

Patient Safety Incident Response Framework (PSIRF) and Incident Reporting and Management Policy for East London NHS Foundation Trust (ELFT)

This replaces the Incident Reporting Policy

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Mental Health and LD	
Community Health Services	

Version Control Summary

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1.1	May 2025	Fabiola Ojo, Head of Incident Management Charlotte Walton, PSIRF Implementation Lead. Abiola Ajayi- Obe, Associate Director of Governance and Risk	Final	Revised to update the timeline to investigations and correct typos for consistency.

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Executive Summary

The Trust's commitment to patient safety remains at the forefront of our operations. This newly revised Patient Safety Incident Review Framework Policy and Incident Management Policy represents a significant evolution in how we handle and learn from incidents, with a focus on fostering a culture of continuous improvement.

This document marks a critical shift in our approach to incident review, moving away from the traditional serious incidents framework and adopting the new Patient Safety Incident Response Framework (PSIRF).

This policy provides comprehensive guidelines while recognising the complex, dynamic nature of healthcare. It is designed to be adaptable, allowing for appropriate responses to unique circumstances while maintaining overall consistency in our approach to patient safety. The PSIRF plan and this policy are living documents, regularly updated to reflect our learning and evolution in implementing PSIRF and its associated learning responses. This approach allows us to align with emerging best practices and the specific needs of our organisation.

Key Highlights

Transition to InPhase System and LFPSE: The Trust has transitioned from the Datix system to the InPhase system for logging and reviewing incidents. Additionally, we have implemented the Learning from Patient Safety Events (LFPSE) system, enhancing our ability to capture, analyse, and learn from patient safety incidents.

Introduction of PSIRF and PSIRP: The PSIRF (Patient Safety Incident Response Framework) and the accompanying Patient Safety Incident Response Plan (PSIRP) align with national guidelines and represent our strategic approach to incident response and investigation. These frameworks emphasise a holistic, learning-oriented approach to patient safety.

We have adopted the Systems Engineering Initiative for Patient Safety (SEIPS) model, moving away from root cause analysis and the blame culture. SEIPS focuses on understanding the interactions between various components of the healthcare system to improve patient safety. This approach fosters a culture of learning and improvement while recognising the need for accountability.

Learning Responses: Our PSIRP plan outlines various learning responses, including:

- Patient Safety Incident Investigations (PSII), which replace the previous Serious Incident investigations
- After Action Reviews (AARs)
- SWARM Huddles for our pressure ulcer pathway

These learning responses are at different stages of implementation, and we will continue to update and refine them as we gain experience and confidence in their application.

Enhanced Oversight Mechanisms: The policy establishes PSIRF Oversight Panels to ensure comprehensive review and decision-making for patient safety investigations.

Updated Pathways and Procedures: Key updates include the 72-Hour Procedure, Co-Reviewer Selection Process, Feedback Meetings and Action Plans, updated Safeguarding Procedures.

The Governance & Risk team provides continuous training, particularly for the 72-hour reporting procedure, ensuring staff are well-equipped to implement these new processes effectively.

The effectiveness of this policy and associated practices is continuously monitored through our established Quality Committee Assurance reporting process. This includes quarterly reviews, monthly exception reports, and an annual comprehensive reporting. These mechanisms ensure we maintain a robust overview of our patient safety initiatives and their impacts.

Ratification and Governance:

This policy will be ratified at the Quality Committee, underscoring its importance in our governance structure. However, it is important to note that the ratification does not make the policy inflexible; rather, it endorses our commitment to continuous improvement in patient safety practices.

This policy underscores the Trust's unwavering commitment to safeguarding our patients through robust, yet flexible incident management and a strong focus on learning and improvement. The adoption of the InPhase system, LFPSE, SEIPS model, and the implementation of the PSIRF framework are significant steps towards ensuring that our incident management processes are not only compliant with best practices but are also reflective of our dedication to delivering the highest standards of patient care while acknowledging the complex realities of healthcare delivery.

1. Introduction

This policy establishes the Patient Safety Incident Response Framework (PSIRF) at East London NHS Foundation Trust (ELFT). It outlines the principles, processes, and expectations for managing patient safety incidents, with the aim of enhancing learning and improving patient outcomes.

Central to this framework is the Patient Safety Incident Response Plan (PSIRP), a separate document that details the Trust's specific criteria and approach for responding to patient safety incidents. The PSIRP, which is publicly accessible, defines which incidents will be investigated, the methods of investigation to be utilised, and how learning will be disseminated and implemented.

This policy delineates the roles and responsibilities of staff in reporting, managing, and investigating incidents. It details the Trust's approach to developing and maintaining effective systems and processes to respond to incidents and issues, fostering a culture of continuous improvement in patient safety.

By aligning with the requirements of the PSIRF and integrating comprehensive incident management practices, this policy ensures a unified and systematic approach to maintaining and enhancing patient safety across ELFT. It emphasises a proportionate response to incidents, focusing on learning and improvement rather than blame, and promotes the involvement of patients, families, and staff in the incident response process.

A. Rationale

This policy supports the requirements of the PSIRF and sets out ELFT's approach to developing and maintaining effective systems and processes for reporting and responding to patient safety incidents. A patient safety incident is any unintended or unexpected event that could have or did lead to harm for one or more patient's receiving healthcare, resulting in no harm or contributing to a fatal outcome. All staff are responsible for reporting any incidents, adverse events, or near misses they become aware of and reviewing them as detailed within this policy.

The Trust acknowledges that adverse events often reflect systemic breakdowns, and that staff are usually trying to perform their duties safely and effectively. While staff actions may contribute to incidents, underlying causes often exist. Therefore, the Trust is committed to exploring these system failures and improving them using a range of learning response tools.

PSIRF advocates a coordinated, data-driven response to patient safety incidents, embedding incident response within a broader system of improvement. This prompts a significant cultural shift towards systematic patient safety management.

This policy supports the 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 Patient Safety Incident Response Plan (PSIRP)

This is a crucial component of our PSIRF implementation. It is a comprehensive, publicly accessible document that:

- Defines our organisation's specific criteria for selecting patient safety incidents for review, based on both national and local priorities.
- Outlines the range of learning response methods we employ, including Patient Safety Incident Investigations (PSIIs), Care Review Tools, and After Action Reviews.
- Details our processes for disseminating insights and implementing improvements.
- Specifies the allocation of resources for patient safety incident responses.
- Aligns with our organisation's unique safety profile, local patient safety risk assessment, and available resources.
- Reflects national patient safety priorities while addressing our specific local needs

The PSIRP is tailored to the Trust's context and learning needs, taking into account the distinct organisational safety challenges and improvement opportunities. The plan will be reviewed and updated annually to ensure its continued relevance and effectiveness in addressing evolving national and local patient safety priorities.

For full details of our PSIRP, including specific criteria, response methods, implementation strategies, and how we balance national and local priorities, please refer to the complete Patient Safety Incident Response Plan document.

Note: This policy should be read in conjunction with the PSIRP to ensure a comprehensive understanding of our approach to patient safety incident response within our unique organisational context.

1.3 Objectives

The objectives of this policy are to ensure:

- An 'open, just and restorative' culture that assures staff of a transparent and fair environment where no individuals or groups are unfairly blamed when things go wrong.
- Effective record keeping and reporting mechanisms.
- Timely and organised management of all incidents.
- Clear lines of accountability and responsibility for all elements of incident management.
- Awareness among all staff, including bank, locum, voluntary, and agency staff, of the communication systems in place for managing incidents, supported by appropriate induction and training.
- Key communication mechanisms with family and/or carers, in line with the Trust's 'Being Open and Duty of Candour Policy' and regulatory requirements of Duty of Candour.

- Lessons are learned from reported incidents, with appropriate actions taken to avoid recurrence, including changes to practice, systems, processes, and the environment to improve safety.
- Appropriate debriefing and communication of lessons learned following incidents.
- Engagement, involvement, and information sharing with all relevant internal and external stakeholders, agencies, and regulatory bodies in line with national legislation and guidelines.

2.0 Scope

This policy is specific to patient safety incident responses conducted solely for learning and improvement across all services and sites provided by the Trust. The PSIRF provides guidance on responding to patient safety incidents without distinguishing between incidents and 'serious incidents' for learning purposes, relevant to all bodies involved in providing, commissioning, supporting, overseeing, and regulating NHS-funded care.

