Trust Docs ID: 977).

Where it has been identified that an incident is suspected of causing moderate or severe harm, or death, then the Statutory Duty of Candour must be enacted by the Clinician responsible for the care of the patient. Adhering to Being Open principles however is good practice and the Trust encourages being open with patients and their families regardless of level of harm.

It is the responsibility of the Division to ensure all Duty of Candour requirements are met and that the accompanying evidence is uploaded to the relevant Datix record.

6. Patient safety incident response planning

PSIRF supports organisations to respond to incidents and safety issues in a way that maximises learning and improvement, rather than basing responses on arbitrary and subjective definitions of harm. Beyond nationally set requirements, organisations can explore patient safety incidents relevant to their context and the populations they serve rather than only those that meet a certain defined threshold.

6.1. Our patient safety incident response plan (PSIRP)

Our plan sets out how the Trust intends to respond to patient safety incidents over a period of 12 to 18 months. It was developed using 4 years previous incident, serious incident, never event, structured judgement review and complaint data together with the Trust claims profile to identify our highest safety risks to focus on as priorities for systems-based investigation.

The plan is not a permanent set of rules that cannot be changed. We will remain flexible and consider the specific circumstances in which each patient safety incident occurred and the needs of those affected, as well as the plan. Our PSIRP which is available to the public via our website is also available on Trust Docs ID: 22787

6.2. Resources and training to support patient safety incident response.

All systems-based Patient Safety Incident Investigations will be carried out by a Patient Safety Incident Investigator. Part of the Patient Safety Team, they will have undertaken specific training in systems-based investigation methodology.

Other learning responses will be coordinated by the Divisional Governance Teams and should be undertaken by staff who have received specific training in these techniques. Specific training in After Action Review and Structured Judgement Review is available and can be accessed via the Patient Safety Team and Learning from Deaths administrator respectively. Training and coaching in other learning responses can be accessed via the Patient Safety Team or in the Patient Safety section of The Beat.

6.3. Reviewing our patient safety incident response policy and plan

Our patient safety incident response plan is a ‘living document’ that will be appropriately amended and updated as we use it to respond to patient safety incidents. We will review the plan every 12 to 18 months to ensure our focus remains up to date; with ongoing improvement work our patient safety incident profile is likely to change. This will also provide an opportunity to engage with stakeholders to discuss and agree any changes made in the previous 12 to 18 months.

Updated plans will be published on our website, replacing the previous version.

A rigorous planning exercise will be undertaken every four years and more frequently if appropriate (as agreed with our integrated care board (ICB)) to ensure efforts continue to be balanced between learning and improvement. This more in-depth review will include reviewing our response capacity, mapping our services, a wide review of organisational data (for example, patient safety incident investigation (PSII) reports, improvement plans, complaints, claims, staff survey results, inequalities data, and reporting data) and wider stakeholder engagement.

7. Responding to patient safety incidents

7.1. Patient safety incident reporting arrangements

7.1.1. General incident reporting procedure

Any member of staff who is involved in or witnesses an incident must ensure that it is documented using the Trust online Datix form.

Clinical staff must record in the patient's health record that there has been an error and any ill effects noted; this includes hospital acquired infections.

The patient's doctor should be informed and should review any patient that may have been harmed from the incident e.g. incidents involving medication or patients falling with or without apparent injury. The results of any examination or investigations must be fully documented in the patient's healthcare record and on the incident form.

The incident form must record as much information about the incident as possible. **The information given must be factual and not opinion**. Exact times, full names of the people involved, and serial numbers of any equipment are required to be completed in the relevant section of the incident form.

As a minimum all mandatory fields marked by a red asterisk on the online Datix form must be completed. These include:

- Nature of incident is (e.g. actual event or near miss - wrong drug given, delay in patient receiving treatment).
- what happened (severity of actual or potential harm, people and equipment involved)
- who was affected by the incident (patient's name, hospital number, date of birth, etc. If the person affected is a staff member it is not necessary to include details of their home address or date of birth etc).
- person reporting the incident.
- where did it happen (location/speciality).
- when did it happen (date and time).
- how did it happen (immediate or proximal causes).
- what action was taken or proposed (managers actions - immediate and longer term).

Any documents capturing a staff members recollection of events provided should be legible, signed, dated and timed and must be attached to the Datix system.