Responses under this policy follow a systems-based approach, recognising that patient safety is an emergent property of the healthcare system resulting from interactions between components rather than from any single component. Responses do not take a 'person-focused' approach where human error is cited as the cause of an incident. Instead, investigations aim to understand the circumstances leading to an incident to drive system learning and improvement.

2.1 Trust Mission & Vision for Safety

2.1.1 Safety Vision

The Trust's vision is to become an organisation that provides the safest possible care for all people, with a positive and equitable safety culture where safety is everyone's primary concern. This vision will be underpinned by strong leadership, people participation, and proactive learning, monitoring, and improvement.

2.1.2 Safety Mission

The Trust's mission is to provide the safest possible care for patients, the safest conditions for staff, and the safest lives for the communities it serves.

2.1.3 Just Culture and Patient Safety

The Trust is committed to fostering a 'Just Culture' that prioritises patient safety through the following principles:

2.1.3.1 Fair and Transparent Approach: Responses to incidents shall concentrate on understanding the underlying systems and processes involved, rather than apportioning blame to individuals. The aim is to identify areas for improvement within the healthcare system, promoting a culture of learning and continuous improvement.

2.1.3.2 Psychologically Safe Environment: The Trust shall actively encourage and support staff in reporting all incidents and near misses without fear of repercussions. This open reporting culture is essential for organisational learning

and improvement, as it allows potential safety concerns to be addressed proactively.

2.1.3.3 Stakeholder Engagement: The perspectives of all stakeholders, including patients, families, carers, staff, and commissioners, shall be valued. Their safety concerns will be carefully listened to and addressed through collaborative efforts, ensuring diverse viewpoints are incorporated into patient safety initiatives.

2.1.3.4 Positive Behaviours and Values: All staff are expected to uphold the organisation's values and behaviours, which are proven to enhance patient safety. By promoting a culture of respect, teamwork, and accountability, an environment conducive to delivering safe and high-quality care will be created.

2.1.3.5 Continuous Learning and Improvement: The Trust's approach to patient safety shall be grounded in continuous learning and improvement. An environment that empowers staff, learns from experiences, and prioritises patient safety as a shared responsibility across the healthcare system will be nurtured.

2.1.4 Scope and Limitations:

2.1.4.1 Patient safety learning responses shall focus on identifying areas for improvement and promoting a culture of learning, rather than apportioning blame or determining liability.

2.1.4.2 Other processes, such as claims handling, human resources investigations, professional standards investigations, coroners' inquests, and criminal investigations, exist to determine liability or identify the cause of death.

2.1.4.3 While information obtained from patient safety learning responses can be shared with those leading other types of learning responses, the primary aim shall remain focused on continuous improvement and fostering a just culture.

Safety Culture

- Safety is a core priority that underpins the delivery of the Trust's strategy and the provision of excellent patient care. The Trust has implemented robust safety structures, including Trust-wide safety huddles, local safety leadership forums, and an executive walk-around programme to promote a culture of safety.
- The Trust's Freedom to Speak Up (FTSU) Guardian service encourages staff to raise concerns and provides support, fostering an environment where safety issues can be addressed proactively.
- The Trust recognises the importance of staff engagement and well-being in achieving positive safety outcomes. While the latest staff survey indicates that the majority of staff feel engaged, view patient care as their top concern, and are confident in raising and addressing safety concerns, the Trust acknowledges the need for ongoing focus on staff experience, morale, and well-being.
- To drive continuous improvement in safety, the Trust has co-designed a five-year Safety Plan in collaboration with staff, stakeholders, and service users. This plan incorporates learning from safety science, as well as local expertise and experience.
- The Trust's mission is to provide the safest possible care for patients, the safest conditions for staff, and the safest lives for the communities it serves.

- The Safety Plan is underpinned by guiding principles that emphasize the importance of safety, accountability, trust, compassion, teamwork, equality, and continuous learning. Maintaining and continuously improving the safety and learning culture is one of three key drivers for achieving the Trust's mission, along with the development of the Safety learning system and strengthened involvement of service users and carers

The Trust has established key elements to support its journey towards continuously improving safety culture, including:

- Service User & Carer participation in Safety
- Leadership, teamwork, and communication
- Behavioural Expectations
- Focus on systems, learning, and improvement
- Raising and Acting on Concerns
- Psychological Safety, Civility, and respect
- Restorative Just Culture
- Staff Safety & Well-being
- Teamwork & Communication

The Trust's plan includes commitments to use culture metrics, adopt the NHS Just Culture Guide or equivalent, embed the principles of a safety culture within and across the organization, implement the patient safety syllabus, address incivility, implement the patient safety incident response framework, and work with those responsible for quality, diversity, and inclusion to enhance the restorative just culture.

By adhering to these principles and implementing the Safety Plan, the Trust strives to create an environment where patient safety is paramount, staff feel empowered to speak up, and continuous learning and improvement are embedded in daily practices.

Addressing Health Inequalities

- The Trust recognises its core role in reducing health inequalities by improving access to services and tailoring those services to meet the needs of the local population in an inclusive manner.
- As a public authority, the Trust is committed to delivering on its statutory obligations under the Equality Act (2010) and will use data intelligently to assess for any disproportionate patient safety risks to patients across the range of protected characteristics.
- The Trust will adopt a flexible approach and intelligent use of data to identify potential disproportionate risks to patients with specific characteristics and understand how this information guides patient safety incident responses.
- The introduction of a new incident management system will allow for the analysis of patient details by protected characteristics, providing insight into any apparent inequalities.

- The Trust will engage and involve patients and families following a patient safety incident, considering their different needs. Available tools, such as translation and interpretation services, and other appropriate methods will be utilised to meet the needs of those concerned and maximise their potential involvement in patient safety incident responses.
- The Trust's quality improvement work has incorporated efforts to address equity, recognising that quality care cannot be provided without being equitable.
- Continued work towards achieving equity is also one of the founding principles and aims within the Trust's Safety Plan.

3.0 Definitions

Definitions of terms used within this policy. The following list is a guide only and not exhaustive.

3.1 Incident

"Incident" is used in this policy to refer to any event which gives rise to, or has the potential to, produce unexpected or unwanted effects involving the safety of service users, staff, visitors on Trust premises or employed by the Trust, or loss or damage to property, records or equipment which are on Trust premises or belong to the Trust. This includes accidents, clinical incidents, deaths, security breaches, violence, and any other category of event which does or could result in harm. It also includes failures of medical or other equipment.

3.2 Hazard

A hazard is a situation or state of affairs which gives rise to the likelihood of harm, loss or damage as described under 'Patient Safety Incident Investigation' below, whether or not any incident has so far occurred.

3.3 Near Miss

A near miss is any occurrence where the effects of which were narrowly avoided due to luck or skilful management. For the purpose of this policy, the term "incident" includes near misses.

3.4 Major Incident

The term Major Incident is defined as, 'a significant event, which demands a response beyond the routine, resulting from uncontrolled developments in the operation of the establishment or transient work activity' (HSE)

The event may either cause, or have potential to cause, either:

- Multiple serious injuries, cases of ill health (either immediate or delayed), or loss of life,
or
- Serious disruption or extensive damage to property, inside or outside the establishment

In the case of a major incident, the Trust Emergency Management Plan should be followed in the first instance.

3.5 Patient Death

All patient deaths, regardless of cause, must be reported promptly through the InPhase system. The specific cause of death may not always be immediately clear to the Trust, as it often requires the results of a post-mortem or, in rare instances, a toxicology investigation to be confirmed. Nevertheless, it is essential that all relevant managers are notified by submitting an InPhase report upon the occurrence of a death. This enables the initiation of any necessary remedial or immediate actions to ensure a timely and appropriate response.

3.6 Manager

Throughout this policy, the term manager is used to refer to the person with first line management responsibility for a team or department at the time when an incident takes place.

3.7 Staff

The term staff is used in this policy to refer to all individuals employed by East London NHS Foundation Trust ("the Trust") and Individuals employed by the other organisations, including partner NHS organisations, Local Authorities, contractors or temporary staffing agencies, whilst they are involved in the provision of care to service users under the management of a Trust clinical team, or undertaking other work on behalf of or under the aegis of the Trust.

3.8 Systems Engineering Initiative for Patient Safety (SEIPS)

A systematic approach for analysing how interactions between different elements of the healthcare system, such as work processes, organisational factors, and external influences, contribute to patient safety incidents. SEIPS supports comprehensive, system-focused analysis during incident investigations.

3.9 Patient Safety Incident Response Framework (PSIRF)

The Patient Safety Incident Response Framework (PSIRF) is a comprehensive, nationally mandated approach introduced by NHS England to replace the Serious Incident Framework. It establishes a systems-based method for NHS organisations to respond to patient safety incidents, emphasising continuous learning, proportionate responses, and engagement with patients, families, and staff to improve safety outcomes.

3.10 Patient Safety Incident Response Plan (PSIRP)

The Patient Safety Incident Response Plan (PSIRP) is a locally tailored, publicly accessible document that each NHS organisation develops to operationalise the PSIRF within their specific context. It details the organisation's criteria for incident selection, outlines various learning response methods (such as Patient Safety Incident Investigations, After Action Reviews, and thematic analyses), and specifies how insights will be implemented to enhance patient safety, all while aligning with both national priorities and the organisation's unique risk profile.

3.10 Patient Safety Incident Investigation (PSII)

A PSII is an in-depth safety review for learning resulting in the production of a written report using a national template.

3.11 Never Event

A Never Event is a particular type of serious safety incident. They are considered to be wholly preventable, where guidance or safety recommendations that provide strong systemic protective barriers are available at a national level. The current Never Events List can be found at <https://www.england.nhs.uk/publication/never-events/>

4.0 **Responsibilities**

4.1 The Trust Board

The Trust Board provides the strategic leadership to promote and develop the Trust's safety culture. This includes responsibility for effective risk management within the Trust, and to ensure that the Trust complies with its statutory obligations.

4.2 The Chief Executive

The CEO is accountable to the Board for ensuring effective resources, policies, and procedures for incident management. They delegate responsibilities to senior staff, oversee patient safety processes, and ensure adequate resourcing. The CEO appoints an executive lead for PSIRF, approves the PSIRP, ensures compliance with reporting requirements, and acts as a spokesperson in high-profile cases.

4.3 Chief Nurse

The Chief Nurse ensures the Trust manages incident reporting and investigations appropriately. Through delegated responsibility, the Chief Nurse ensures internal and external reporting and commencement of investigations in accordance with this policy and procedure. The Chief Nurse leads clinical standards related to the quality and safety of patient care and provides clinical advice to the Board.

4.4 The Chief Medical Officer

The Chief Medical Officer ensures incidents involving doctors are managed according to policy, jointly signs off PSIs with the Chief Nurse, and leads clinical standards for patient care quality and safety. They provide clinical advice to the Board and collaborate with the Chief Nurse or CEO on defining PSIs.

4.5 Senior Responsible Officers for PSIRF

Working together, our Director of Patient Safety and Director of Nursing for Mental Health for London Services, acting on behalf of the Chief Medical Officer and Chief Nurse, jointly maintain oversight for PSIRF implementation and co-chair the PSIRF oversight group. Additionally, our Director of Nursing for Mental Health Services for London line manages the risk and governance team, ensuring that all incidents are appropriately investigated, learning from these incidents is effectively disseminated, and implementing measures to prevent recurrence. Our Director of Safety provides strategic leadership of the Trust Safety Plan, aiming to foster cultures of safety, strong safety systems and continuous improvement within the organisation

Director-Level Safety graders

These are a group of our directors with patient safety expertise, who act on behalf of the CMO and CN in our safety forums, who contribute to making decisions at our incident huddles and decision-making forum, sign-off PSIs and other learning responses and take joint responsibility for supporting the incident management

system at a senior level. The group consists of medical directors, directors of nursing and our director of social care, and is supported by the director of patient safety in maintaining their specialist safety knowledge and shared leadership of the system.

4.6 The Governance & Risk Management Department

The Governance & Risk Management Department, led by the Associate Director of Governance & Risk Management, is responsible for the day-to-day operational implementation and monitoring of this policy.

4.7 Medical Examiner Service

The Medical Examiner Service provides greater safeguards for the public by scrutinising all non-coronial deaths. It ensures proper direction of deaths to the coroner and maintains independence for professional accountability. It scrutinises all deaths to provide advice on cause of death, identify problems in care, discuss with the bereaved, and ensure legal compliance.

4.8 Patient Safety Oversight Panels

4.8.1 Daily Incident Panel

The Daily Huddle is a meeting held daily where Patient Safety Incident Reviewers discuss incidents, they feel may require further investigation or next steps. The Huddle, chaired by a Director-Level Safety Grader, also determines which learning response might be suitable for each incident. This ensures real-time discussion and decision-making on emerging patient safety issues. For the SOP/Guidelines on Daily Huddles, please refer to Appendix C.

4.8.2 PSIRF Decision Making Panel

The Decision-Making Panel reviews and discusses 72-hour reports requested during the Daily Huddle. This panel evaluates the appropriate and proportionate learning response for each incident. It is chaired by a director-level safety grader. For the SOP/Guidelines on the Decision-Making Panel, please refer to Appendix C.

4.8.3 PSIRF Sign off Panel

The Sign-off Panel is responsible for the final approval of patient safety incident investigations and Care Review Tool reviews (CRT). This panel ensures that all reviews are thoroughly undertaken and identify the relevant opportunities for learning and/or improvement. Additionally, the panel assess whether necessary actions have been taken, and that reports meet the required standards before they are formally signed off. It is chaired by a Medical Director and a Director of Nursing. For the SOP/Guidelines on the Sign Off Panel, please refer to Appendix C.

4.9 Patient Safety Forum

The Patient Safety Forum, chaired by the Chief Medical Officer, includes a wide range of central and directorate patient safety leadership within the trust along with service user and carer representatives. This forum is focussed on sharing of

learning re safety and oversight of safety improvement work aligned to the PSIRP priorities. It also provides monthly oversight through reports on the implementation of the PSIRF.

4.10 Safety Plan Oversight Group

The Safety Plan Oversight Group is a quarterly group which provides oversight and assurance in relation to implementation of the trust Safety Plan. Membership includes an independent safety specialist, executive directors with safety leadership positions, Director of Patient Safety, and safety specialist and people participation representatives.

4.11 Patient Safety Learning Committee

The Patient Safety and Learning Committee, chaired by the Chief Medical Officer, is a forum where completed Learning Responses are presented by the Clinical Director and insights are shared. Its membership includes Clinical Directors, Learning Review authors, Associate Director of Governance & risk, Head of Incident Management, the Director of Patient Safety, Medical Directors and the Director of Nursing. The committee plays a crucial role in disseminating knowledge, identifying trends and implementing improvements to enhance patient safety across the organisation.

4.12 PSIRF Oversight Group

The PSIRF Oversight Group, chaired by the Senior Responsible Officer for PSIRF, includes sub-group leads and members. This group meets quarterly to provide strategic planning and oversight for the delivery of PSIRF through its sub-groups, with support from departments such as Risk and Governance, People and Culture, and Quality Improvement.

4.13 PSIRF Sub-Groups

PSIRF Sub-Groups are chaired by sub-group leads and include a broad representation of staff, patient safety partners, and service users. These groups meet weekly or bi-weekly to focus on the development of key tasks within their work streams, aligned with the aims of PSIRF.

4.14 Directors and Senior Managers

Directors and senior clinicians/managers in each service area are responsible for implementing this policy within their respective areas.

Managers are responsible for:

- Ensuring all staff within their department or team are familiar with this policy and the process for reporting incidents.
- Providing guidance on incident reporting procedures to temporary or agency staff as part of their local induction.
- Ensuring any delegated staff in charge of a team or department are familiar with this policy as part of their induction.
- Taking action to contain incidents and minimise harm.

- Communicating with staff, service users, carers, and families, and providing appropriate support.

4.14 Directorate Governance Boards

Directorate Governance Boards are responsible for:

- Reviewing reported incidents applicable to their service.
- Monitoring associated action plans.
- Identifying trends and taking action to improve practice where possible.
- Ensuring information is communicated widely to all staff, particularly those pivotal to implementing change.

4.16 Staff

All staff must follow the procedures outlined in this policy. In the event of an incident involving staff not directly employed by the Trust, appropriate Trust managers will provide guidance on the procedures. Under the Health & Safety at Work Act 1974, individual employees at every level are responsible for taking care of their own health and safety at work, as well as the safety of others who may be affected by their actions. Employees must cooperate with management in complying with health and safety obligations, particularly by reporting any defects, risks, or potential hazards. Staff must cooperate with all reviews undertaken by the Trust, in accordance with various NHS and professional codes of conduct and Trust policies.