Where urgent action is indicated out of hours, the Site Manager should be informed who may need to escalate to the manager on-call.

Where the incident involves a patient or visitor, a member of staff will complete the online incident form.

Where an incident involves a visitor or a member of staff, the online Datix report form will be completed and identifying the type of incident as 'Patient, Public/Contractor/Visitor, Staff, Trust, or Other – no actual or potential harm to patients/staff'. These incidents are reviewed daily by the Health and Safety Advisor and where necessary are RIDDOR reported.

Indicative level of harm assigned following the NRLS levels of harm guidance, which is on the Datix form, this will change to LFPSE levels of harm guidance when published.

7.1.2. Reporting incidents resulting in severe harm or death.

In addition to the completion of an incident form the member of staff should:

- Report the incident immediately and verbally to the most senior manager of the department or service. For out of hours this will include the Site Manager, who will contact the Director on call who will escalate to the Executive on Call.
- Keep a concise and contemporaneous record of events. This should include decisions taken and by whom, and details of any witnesses or conditions at the time ensure the physical security of all healthcare records making photocopies if necessary and any faulty equipment or other evidence in preparation for a full investigation.

The senior manager should:

- Hold an immediate 'hot debrief' to ensure patient and/or family members and staff are supported in the immediate period following an incident.
- Ensure staff involved or witness to the event document their recollection of events whilst they are fresh.
- Ensure staff and the patient, relative or carers are kept informed and supported through the event as necessary.
- Inform Triumvirate/Divisional Governance Manager

7.2. Patient safety incident response decision-making

7.2.1. Daily Divisional Incident Triage

The Divisional Governance teams will conduct a daily incident triage of all incidents reported in the preceding 24 hours (72 hours if after a weekend) regardless of level of harm, and signpost them for review as per the Trust PSIRP (Trust Docs ID: 22787) as follows:

Green Pathway	Amber Pathway	Red Pathway
• No harm/ low harm incidents not identified as Local Priority, limited concerns. • Moderate or severe harm incidents where contributory factors are fully understood and linked to Quality Improvement work. • Meet Duty of Candour as required.	• Incidents where contributory factors are not fully understood. • Limited improvement activity in place. • Concerns raised by family, patient, other. • Areas of increased reporting. • Concerns identified through Thematic Analysis. • Incidents where more than one Division are involved. • Meet Duty of Candour as required.	• Incidents that meet national priority or local priority for PSII as outlined in Trust PSIRP.
Learning Response Facts confirmed and logged on Datix. Incident validated at local level *. Monthly Thematic Analysis of all low and no harm incidents by Division to identify emerging risks.	**Learning Response** Division to agree type of patient safety review: AAR/ Debrief/ Case Note Review/MDT review/ SJR. If unsure add incident or concern to Complex Case Dashboard Meaningful engagement with patient or family Meaningful engagement with staff involved as indicated. Insight to inform Safety Quality Improvements	**Learning Response** PSII by named investigator using SEIPS methodology and national report template. Full involvement of patient and/or family. Meaningful engagement with staff involved. Safety recommendations inform new and ongoing Safety Quality Improvements

*A SWARM/hot debrief can be used to validate facts at a local level. This response should be coordinated by the ward or department lead.

At any point the Divisional Governance team can ask for further validation of facts or more information from those involved to triage the incident appropriately. If a decision is unable to be made the incident must be logged onto the complex case dashboard for further discussion.

Divisions will be responsible for conducting a monthly analysis on all no and low harm incidents to identify any themes or emerging risks. These if identified can be logged onto the complex case dashboard for discussion.

There are three groups that have a responsibility to review incidents, and this will continue in order for organisational oversight on these categories of incident:

- Clinical Harm Incident Group
- Medicines Management Incident Review Group
- Reducing Restrictive Interventions Scrutiny Panel (RRISP)

Incidents in these categories should be triaged as above, however the monthly analysis of incidents will not be required as the above groups will identify themes and emerging risks and log them onto the complex case dashboard.

There are some incidents which are externally reportable. Please see Appendix 1 - Reporting Criteria external to the Organisation for a list. If an incident is identified as one of these at triage, the Patient Safety Team should be contacted, who will ensure it is reported to the appropriate body.

Maintain a list of learning responses.