4.17 Ward Managers/Operational Managers / Head of Departments /Line Managers/

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

- Ensure 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 severe harm and above incidents/Never Events are reported immediately and escalated in accordance with this policy, and that the appropriate Directorate Director and the Governance and Risk Team are notified.
- For incidents with lower harm levels, ensure the facts are captured and validated thoroughly and timely.
- Ensure procedures within their area consider incidents brought to their attention.
- Make safe any area or equipment following an accident and retain equipment for inspection where required.
- Ensure 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' Appendix E
- Ensure recommendations and actions are disseminated and carried out as a result of any PSII, 72hrs or CRT.
- Ensure all staff involved in an incident are supported through the process and maintain confidentiality.
- Ensure lessons learned are cascaded to relevant staff through team meetings, training, education sessions, newsletters, and posters.

- Ensure aggregated quantitative and qualitative data on types, numbers, and themes from incidents are produced and reviewed through local governance groups.

4.18 Directorate Governance Managers/Leads

Directorate Governance Managers/Leads are responsible for ensuring:

- All reported incidents are reviewed through a daily incident triage within the Directorate and allocated to the most appropriate review and management route, seeking further information from clinical teams if required.
- 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' (Appendix D) and escalated where needed.
- A named patient / family contact is identified for non PSII incidents where required to undertake meaningful engagement about the incident.
- A named staff contact is identified for those involved in non PSII incidents where required to undertake meaningful engagement and signpost them to support.
- Incidents are tracked to ensure review within required timescales and management, escalating any concerns as required.
- Actions associated with an incident or Learning Response are logged and tracked.
- Appropriate reporting and grading of reported incidents are monitored, seeking clarification from relevant managers should grading be inconsistent with trends.
- Directorates are accountable for the timely delivery of the learning response and agreed actions and learning following a patient safety review.

4.19 InPhase Systems Manager

The InPhase Manager oversees the administration and functionality of the InPhase system, ensuring it aligns with the Trust's operational requirements. Key responsibilities include:

Key Responsibilities:

- Resolving technical issues and escalating complex problems to manufacturers, managing technical aspects of the system to maintain robust performance and reliability.
- The Inphase team collaborates with stakeholders to align system functionality with evolving operational needs, identifying and implementing improvements to enhance the system's capabilities

The InPhase Manager is essential in maintaining the integrity and effectiveness of the InPhase system, supporting the Trust's overall operations.

4.20 Patient Safety Lead Reviewers

Patient Safety Lead Reviewers are essential in ensuring thorough and effective reviews of safety incidents within the organisation. They lead and coordinate investigations, collaborate with professional leads, and stakeholders, ensure compliance with policies and legal requirements, facilitate inclusive communication with staff, patients, and families, and promptly report findings and recommendations. They also support the implementation of action plans to prevent recurrence.

4.21 Co-Reviewers

A Co-Reviewer is a clinician who brings expert and specialist knowledge to the investigation process. The Co-Reviewer contributes valuable insights, viewpoints, and clinical understanding crucial for a comprehensive analysis of the incident. Their role encompasses evaluating the operational and clinical aspects of the service, ensuring alignment with established clinical protocols, and identifying deviations from standard and best practices.

4.22 Associate Director Governance and Risk Management

The Associate Director of Governance and Risk holds ultimate accountability for governance and risk management processes across the trust, ensuring all functions under their remit adhere to established standards and best practices. This senior role provides strategic direction and oversight, supporting the trust's overarching safety and quality objectives, while managing a team of heads responsible for specific areas such as incident management, risk and policies, and health and safety. The Associate Director plays a crucial role in maintaining a robust governance framework that underpins the trust's commitment to patient safety and quality care.

4.23 Head of Incident Management

The Head of Incident Management provides comprehensive oversight for incident management and patient safety functions within the trust, ensuring alignment with the NHS Patient Safety Incident Response Framework and Patient Safety Incident Review Plan. This role is responsible for maintaining high-quality reporting standards, managing operational aspects, and fostering a culture of continuous improvement and learning. Additionally, the Head of Incident management oversees the implementation of patient safety initiatives and ensures compliance with national and local standards, contributing to the overall safety and quality objectives of the trust.

5.0 Engaging and Involving Patients, Families, and Staff Following a Patient Safety Incident

5.1 Principles

The Trust recognises that learning and improvement following a patient safety incident can only be achieved if supportive systems and processes are in place. The Trust is committed to developing 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.

5.2 Engagement with Patients and Families

- The Trust will make every effort to contact, engage, and support families in line with the Patient Safety Incident Response Framework (PSIRF) guidance on engaging and involving patients, families, and staff following patient safety incidents.

- The Trust will work 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.
- The Trust's Duty of Candour Policy stipulates that families and carers must be notified when a related service user is involved or affected by a patient safety incident, within the context of confidentiality.
- The Trust will use feedback from patients and families involved in the existing serious incident process to evaluate how involved and engaged they feel and how compassionate the Trust is during this process.

5.3 Engagement with Staff

- Where a trainee member of staff is involved in or affected by a patient safety incident, their supervisor will be contacted in the first instance so that appropriate support can be put in place.
- Efforts will be made to include all relevant members of staff in learning responses or safety reviews, including those who have left the organisation, trainees, bank staff and non-clinical team members.
- In addition to existing and new structures that underpin staff support, there is a Task and Finish Group working on continuous improvement of the support pathway for staff involved in or affected by a patient safety incident.

5.4 Further Information

For more information on how the Trust will engage and involve patients, families, and staff following a patient safety incident, please refer to the Trust's Patient Safety Incident Response Plan (PSIRP).

6.0 Patient Safety Partners

The Trust established Patient Safety Partner roles in line with the NHS England guidance, <https://www.england.nhs.uk/publication/patient-safety-incident-response-framework-and-supporting-guidance>. The Trust is committed to working with members of the public and has embarked on a Patient Safety Partner (PSP) programme to support its Quality and Safety Improvement work. The PSPs will provide strong leadership, advice, and practical project work across all aspects of patient safety in the development of a culture that is socially inclusive and values diversity.

Roles and Responsibilities

Patient Safety Partners (PSPs) will:

- 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 of the Trust's Safety oversight committees and groups, including the Safety Review Learning Committee and Patient Safety Forum.
- Participate in Safety Review Panels.
- 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 safety reviews, particularly around actions that address the needs of patients.

6.1 Alignment with NHS Framework

The NHS Framework for Involving Patients in Patient Safety, part of the NHS Patient Safety Strategy 2019, sets out the requirement for people to support and contribute to healthcare organisations' governance and management processes for patient safety.

6.2 Partnership Working

- Partnership working is fundamental to providing effective and integrated care within Patient Safety. At ELFT, we work closely with staff, service users, and carers to ensure the safety of everyone under our care.
- PSPs will support and maintain effective communication, contributing to the training needs of service users and staff in this aspect of their work.

6.3 Involvement in Patient Safety Initiatives

- PSPs will be involved in the further work around the Trust's patient safety incident response policy and plan development and maintenance.
- PSPs will advise and lead on the involvement of service users and carers in all of the Trust's safety forums, e.g., Safety Learning Review Committee, Patient Safety Forum, Decision-making Panel, and Sign Off Panel.
- PSPs will also be involved in the operational decision-making pathway, PSIRF Steering Group, and various sub-groups, e.g., Operational, Family Engagement and Involvement, Staff Support, Safety Oversight Panel (future), Learning Lessons Seminars Forum, and Learning from Patient Safety QI Project.

6.4 Patient Safety Incident Response Planning

- 6.4.1 The Trust has a centrally resourced incident team consisting of 9.0 WTE dedicated patient safety lead reviewers, 2.0 WTE incident coordinators, and 2.0 WTE risk and governance assistants to support patient safety incident response.

7.0 Patient Safety Incident Response Plan (PSIRP)

- 7.1 The Trust's PSIRP sets out how the Trust intends to respond to patient safety incidents over a period of 12 to 18 months. It was developed using five years of previous incident, serious incident, never event, structured judgement review and complaint data, together with the Trust's claims profile, to identify the highest safety risks to focus on as priorities for systems-based investigation.
- 7.2.1 The PSIRP is not a permanent set of rules that cannot be changed. The Trust 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.

7.2.2 The Trust's PSIRP, which is available to the public via the Trust's website. The PSIRP sets out how the Patient Safety Incident Response Framework will be embedded by:

- Compassionately engaging and involving those affected by patient safety incidents
- Applying a range of system-based approaches to patient safety learning
- Providing considered and proportionate responses
- Providing supportive oversight, focused on strengthening response system functioning and improvement

The PSIRP should be read in conjunction with this policy.

7.2 Reviewing the Patient Safety Incident Response Policy and Plan

- The PSIRP is a 'living document' that will be appropriately amended and updated as the Trust uses it to respond to patient safety incidents. The plan will be initially reviewed every 12 to 18 months to ensure the focus remains up to date, with ongoing improvement work to reflect changes in the Trust's patient safety incident profile.
- Updated plans will be published on the Trust's website, replacing the previous version.
- A rigorous planning exercise will be undertaken every four years, or more frequently if appropriate (as agreed with the Integrated Care Board (ICB)), to ensure efforts continue to be balanced between learning and improvement. This in-depth review will include reviewing the Trust's response capacity, mapping services, reviewing organisational data (e.g., PSII reports, improvement plans, complaints, claims, staff survey results, inequalities data, and reporting data), and wider stakeholder engagement.

7.3 Responding to Patient Safety Incidents

Patient safety incident reporting arrangements

"Where an incident type is well understood – for example, because previous incidents of this type have been thoroughly investigated and national or local improvement plans targeted at the contributory factors are being implemented and monitored for effectiveness – resources may be better directed at improvement rather than repeat investigation (or other type of learning response)."

Taken from PSIRF supporting guidance, Guide to responding proportionately to patient safety incidents (NHSE 2022)

7.4 Incident Reporting

7.4.1 Patient safety incident reporting will remain in line with the Trust's Incident Management Policy. It is recognised that staff must continue to feel supported and able to report any incidents, or concerns in relation to patient safety, to promote a system of continuous improvement and a just and open culture.

7.4.2 Where two or more teams are involved in a service user's care, the team identifying the incident will be responsible for reporting it on the Trust's risk management

reporting system and identifying if, to their knowledge, there are other services involved in the service user's care. This will also be captured during the daily incident review process.

- 7.4.3 It is the responsibility of the line manager to review reported incidents. An automatic notification will be sent to their inbox informing them that an incident report has been submitted by a member of their staff. As soon as practical, the manager must review the incident with the rest of the team to identify learning and remedial actions that need to be taken to prevent similar incidents from occurring.

7.5 Incident Oversight and Reporting

The Governance and Risk Management Department is responsible for ensuring that all relevant internal and external parties are informed of incidents.

7.6 Responding to Cross-System Incidents/Issues

7.6.1 Cross-System Reviews

- 7.6.1.1 If more than one organisation is involved in the care and service delivery in which a patient safety incident has occurred, the organisation that identifies the incident is responsible for recognising the need to alert relevant stakeholders to initiate discussions about subsequent learning review/response and action.
- 7.6.1.2 All relevant stakeholders involved should work together to undertake one single safety review wherever possible and appropriate. The Integrated Care Board (ICB) should help facilitate discussions relating to which organisation is the most appropriate to take responsibility for coordinating the investigation process. Please see Appendix D for the North East London ICB process. BLMK is still being developed.

7.7 Timeframes for Learning Responses

Learning responses must balance the need for timeliness and capture of information as close to the event as possible, with thoroughness and a sufficient level of investigation to identify the key contributory factors and associated learning for improvement.

One of the most important factors in ensuring timeliness of a learning response is thorough, complete and accurate incident reporting when the circumstances are fresh in the minds of the incident reporter and the wider team. These principles are set out in the current incident reporting guidance but must be reinforced through the PSIRF. The Trust's PSIRP provides more detail on the types of learning response considered most appropriate to the circumstances of the incident. Highly prescriptive timeframes for learning responses may not be helpful so the following are included as a guideline only:

- 72hrs Report: - Directorate Leads are required to complete 72hrs report within 72 hours of the incident being highlighted as requiring one.
- After Action Review – 2 to eight weeks of the initial report.

- CRT – To be completed within 10 working days from date of allocation. Extension may be granted depending on the complexity of the incident and where additional insight is required.
- Thematic Review – 1 to 4 months depending on complexity.
- Patient Safety Incident Investigation – comprehensive, aimed to be completed in 3 to 5 months depending on complexity, up to 6 months or over, where exceptional circumstances applies*

**Note: The 6-month maximum timeframe for Patient Safety Incident Investigations is a guideline and may be extended in exceptional circumstances where external bodies or those affected cannot provide information to enable completion within this timeframe. In this case, any extension to timescales should be agreed with those affected (including the patient, carers and staff).*

Appendix S sets out the timeframes for all Patient Safety Incident Response Framework (PSIRF) tools and learning responses.

7.8 Safety Action Development and Monitoring Improvement

- 7.8.1** A SMART (Specific, Measurable, Attainable, Relevant, and Time-Bound) approach to action planning is essential. The Directorate is responsible for designing and agreeing actions with PSLR and ensuring a robust system is in place to track and have oversight of outstanding actions. Further guidance on this can be found in NHSE Guidance at <https://www.england.nhs.uk/wp-content/uploads/2022/08/B1465-Safety-action-development-v1.1.pdf>.
- 7.8.2** Trust-wide safety actions are identified in patient safety reviews and scheduled at the Patient Safety Forum or the relevant Trust-wide improvement group. It is the responsibility of the patient safety lead reviewer, under the guidance of the relevant panel. Actions are logged on InPhase and must be monitored within the directorate governance arrangements to ensure that any actions put in place remain impactful and sustainable.
- 7.8.3** Where actions may have wider significance for improvement or learning, e.g., in relation to system partners or processes outside of ELFT, these would be raised to the relevant system partner, at the ICB-led monthly System Safety Groups or with NHSE as appropriate.

7.9 Safety Improvement Plans

Safety improvement plans bring together findings from various responses to patient safety incidents and issues:

- Creating an organisation-wide safety improvement plan summarising improvement work
- Creating individual safety improvement plans that focus on a specific service, pathway, or location
- Collectively reviewing output from learning responses to single incidents when it is felt that there is sufficient understanding of the underlying, interlinked system issues

- Creating a safety improvement plan to tackle broad areas for improvement (i.e., overarching system issues)

There are no thresholds for when a safety improvement plan should be developed; for example, after completing a certain number of learning responses. The decision to do so will be based on knowledge gained through the learning response process and other relevant data.

The Trust's Patient Safety Incident Response Plan (PSIRP) has outlined the local priorities for the focus of investigation under PSIRF and how existing improvement work will be used to determine how well understood an area is and the most appropriate learning response type.

Oversight roles and responsibilities

"When working under PSIRF, NHS providers, integrated care boards (ICBs) and regulators should design their systems for oversight "in a way that allows organisations to demonstrate [improvement], rather than compliance with prescriptive, centrally mandated measures". To achieve this, organisations must look carefully not only at what they need to improve but also what they need to stop doing (e.g. panels to declare or review Serious Incident investigations). Oversight of patient safety incident response has traditionally included activity to hold provider organisations to account for the quality of their patient safety incident investigation reports. Oversight under PSIRF focuses on engagement and empowerment rather than the more traditional command and control."

Taken from NHSE, PSIRF Guidance 'Oversight roles and responsibilities specification and Patient safety incident response standards' (p2).

Responsibility for oversight of the PSIRF for provider organisations sits with Trust Boards. The 'responding to patient safety incidents' section above also describes some of the more operational principles that underpin this approach. In Appendix 1, the following governance and oversight groups will be responsible for steering our responses to patient safety incidents:

8.0 Patient Safety Incident Reporting.

8.1 General Incident Reporting Procedure

Responding effectively to incidents in healthcare is essential for continuous improvement in service safety within the Trust and the wider NHS. This policy sets forth the procedures for reporting and managing incidents affecting patients, visitors, staff, or Trust services. It covers both clinical and non-clinical incidents across all levels of harm.

For incidents that are serious and likely to affect many people, causing significant safety risks or impacting business continuity, an incident management structure will be established. This structure is typically led by the local directorate management team, with support from wider trust leadership as required, to ensure a coordinated and effective response.