7.2.2. Complex Case Review Group

This multidisciplinary group will meet weekly and discuss all incidents on the complex case dashboard. The group will oversee that the most effective proportionate learning response tool is selected and triangulate incidents, inquests and any complaints linked to these, to ensure they meet all statutory requirements and have clear key lines of enquiry for the review.

Notes will be taken of the discussion, decision and rationale for the selected learning response which will be kept with the incident record on Datix.

The ICB will be represented at this group to enable them to have oversight of the learning response activity being undertaken and to identify incidents or issues that require a cross-system learning response.

7.2.3. Multi-agency incidents

Where more than one organisation is involved in an incident requiring a formal and coordinated response, the relevant commissioner will be responsible for deciding who will act as the lead organisation for the purposes of investigation and incident management and be responsible for reporting the incident. The Patient Safety Team will liaise with the ICB and advise accordingly.

Where there are instances involving agencies which the Trust sub-contracts to, the agencies are required to support the Trust investigations in accordance with contracts. Where there are issues with engagement, this should be escalated to the Patient Safety Team who will liaise with the Trust Contracts team for support or escalate accordingly.

7.2.4. PSII Review and Sign Off Group

This group will be chaired by a member of the Trust Executive. All systems based PSII reports will be on the national report template and will be reviewed by this group to ensure that the terms of reference have been robustly explored, that the report meets the national standards required of a PSII and will sign off the final report accepting the safety recommendations made which will inform the Quality Improvement or Transformation work programmes.

The ICB will be represented at this group to enable them to have oversight of the insight gained and the safety recommendations made to identify learning or recommendations that may have Integrated Care System consideration or impact.

A PSP will also be represented at this group to ensure that the patient, family or carer have been engaged with meaningfully and to contribute to safety recommendations following investigation, particularly around actions that address the needs of patients.

7.2.5. Timeframes for learning responses

Activity	Timescale	Detail
Incident reporting	**As soon as possible** following incident occurring – maximum within the same working day	It is vital to ensure a rapid incident report so that all relevant detail can be entered, and key facts are not lost.
Divisional Incident Triage	Within **24 hours** of incident being reported (72 hours if following a weekend).	To ensure that the most appropriate incident management pathway used and where relevant a proportionate learning response is selected.
Incident for local level validation	To be started within **24 hours** of incident being reported.	To ensure that immediate safety actions can be taken to mitigate risk to patients, staff and the public
Closure of low and no harm incidents	Within **20 working days**	Evidence of action by departmental teams to validate facts, action and maintain patient, staff and public safety
Information gathering for potential PSII or PSR	Within 5 working days following incident being reported	To ensure that an initial review is undertaken by the team and that immediate actions have been taken to minimise risk to patient safety

Activity	Timescale	Detail
Incident logged on complex case dashboard	Within 5 working days of information gathering	To provide the Trust of assurance of the investigation approach
Patient Safety Review (PSR)	Complete review using agreed learning response method and provide approved report within **30 working days**	To provide the Trust of assurance that a thorough review has taken place and actions have been taken to minimise risk to patient safety
Actions agreed to be completed following PSR	All evidence for each action within **60 working days of completion and approval of report.**	To ensure that all actions have been undertaken to provide assurance to patients, relatives and Trust Board that areas have improved practice and quality of care to maintain patient safety.
Patient Safety Incident Investigation (PSII)	Complete investigation and provide approved report within **3 months and no longer than 6 months**	Nationally agreed in alignment with PSIRF, timescales to be agreed with patient/family. Safety recommendations will inform new or ongoing Quality Improvement or Transformation programmes and will be monitored via these established governance routes.

8. Safety recommendations and improvement plans

The following mechanisms are used to develop and support improvements following PSIIs:

- The Trust uses quality improvement methodology as the way we do business across the Trust, constantly evaluating our work processes and making changes to improve services for patients and the working environment for staff.
- Our processes for improvement are described in our Quality Improvement and Safety Strategy (Trust Docs ID; 11663). The recommendations from our Patient Safety Investigations and PSRs will flow through these processes linking them in directly to the Trusts Quality Improvement and Transformation work.
- At the conclusion of a PSII the final report will be submitted to the PSII Review and Sign off Group for discussion and agreement of the safety recommendations. Once agreed these will be referred through the most appropriate governance route for the recommendation, Hospital Management Board, Quality Programme Board or Transformation Board.
- At the conclusion of a PSR the Divisional Triumvirate will sign off the response and the outputs from these whether insight, action or improvement will be logged onto Datix and monitored by the Divisional Governance Team until completion via the Divisional evidence groups.