8.2 Immediate action to be taken following an incident:

- 8.2.1** Any member of staff present when an incident is discovered must take immediate action to reduce further risk and, in maintaining safety, ensure that their own safety is not compromised.
- 8.2.2** Once the immediate situation has been addressed and made safe, it is the responsibility of all members of staff to bring any incident or near miss to the attention of their manager or the most senior person on duty in the area (e.g. team leader or ward manager).
- 8.2.3** The immediate safety and well-being of all involved in an incident is paramount. The Incident response should be proportional to the severity and impact, potentially involving first aid, emergency treatment, or contacting emergency services. Environmental safety should also be considered, especially if the incident is related to ongoing activities or the physical setting.
- 8.2.4** For incident involving in-patient death or homicides, immediate notification to the senior management team on-call out of hours, Emergency Services and the police is required. An incident report must be completed as soon as possible. The InPhase System is used to facilitate reporting.
- 8.2.5** Where there are two or more teams involved in a service user's care, the team identifying the incident will be responsible for reporting on InPhase. Guidance for staff on how to report incidents is set out in Appendix A.
- 8.2.6** The Governance & Risk Management Department is responsible for ensuring that all relevant internal and external parties are informed of incidents. This is set out in Appendix B.

8.3 Role of Senior Staff and Immediate Responsibilities during an Incident:

- 8.3.1** The senior person on duty at the time of an incident has the immediate responsibility for managing the incident. This includes ensuring care for those directly involved, assessing the situation to determine the appropriate response, and considering factors such as the extent of harm, need for specialist support, environmental safety, and the necessity to inform external agencies or escalate to senior management.
- 8.3.2** In the event of an in-patient fatality, it is important to approach the situation with sensitivity and professionalism. Formal written statements shall be provided to the Governance & Risk Team and the police.

8.4 Recollection of Events

- 8.4.1** When an in-patient fatality, serious assaults or other significant inpatient incidents occurs, the ward manager should request that staff members provide a recollection of the events in documentary form. This serves two important purposes:

- 8.4.1.1 Contemporaneous Documentation:** Capturing the staff's recollection of events as soon as possible helps to ensure accurate and detailed information is available, should it be required for any subsequent inquests or legal proceedings.

- 8.4.1.2 Staff Support:** The process of recollecting and documenting the events can also provide an opportunity for staff to receive support and guidance, particularly in the face of a potentially traumatic incident.

8.5 Incident Reporting on InPhase

- 8.5.1 All incidents must be reported on the Trust's incident reporting system, InPhase, within 24 hours of occurrence or identification. InPhase, accessible through all trust devices, provides a robust framework for capturing incident data and trends. For confidentiality, patient and staff names should be added as separate contacts, not in the incident description.

8.6 Categorisation of Incidents

- 8.6.1 **Learning from Patient Safety Events (LFPSE) Reporting:** Choose this category for incidents related to patient safety incidents, including unintended or unexpected events that could have or did lead to harm. LFPSE also enable the reporting of patient safety events showcasing examples of good care.

- 8.6.2 **Non-LFPSE Reporting:** Select this for incidents not directly related to patient safety or which outside the LFPSE criteria. This ensures the proper capture and addressing of incidents which are not part of the national patient safety dataset.

8.7 When the InPhase system is not available electronically:

- 8.7.1 Local business continuity plans must recognise the incident reporting and management system's critical nature. In case of system unavailability, alternative methods such as paper or digital copies of incident report forms must be used. Staff should ensure these incidents are entered into the InPhase system within 48 hours of its reactivation for comprehensive data capture.

8.8 Responsibilities of the Designated Incident Manager (DIM)

- 8.8.1 Unless specifically assigned to another individual, the responsibility for handling a reported incident will fall to the line manager or Service Manager of the person who has reported the incident. This individual shall then be designated as the Designated Incident Manager (DIM).

In their role as DIM, they will:

- 8.8.2 Review of all reported incidents where they have been appointed as the designated manager.
- 8.8.3 **Prompt Escalation of Patient Safety Incidents:** The DIM is responsible for the rapid escalation of serious patient safety incidents, such as unexpected inpatient deaths, homicides, or suspected suicides. This involves promptly notifying senior staff and directors, including the Associate Director of Risk & Governance and the Incident Management Team, ensuring a coordinated and effective response.
- 8.8.4 **Staff Support and Debriefing Post-Incident:** The DIM ensures that, following the escalation of a Patient Safety Incident Investigation, senior managers conduct comprehensive debriefs with the staff involved. These debriefs aim to gather essential information and offer care and support to staff affected by the incident. The well-being of the staff is a priority, and they may be requested to provide written accounts of their experiences and observations related to the incident.
- 8.8.5 **Efficient Incident Processing:** The DIM is tasked with ensuring the efficient processing of incidents within the InPhase system. This includes moving incidents from the 'In Holding Bay' stage through to the 'Awaiting Final Approval' stage and completing this process within a 14-working-day timeframe. Such efficiency is

crucial for ensuring a swift response to incidents and facilitating effective resolution and learning.

- 8.8.6 **Feedback Loop and Reporter Engagement:** The DIM is responsible for maintaining an effective feedback loop, particularly with the reporter of the incident. Utilising the InPhase system's feedback section, the DIM communicates review outcomes, lessons learned, and remedial actions taken to the reporter. This not only keeps the reporter informed but also encourages a culture of active reporting and transparency within the Trust, enhancing patient safety initiatives.

8.7 Others

8.7.1 Service Users

The team responsible for providing care to the service user at the time of the incident will continue to provide support in most circumstances. Where this is not possible, another team will be identified to take over this responsibility.

8.7.2 Staff

- 8.7.2.1 It is the responsibility of the immediate line manager and the service manager of the directorate to ensure that a debriefing meeting is offered following an incident that is likely to have affected their staff.
- 8.7.2.2 As part of the debriefing process the line manager must ensure that all staff are aware of how to seek support, including via the trust employee assistance programme.
- 8.7.2.3 If the staff member is experiencing difficulties associated with the incident then a referral to Occupational Health services should be made by the line manager.
- 8.7.2.4 In the event of a sudden and unexpected inpatient death, the Associate Director of Governance & Risk Management will provide guidance and/or additional support with meetings on the ward with all staff with respect to the PSII or other Learning Method chosen to investigate the incident.
- 8.7.2.5 All staff that are required to provide information in relation to a patient safety incident investigation (PSII) will be provided with the terms of reference of the review, an outline of the investigation process and details of how to access additional support from the Employee Assistance Programme can be found.
- 8.7.2.6 The Trust has an 'Employee Assistance Programme' in place. The scheme is a 24hr, 7 days a week, free and confidential support service available to all Trust employees.
- 8.7.2.7 Support to staff including debriefing meetings should be documented on the electronic incident report form as part of the managers' sign off and in the 72 Hour Report and Patient Safety Incident Investigation Review Report.
- 8.7.2.8 Staff should report all incidents of actual or threatened violence and aggression as reflected in the Trust Policy for the Recognition, Prevention and Management of Violence and Aggression.

8.8 Patients, Families and Carers

- 8.8.2 The Trust has Being Open and Duty of Candour Policies which stipulates that Families and Carers must be notified when a related service user is involved or affected by a Patient Safety Incident Investigation, within the context of

confidentiality as outlined in Appendices F and G Further guidance on making contact with bereaved families is given under the 'Responding to deaths' section.

- 8.8.3 The Trust will make every effort to contact, engage and support families in line with PSIRF guidance on engaging and involving patients, families and staff following a patient safety incident as outlined in Appendix X.

8.9 External reporting

The Associate Director of Governance & Risk Management is responsible for ensuring all relevant agencies are notified as appropriate of those incidents requiring external reporting as follows;

8.9.1 Reporting to Integrated Care Board.

- 8.9.2. When a notifiable safety incident occurs the ICB must be notified within 48 hours of the incident being reported via LFPSE. The Trust must provide a copy of the 72 Hours report within a week of the incident being identified and after the report has been agreed at the Decision Making Panel.

8.9.3 Reporting to CQC

The Trust will notify the Care Quality Commission (CQC) of all serious incidents relating to the death of a detained patient and those patients who die following their going Absence without Leave within (AWOL) 72hrs of the incident being reported in accordance to their reporting requirements.