- The Patient Safety Learning Coordinator will also be informed to facilitate cascade of relevant content across the organisation through a range of media including The Beat, safety bulletins, social media streams, video, podcasts etc.
- Improvement plans will be shared with the relevant teams to enable delivery of actions, monitoring and evaluation of improvement outcomes. The Quality Improvement Team will provide update reports on progress to the Quality Programme Board.
- The Quality Improvement Team or Transformation Team will have oversight and undertake monitoring of all improvement plans created following a PSII safety recommendation. The Quality Improvement Team reports to the Clinical Safety and Effectiveness Sub-Board and then up to Quality and Safety Committee.
- Monitoring through audit should be undertaken when improvement plans are complete to ensure that changes are embedded and continue to deliver the desired outcomes. When changes have led to measurable improvements then these will be shared, adapted and adopted with other areas of the organisation and peer organisations via the Patient Safety Specialist to the ICB Patient Safety Specialist Network and/or System Quality Group.

9. Complaints and appeals.

Local and national arrangements for complaints and appeals relating to the organisation's response to patient safety incidents are available via the Trust's Patient Advice and Liaison Service.

The Trust fully upholds the NHS Constitution, aspiring to put the patient at the heart of everything it does. Any concerns or complaints raised about a service provided by the Trust will be taken seriously and will be managed in a way that reflects the Trusts' PRIDE values.

The Trust encourages patients, families or carers to raise any concerns they may have immediately and at the time they occur by speaking to a member of staff. The Trust's complaints policy focuses specifically on those concerns or complaints that require management through the Patient Advice and Liaison Service and the Complaints Team. The process for raising concerns through this route can be found in the Complaints Handling Policy – Trust Docs ID: 20352

10. Related Documents

- Being Open and Duty of Candour Policy – Trust Docs ID: 977
- Patient Safety Incident Response Plan – Trust Docs ID: 22787
- Speak up Policy – Trust Docs ID: 688
- Risk Management Policy – Trust Docs ID: 1041
- Complaints Handling Policy – Trust Docs ID: 20352
- Claims Management Policy – Trust Docs ID: 646
- Responding to Deaths (Mortality Review) Policy – Trust Docs ID: 14401

- Misconduct Policy – Trust Docs ID: 15355
- Capability Policy – Trust Docs ID: 694
- Health and Safety Policy – Trust Docs ID: 607
- Safeguarding Adults Policy – Trust Docs ID: 1105
- Safeguarding Children Policy – Trust Docs ID: 1179
- Ionising Radiation Policy – Trust Docs ID: 1007
- Quality Improvement and Safety Strategy – Trust Docs ID: 11663
- Information Investigation Policy - – Trust Docs ID: 11010
- Reducing Restrictive Interventions and Restraint – Trust Docs ID: 14651
- Medicine Policy and Procedures - Trust Docs ID: 423
- Reporting of Injuries, Diseases and Dangerous Occurrences (RIDDOR) – Trust Docs ID: 590
- Accessible Information Standards Policy – Trust Docs ID: 20348

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Patient Safety Incident Response Framework (2020) NHS England.

Policy Guidance on Recording Patient Safety Events and Levels of Harm (2023), NHS England.

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With thanks to PSIRF Early adopter organisations; East Suffolk and North Essex NHSFT, West Suffolk Hospital NHSFT, North Bristol NHS Trust, Leeds Teaching Hospitals NHS Trust, East Lancashire Hospitals NHS Trust.

12. Monitoring Compliance / Audit of the process/policy principles/service to be delivered

Compliance with the process will be monitored through the following:

Key elements	Process for Monitoring	By Whom (Individual / group /committee)	Responsible Governance Committee /dept	Frequency of monitoring
Compliance with policy	Internal Audit	Internal Auditors	Audit Committee	Minimum every 3 years
Activity against agreed PSIRP	Activity and assurance reports	Head of Patient Safety	CSESB/ IPR	Monthly
Compliance against PSR timelines	Performance and Assurance Framework	Datix Team	PAF	Monthly

The audit results are to be discussed at relevant governance meetings and taken to Clinical Safety and Effectiveness Sub Board to review the results and recommendations for further action. Then sent to Hospital management Board who will ensure that the actions and recommendations are suitable and sufficient.

13. Equality Impact Assessment (EIA)

Type of function or policy	New Policy

Division	Corporate	**Department**	Risk & Patient Safety
Name of person completing form	Karen Kemp	**Date**	01/08/2023

Equality Area	Potential Negative Impact	Impact Positive Impact	Which groups are affected	Full Impact Assessment Required YES/NO
Race	N	N	N/A	No
Pregnancy & Maternity	N	N	N/A	No
Disability	N	N	N/A	No
Religion and beliefs	N	N	N/A	No
Sex	N	N	N/A	No
Gender reassignment	N	N	N/A	No
Sexual Orientation	N	N	N/A	No
Age	N	N	N/A	No
Marriage & Civil Partnership	N	N	N/A	No
EDS2 – How does this change impact the Equality and Diversity Strategic plan (contact HR or see EDS2 plan)?				

- **A full assessment will only be required if: The impact is potentially discriminatory under the general equality duty.**
- **Any groups of patients/staff/visitors or communities could be potentially disadvantaged by the policy or function/service.**
- **The policy or function/service is assessed to be of high significance.**

IF IN DOUBT A FULL IMPACT ASSESSMENT FORM IS REQUIRED

The review of the existing policy re-affirms the rights of all groups and clarifies the individual, managerial and organisational responsibilities in line with statutory and best practice guidance.

Appendix 1 - Reporting Criteria external to the Organisation

The following are reporting criteria required external to the organisation:

Suicides

The Trust does not provide acute adult psychiatric services; however, this does not preclude the possibility of a Trust patient suicide occurring.

The suicide(s) or suspected suicide(s) of any person in receipt of NHS services on or off NHS premises may result in an incident requiring a higher level of investigation such as PSII. Consideration of the circumstances should be made and communicated to the relevant psychiatric service provider who will be the lead organisation in coordinating the investigation in instances where the patient was under the care of the mental health services.

Safeguarding Children and Vulnerable Adults

Incidents reported where child or vulnerable adult safeguarding issues are identified at any stage must be referred to the Named Safeguarding Leads who will ensure the appropriate procedure is followed. All safeguarding issues will be considered within the requirements of the Trust's PSIRP and advice and guidance from the Safeguarding Teams.

Healthcare Associated Infections

Any healthcare associated infection (including, but not limited to, MRSA bacteraemia, MSSA bacteraemia, *E. coli* bacteraemia, GRE bacteraemia and Clostridium difficile infection) that has significantly contributed to death or serious harm and/or is recorded in part 1 of the death certification must be reported and investigated.

Outbreaks of Clostridium difficile infection (defined as two or more cases) caused by the same strain, related in time and place, within a 28-day period, should be reported and reviewed. All Healthcare Associated Infections must be referred to the Head of Infection, Prevention and Control who will ensure that the appropriate Post Infection Review process is followed.

Health Protection Agency

The Health Protection Agency's guidance on healthcare associated infection operational guidance and standards for health protection units provides information on the steps that should be followed in escalating concerns about the management of a healthcare associated infection situation, incident or outbreak. All reporting to the Health Protection Agency is via the Director of Infection Prevention and Control (DIPC) or the Infection Control Team.

Coronial process

HM Coroner is notified of any deaths that require notification under the 2019 Notification of Deaths Guidelines. When a death is unexpected, the cause cannot be identified, violent or unnatural, HM Coroner will decide whether to hold a post-mortem and, if necessary, an inquest. When a person dies in the custody of the legal

authorities, including detention under the Mental Health Act, an inquest must be held.

HM Coroner's court is a court of law, and accordingly HM Coroner may summon witnesses to attend in person or virtually to provide evidence. It is a legal requirement to attend, and failure to do so may result in a charge of contempt of court.

All incidents, incident learning response reports and records of recollection of events are subject to submission to HM Coroner.

Learning from Deaths and Medical Examiner Service

The Trust has a robust process for the review of inpatient deaths. The Medical Examiner Service reviews all inpatient deaths and identifies any patients which require escalation through our mortality governance system. The Medical Examiner Service can also escalate any concerns via incident reporting on Datix, to existing mortality and morbidity meetings or by requesting a Structured Judgment Review.