<http://www.cqc.org.uk/organisations-we-regulate/mental-health-services/mental-health-act-guidance/mental-health-act-notifi>

8.9.4 RIDDOR Reporting

- 9 The Trust has an obligation to report serious work-place accidents, occupational diseases and specified dangerous occurrences (near misses) to the Health and Safety Executive (HSE) in accordance to the Reporting of Injuries, Diseases and Dangerous Occurrences Regulation 1995 (RIDDOR).

- 10 The Governance & Risk Management department will identify such incidents via InPhase and make the necessary escalation to the HSE. All RIDDOR report and receipt notifications will be attached to InPhase.

- 11 For a full list of RIDDOR reportable incidents see:

<http://www.hse.gov.uk/riddor/index.htm>

Reporting Faulty Medical Devices to the Medical and Healthcare Regulatory Agency (MHRA)

- The Medicines and Healthcare products Regulatory Agency (MHRA) is the executive agency of the Department of Health charged with protecting and promoting public health and patient safety by ensuring that medicines, healthcare products and medical equipment meet appropriate standards of safety, quality, performance and effectiveness, and that they are used safely.
- Where a medical equipment or device has not met this product standard or is deemed faulty, the Trust will notify MHRA via the online Adverse Incident Centre (AIC) reporting database. A record of the notification will be kept on InPhase. In some circumstances, the Trust may find it appropriate to carry out

a Patient Safety Incident Investigation review, and put in place corrective actions to reduce the risk of recurrence.

- The Agency will sometimes issue a Medical Device Alert (MDA) warning of hazardous products, potential safety issues or unsafe procedures, and providing relevant advice.
- For all MHRA reporting, please refer to:
<http://www.mhra.gov.uk/#page=DynamicListMedicines>

Involving the Police and Criminal Justice Service in a Criminal Incidents that Affects a Health Body

- The Police, Crime Prosecution Service and the NHS have jointly agreed a process for managing and reducing violence and antisocial behaviour in the NHS. The National Memorandum of Understanding (Tackling violence and antisocial behaviour in the NHS; Joint Working Agreement between the Association of Chief Police Officers, the Crown Prosecution Service and NHS Protect) sets out arrangement for best practice of joint working between the 3 agencies. It is expected that all NHS organisation adopt the core guidance of this memorandum and build it into any local policy or arrangement.
http://www.nhsbsa.nhs.uk/Documents/SecurityManagement/Joint_Working_Agreement_between_ACPO_CPS_NHS_Protect.pdf
- The Local Security Management Specialist will aim to ensure that all security related crime that affects the Trust are reported to the police, including offences involving NHS staff, patients or visitors, offences involving property or other offences committed on Trust premises.

9.0 Learning From Patient Safety Events (LFPSE)

This policy provides guidance on the use and objectives of the LFPSE system within our healthcare setting.

9.1 Objective of the LFPSE System

The LFPSE system is designed to enhance the safety of patients through a structured and efficient approach to reporting, analysing, and learning from patient safety incidents. Its primary objectives are:

9.2 Levels of Harm Grading

The LFPSE system's approach to harm grading is based on the actual impact on a patient from a reported incident. This grading can be revised as more information becomes available but should not be speculative.

Previous Grade	New Physical Harm Grades	New Psychological Harm Grades	Near Misses (Harm Prevented)
No Harm	No physical harm	No psychological harm	No harm, but detailed documentation required
Low Harm	Low physical harm Minimal harm requiring observation or minor treatment. Does not significantly affect independence or existing health conditions	Low psychological harm: Distress not requiring extended treatment. Does not affect normal activities for more than a few days	N/A
Moderate Harm	Moderate physical harm:- Requires healthcare beyond basic first aid. May limit independence for less than 6 months	Moderate psychological harm: Requires treatment for less than 6 months. Affects normal activities, but not independent living	N/A
Severe Harm	Severe physical harm: Permanent harm or life-saving intervention needed. Reduced life expectancy. Exacerbates or hastens disability	Severe psychological harm: Requires treatment for more than 6 months. Affects normal activities or independence significantly	N/A
Death	Fatal: Incident may have contributed to the patient's death	Not applicable	N/A

9.3 Recording Incidents of Suicide, Self-Harm, and Deaths from Drugs or Alcohol under LFPSE:

The table below provides scenarios to be considered when determining the need to report incidents such as apparent or actual suicide, self-harm, and deaths due to drugs or alcohol. This guidance aims to ensure accurate, consistent, and timely reporting of these sensitive incidents, contributing to the overarching goal of enhancing patient safety and care within our organisation.

Incident Type	Patient Status	Is Incident Reportable to LFPSE?	Criteria for Reporting	Additional Guidance
Suicide (Apparent/Actual)	Former Patient	Yes	Report only if there's a safety concern or further investigation is required.	Not required if no PSI is indicated and no safety concern.
	Current Patient	Yes	Always reportable for	-

			current patients.	
Self-Harm (Not Resulting in Death)	Former Patient	Yes,	Report if there's a safety concern or further investigation is required.	Not required if no PSI is indicated and no safety concern.
	Current Patient	Yes,	Always reportable but investigate if a safety concern is indicated.	-
Death from Drugs or Alcohol	Former Patient	Yes,	Report if linked to drugs/alcohol or investigate if uncertain.	Not required if no PSI or suicide is indicated and no safety concern.
	Current Patient	Yes	Report if safety concern or suicide is indicated or investigate if uncertain.	-
Incident with No Direct Patient Harm	Any	Yes	Reportable as 'no physical/no psychological harm'.	Includes near misses or incidents where harm was prevented.
Incident with No Patient Involvement	Any	No	Not reportable if no specific patient is involved.	Includes administrative or equipment issues not directly affecting patients.

All patient safety learning responses will be recorded and monitored by the Governance & Risk Management Department through the InPhase Risk Management system.

In some situations, the investigation process will be complicated by other factors, such as:

- The need to conduct a joint investigation with other NHS Trusts, local authorities or other agencies
- The incident being subject to a Coroner's Inquest, investigation by the Police, Health & Safety Executive or other external agency
- The incident being subject to a complaint or legal claim
- Staff being subject to a HR investigation relating to the incident
- The possibility of the incident being subject to independent investigation under HSJ 94(67)

In any of these circumstances the Governance & Risk Management Department will liaise with relevant staff and external agencies in order to ensure that correct procedures are followed.

Incidents involving homicide or other Patient Safety Incident Reviews may be subject to independent investigation under HSJ 94(67). Independent investigations are commissioned by NHS London and the responsibility for conducting the investigation does not fall to the Trust. The Governance & Risk Management Department will coordinate the Trust's liaison with the independent investigation. A protocol has been developed and is included in Appendix J.

9.4 **Responding to cross-system incidents/issues**

- 9.4.1 If more than one organisation is involved in the care and service delivery in which a patient safety incident has occurred, the organisation that identifies the incident is responsible for recognising the need to alert relevant stakeholders to initiate discussions about subsequent investigation and action.
- 9.4.2 All relevant stakeholders involved should work together to undertake one single review wherever this is possible and appropriate. The Integrated Care Board (ICB) should help to facilitate discussions relating to who is the most appropriate organisation to take responsibility for co-ordinating the investigation process. Please see Appendix D for the North East London ICB process. BLMK is still in development.

10.0 **Learning from incidents**

The Chief Medical Officer has overall responsibility for ensuring that learning from incidents takes place. Quality Committee monitors learning from incidents.

All the protocols and templates used for incidents, regardless of grade, ensure that causes of incidents, and action taken, are systematically recorded. The data should aid the facilitation of analysis of levels of reporting, trends and hotspots.

The whole system of reporting and investigating incidents is designed to improve the quality and safety of services. To do this, it is important that learning is well defined and understood, and capable of being measured. The Trust categorises learning in four levels and defines it as follows:

Level:	How learning takes place:	Examples of learning:
Individual	Reflective practice Involvement in learning responses, such as After Action Reviews.	Improved Individual performance/development
Team	Reflective practice/Case-study discussion/learning responses such as After Actions Reviews.	Improved team performance indicators Changes to environment, practice etc

	Promoting learning from other areas	
Service/directorate	Governance committee(s) review of incidents Promoting learning from other areas Sharing of learning from local, Trustwide and system-wide learning responses?	Changes to functioning/management of services Improved service/directorate performance indicators
Trust	Trust Board/committee(s) review of incidents Promoting learning from other areas/external sources Sharing of learning from local learning responses, PSIs and system learning reviews.	Changes to Trust policy/training Commissioning of service reviews/additional resources Improved Trust performance indicators

To promote the learning set out above, the following processes will take place:

10.1 Individual

- Incidents to be discussed as part of staff supervision
- Healthcare Governance and Medicines Safety Alerts to be made available to all staff
- Direct involvement in relevant learning responses, such as After Action Reviews, for incidents they were involved in.