Following completion of a Structured Judgement Review and in cases where the death is found to be definitely avoidable or strong evidence of avoidability, the PSII process of investigation will commence. Following the initial fact finding process a decision will be taken as to the level of investigation required.

Incidents involving National Screening Programmes

All incidents involving National Screening Programmes must follow the Public Health England (PHE) *Managing Safety Incidents in NHS Screening Programmes (2017)* The PHE policy can be found at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/672737/Managing_safety_incidents_in_National_screening_programmes.pdf.

The guidance sets out the requirements for managing safety concerns, safety incidents in NHS Screening Programmes. It is important that actions are in proportion to the risk of harm and based on accurate investigation. It is relevant to healthcare staff that may identify or manage a screening incident including those who provide and commission NHS funded services. It is for staff of NHS Screening Programmes who advise on screening incidents.

Screening safety incidents include:

- any unintended or unexpected incident(s), acts of commission or acts of omission that occur in the delivery of an NHS screening programme that could have or did lead to harm to one or more persons participating in the screening programme, or to staff working in the screening programme.
- harm or a risk of harm because one or more persons eligible for screening are not offered screening.

The appropriate Quality Assurance Reference Centre must be informed by the Trust's hospital-based programme coordinator (e.g. Breast Screening Programme Manager

or Head BMS – Histopathology) where an incident involves any National Screening Programme. When a screening safety incident is suspected or declared, the provider will:

- notify Screening Quality Assurance Service (region) and the PHE Screening and immunisation team embedded in/associated with the commissioner of the service.
- fact find, manage and review the safety issue taking account of Quality Assurance advice and reporting to the screening and immunisation team.
- collaborate effectively with other providers and, where agreed, assume a lead provider role.

Information Governance Incidents

The Department of Health (DH) definition of an information governance serious incident is: *Any incident involving the actual or potential loss of personal information that could lead to identity fraud or have other significant impact on individuals'.* This definition applies irrespective of the media involved and includes both loss of electronic media and paper records. All information governance incidents must be referred to the Head of Information Governance who will ensure the incident is managed in line with the Trust's Information Governance policy; DH Information Governance Policy; and the Information Commissioner's reporting requirements and the DH full guidance *Checklist for Reporting, Managing and Investigating Information Governance Serious Untoward Incidents*

Police

The Police are likely to investigate incidents where there is evidence, or suspicion of, a criminal offence having been committed, for example if an incident has arisen from or involves criminal intent or gross negligence. In the first instance the incident should be reported following normal incident reporting procedures. Reporting to the Police is undertaken by one of the following: Medical Director, Chief Nurse, CDAO (to the CD Liaison Officer where in post, in instances of CDs) or their delegates.

Controlled Drug Local Intelligence Network (CD LIN)

The CD LIN must be notified by the CDAO in incidents related to CDs.

Professional Regulators and Professional Misconduct

If grounds for professional misconduct are suggested it is important that the appropriate lead (e.g. Medical Director/the Responsible Officer or Chief Nurse) is alerted within two days to ensure that appropriate action is taken.

Incidents involving radiation (ionising or non-ionising)

Incidents involving radiation could be because of equipment failure or operator error and could involve patients, members of the public or employees.

All details of radiation incidents must be reported on Datix. The Radiation Safety / Quality Assurance Lead will assist with the review and use guidance issued by the enforcing bodies to decide as to whether an incident is required to be reported

externally. The appropriate person will report and liaise with the external body until closure of the incident.

Further information can be found in the relevant Ionising Radiation Policy.

Incidents relating to deceased patients as described in the Trust Policy Human Tissue Authority Reportable Incidents

Human Tissue Authority (HTA) licensed establishments in the post-mortem sector are required to notify the HTA of any reportable incidents (HTA Reportable Incident – HTARI), including near misses, **within five working** days of the incident being discovered. Establishments must not wait until any internal review or investigation is complete before reporting the incident. To meet this deadline, any potentially significant incident involving mortuary services, or any other potential breach of the Human Tissue Act must be reported using the Trust's process in the normal way for executive approval to allow the Designated Individual (DI) to inform the HTA in accordance with HTA current guidelines.

It should be noted that the HTA Serious Incident classifications differ from the NHSE published criteria and therefore HTA current guidance should be referred to when deciding on the incident grade, and whether it meets the HTA and NHSE thresholds. It is the responsibility of the Trust's Designated Individual (DI) to ensure HTARIs are reported to the HTA via the web portal. Only DI's and Persons Designated (PDs) are able to submit notifications using the web portal.

The DI must ensure a follow-up report is submitted to the HTA via the web portal within 90 days of making the initial notification. This should ideally be a copy of the Trust's internal investigation report.

Healthcare Safety Investigation Branch

The Healthcare Safety Investigation Branch (HSIB) was established in 2017 by an expert advisory group following recommendations from government inquiry into clinical incident investigations with the purpose to improve safety through effective and independent investigations that don't apportion blame or liability. The HSIB conduct national investigations into subject areas identified by them using certain selected index cases from StEIS as staring point. Organisations approached to take part in a national investigation are not identified.

The HSIB also undertake maternity investigations which meet the 'Each Baby Counts' criteria and a defined criteria for maternal deaths.
https://www.hsib.org.uk/maternity-information/

The Trust will follow the Patient Safety Incident Review Policy through the patient safety review process.

- The Division will undertake an initial investigation and identify whether it may meet the requirements of an HSIB investigation. An incident may meet the requirements for an HSIB investigation whether or not it meets PSR Criteria.

- Following agreement with the Patient Safety Team, the incident will be sent to the HSIB through the Trust's nominated Leads, one of which will consistently be the Director of Midwifery or their nominated deputy.
- The HSIB will make an immediate decision as to whether or not the incident meets the criteria for HSIB investigation.
- Where the incident is not accepted for investigation by the HSIB, the decision for further investigation will be discussed with the Patient Safety Team to identify the most appropriate investigation.
- Where the HSIB agree to undertake the investigation, all processes will be followed as per HSIB guidelines.
- The Division will inform the patient/carer that the HSIB will be conducting the investigation and perform Duty of Candour.
- The HSIB will contact the family and discuss timelines for completion, however the Division has full responsibility for Duty of Candour.
- The HSIB will keep the Division informed throughout the investigation including updates on expected date for completion.
- The HSIB will ensure the draft report is agreed by the Division and will present to PSII Review and Sign off group for executive sign off prior to sharing with the family.
- The Trust will ensure a summary of the investigation is shared with the Norfolk and Waveney system
- The Division will complete the action plan within the timescales set out and the action plan monitored until completion.

N.B. HSIB is going through organisational transformation to become the Health Services Safety Investigations Body (HSSIB)

At the same time the Maternity investigations programme will move to be hosted by the CQC

This is expected to become operational from October 2023.

MBRRACE-UK: Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries

MBRRACE programme of work of work involves the national confidential enquiry into maternal deaths and national surveillance of late fetal losses, still births and infant deaths.

All eligible deaths should be reported via the MBRRACE-UK online reporting system by the authorised person within the Women's and Childrens Division. All perinatal deaths will be reviewed using the Perinatal Mortality Review Tool (PMRT).

All maternal deaths will be reported by the authorised person by contacting the MBRRACE-UK team in Oxford directly by phone 01865 289715 or e-mail mbrrace-uk@npeu.ox.ac.uk.

Health and Safety Executive (HSE)

The HSE is responsible for the enforcement of the Health and Safety at Work Act 1974 and ensuring that 'risks to people's health and safety from work activities are properly controlled'. Incidents may need to be reported under the RIDDOR.

Definitions include:

- Work-related accidents which cause death
- Specified injuries: e.g., fractures, amputations, loss of sight, serious burns
- Occupational Diseases: e.g., skin diseases, lung disease, carpal tunnel syndrome
- Dangerous occurrences: explosions, fire.
- Over-seven-day incapacitation of a worker: the employee is away from work or unable to perform their normal work duties for more than 7 consecutive days (not counting the day of the accident).

For incidents that result in a person being off work or unable to perform the full range of their normal duties for more than 7 days a report must be submitted to the HSE by law within 15 days of the incident occurring. In the case of death, serious injury or a dangerous occurrence then the initial report must be submitted immediately by telephone or online and followed up within 10 days with any additional information.

A full list of reportable incidents is available on the HSE website www.hse.gov.uk/riddor . The Trust Lead Health and Safety Adviser will inform the HSE of any reportable incidents.

Where incidents relate to a defect or failure involving engineering plants, infrastructure and/or non-medical devices, a defect and failure report should be submitted to the Department of Health via the defect and failure reporting portal http://efm.hscic.gov.uk/ by the Lead Health and Safety Adviser.

Medicines and Healthcare products Regulatory Agency (MHRA)

An online service for the reporting of incidents involving equipment or adverse drug reactions are made to the MHRA.

- A medicine causes side effects
- Someone injured by a medical device
- A patient's treatment is interrupted because of a faulty device
- Someone receives the wrong diagnosis because of a medical device
- A medicine doesn't work properly
- A medicine is of poor quality
- You think a medicine or medical device is fake or counterfeit.

Further information and advice can be sought from the Trust Medication Safety Officer or the Medical Devices Safety Officer.

Incidents involving blood products are also reported online to the MHRA via the Serious Hazards of Transfusion (SHOT) and Serious Adverse Blood Reactions and Events (SABRE) systems. A copy of all reports should be retained, and a copy sent to the Risk and Patient Safety team with the related incident form or incident number.

NHS Resolution

NHS Resolution will be contacted by Legal Services where an incident, letter of complaint or claim is the first indication to:

- An incident reported as major or catastrophic which reveals a possible breach of duty leading to a potentially large claim (over £250,000).
- Claims arising from complaints where the response implies a possible admission of liability.
- Where preliminary analysis following requests for disclosure of records reveals a significant litigation risk.

Once the claim has been reported, NHS Resolution will either recommend that it be handled in house or assigned to solicitors for further conduct. See the Claims Management Policy and the Complaints Policy.

Appendix 2 – Review techniques / Learning response tools

Technique	Method	Objective
Sharing an anonymized incident report	Disclosure of an incident	To provide a written overview of the incident (what happened).
'Being open' discussion	Disclosure of an incident	To provide the opportunity for a verbal discussion about the incident (what happened) and to respond to any concerns. Duty of Candour.
Incident timeline	Review	To provide a more detailed documentary account of an incident (what happened) in the style of a 'chronology'.
Case record/note review	Review	To determine whether there were any problems in the care provided to a patient by a particular service. (To routinely identify the prevalence of issues; or when bereaved families/carers or staff raise concerns about care).
LeDeR – report and review of the death of a person with a learning disability	Review	To review the care of a person with a learning disability (recommended alongside a case note review).
Debrief (SWARM)	Review	To conduct a post-incident/event review as a team by answering a series of questions.
Safety huddle	A short multidisciplinary briefing held at a set time and place, and informed by visual feedback of data	• To improve situational awareness of safety concerns • To focus on the patients most at risk • To share understanding of the day's focus and priorities • To agree actions • To enhance teamwork through communication and collaborative problem-solving • To celebrate success in reducing harm
After-action review	A structured, facilitated	To identify a group's strengths, weaknesses and areas for improvement by understanding the

Technique	Method	Objective
	discussion on an event	expectations and perspectives of all those involved and capture learning to share more widely.
Clinical review	A care and treatment review	To determine and describe how the care provided compared with accepted standards.
Mortality review	A systematic review of a series of case records using a structured or semi-structured methodology	To identify any problems in care and draw learning or conclusions that inform action needed to improve care within a setting or for a particular patient group.
Perinatal mortality review tool	Systematic, multidisciplinary, high-quality audit and review	To determine the circumstances and care leading up to and surrounding each stillbirth and neonatal death, and the deaths of babies in the post-neonatal period having received neonatal care.
Transaction audit	Audit	To check a trail of activity through a department, from input to output.
Process audit	Audit	To determine whether the activities, resources and behaviours that lead to results are being managed efficiently and effectively.
Outcome audit	Audit	To determine systematically whether the outcome was as expected/intended.
Clinical audit	Outcome audit	A quality improvement cycle involving measurement of the effectiveness of healthcare against agreed and proven standards for high quality and acting to bring practice into line with these standards to improve the quality of care and health outcomes.
Risk assessment	Proactive hazard identification and risk analysis	To determine the likelihood of an identified risk and its potential severity (eg clinical, safety, business).