10.2 Team

- Teams (through local governance forums or otherwise) review incidents that have taken place in their area, and learning set out in newsletters and other briefings and host local learning responses, such as After Action Reviews.
- Feedback sessions following Learning Responses.

10.3 Service/Directorate

- Governance Committee(s) to review incidents on a regular basis, and individual Learning Review, as well as reports from individual teams
- Monitoring of progress against action plans
- Promoting of learning and best practice through links between directorate and corporate healthcare governance structures and staff
- Regular mandatory learning lessons seminars to include the review of a Patient Safety Incident Investigation from another Directorate
- System for coordination of learning responses including allocation of conductors, oversight of completion and leading shared learning from responses?

10.4 Trust

- Trust Board/Committee(s) to review incidents on a regular basis, and individual Learning Reviews.
- Monitoring of progress against action plans
- Promoting of learning and best practice through links between directorate and corporate healthcare governance structures and staff
- Incorporation of learning from incidents into relevant training courses
- Service/policy/training reviews to take findings from incident reviews into account
- Review of external reports/investigations
- Dissemination of safety alerts
- Trust-wide learning lessons seminars
- Patient Safety Forum
- Patient Safety Learning Committee
- Integrated Care Board led Learning lessons
- Clinical Audit programme
- Implementation of research findings
- Attendance at relevant external meetings (i.e. Local Safeguarding Children Boards, NHS London meetings etc)
-

11.0 **Responding to Deaths**

Whilst the incident policy sets out standards and processes for managing incidents including when a death occurs, the National Quality Board contains specific requirements in its 'National guidance on learning from deaths'. The following points therefore specifically set out how the Trust responds to the deaths of patients who die whilst under active treatment.

11.1 The Learning from Deaths Review Panel meets monthly to specifically review the following deaths:

- Patients who received palliative / end of life care within the last six months of their life.
- Patients who received non palliative / end of life care within the last six months of their life.
- Infant mortalities
- Fast track community health patients
- Patients not seen within the last six months of their lives and not recorded on InPhase
- The Panel will decide which deaths are subject to an in depth case record review, to be undertaken by a clinician not involved in the patient's care. These will be selected where:
 - An alarm has been raised (e.g. through CQC)
 - Patients are not expected to die

11.2 Learning disability and Autism/Deaths

- All learning disability deaths will be reported to the Learning Disabilities Mortality Review Programme (LeDeR). In parallel, these will be automatically flagged to the weekly Decision Making Panel where a decision will be made on further investigation via the incident review

process. LeDeR reviews will be commissioned by the relevant commissioner.

11.3 Support for bereaved families, carers and staff involved

- On notification of a death immediate contact will be made by a senior manager of the service where the care took place, offering condolences, support and practical advice including how to obtain legal advice or the support of an advocate
- Contact will be maintained when appropriate according to the wishes of the family / carer
- Service / clinical directors will ensure staff are given support in the event of the death of a patient known to them
- The Trust will make every effort to contact, engage compassionately and support families in line with PSIRF guidance on engaging and involving patients, families and staff following a patient safety incident as outlined in Appendix X.

12.0 Monitoring

The implementation of this policy will be monitored by the following:

- Number of outstanding action plans/recommendations
- Trust Board review of the annual Incident Report, including analysis of learning that has taken place
- Internal audit/LFPSE review of Incident Policy/procedures

13.0 References:

1. *Department of Health (2000). An Organization with a Memory.*
2. *National Patient Safety Agency (NPSA) Seven Steps to Patient Safety.*
3. *Health and Safety Executive (HSE) The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR), HSE Books.*
4. *NHSLA Risk Management Standards 2010-11*
5. *NHS London Serious Incident Procedures August 2009*
6. *National Patient Safety Agency (NPSA) National Framework for Reporting and Learning from Serious Incidents Requiring Investigation (Winter 2010)*
7. *National Patient Safety Agency (2009) Being Open: Communicating Patient Safety Incidents with Patients and their Carers.*
8. *Department of Health (2015; revised 2017) Working Together to Safeguard Children: A guide to inter-agency working to safeguard and promote the welfare of children, Chapter 4: Serious Case Reviews*
10. *Department of Health (2014) The Care Act : Safeguarding Adults.*
11. *Department of Health (2010) Clinical Governance and Adult Safeguarding, An Integrated Process*
12. *Memorandum of Understanding Investigating patient safety incidents involving unexpected death or serious harm: a protocol for liaison and effective communications between the NHS, Association of Chief Police Officers and HSE; Guidelines for the NHS In support of the Memorandum of Understanding*
13. *National guidance on learning from deaths, National Quality Board March 2017*

Appendix A

Incident Reporting Guide

1. What is an incident?

An incident is any event which gives rise to, or has the potential to, produce unexpected or unwanted effects involving the safety of service users, staff, families / carers, visitors on Trust premises or employed by the Trust, members of the public (where affected by the actions of service users), loss or damage to property, records or equipment which are on Trust premises or belong to the Trust. It includes accidents, clinical incidents, security breaches, violence, and any other event which does or could result in harm or damage.

These may include incidents of violence and aggression, accidents and injuries, errors and omissions, data loss and breaches of confidentiality, absence without leave and breaches of Mental Health law etc.

The Trust strongly encourages staff to report clinical and non-clinical incidents including staff incidents

2. Why report incidents

Incident Reporting:

- Allows individuals, teams, Directorates and the Trust to learn from incidents and improve the quality and safety of the services. The Trust encourages staff to report every incident and near miss that takes place.
- Helps ensure that everyone who needs to know that an incident, or near miss, has happened knows. This means appropriate remedial action is taken, and appropriate support is available to service users, staff, visitors and others who are involved. It also facilitates appropriate follow up, such as police involvement.
- Enables the appropriate level of investigation into incidents to take place, for the Trust to learn from adverse events, and improve the quality and safety of its services.
- Provides formal record of the incident.

3. Who reports incidents?

Any Trust employee who can provide the necessary details of an incident can complete an incident form. It is recommended that new or inexperienced staff initially do so under the supervision of more experienced colleagues. An individual does not need to have been directly involved in an incident to report it, however they must be able to give accurate and comprehensive information.

It is the responsibility of the individual or the team/ward identifying the incident to ensure that it is reported on InPhase.

4. How to report an incident?

- The incident form is accessed by clicking on the InPhase icon located on all Trust mobile devices. Click on the quick link on the home page
- Reporters log onto InPhase using their NHS mail credentials. The form entails choosing from drop-down menus and completing free text fields. Some choices may bring up some additional sections of the form. Guidance notes are featured throughout the form where necessary.
- All mandatory sections are marked with a red asterisk. It is not possible to submit the form without completing mandatory sections.
- Users will be asked to provide details of the individuals involved in the incident up to 10 patients and staff members can be recorded on an incident form.
- To avoid any potential breach of confidentiality, person identifiable information (names, phone numbers, addresses etc.) are recorded in the contacts section of the form and must not be recorded in any free text boxes.
- There are boxes to record, a description of the incident itself, and the actions taken to manage the incident (antecedent – behaviour - consequence).
- To ensure the appropriate response to an incident and so learning can be taken from it, it is vital that the incident is categorised accurately. Contact the Governance & Risk department if advice is required. Once the report is completed click on submit
- **Good incident reports aid improvement, and are:**
 - **Factual** – do not state opinions, stick to facts.
 - **Accurate** – ensure that the incident type/category and directorate/site is accurate and include a clear description of what the actual incident is
 - **Comprehensive** – to allow decisions to be made quickly and alleviate for a further information request
 - **Timely** – ensure that the reporting time limits are adhered to.

5. When to report an incident?

All incidents and near misses should be reported as soon as possible.

Immediate remedial action is often likely to take priority over completion of an incident report. In the event of a 'Patient Safety Incident Investigation' (as defined by Trust Policy) it is expected that an incident report will be submitted within two **hours** of the incident taking place, although the incident may be reported in person/by phone in the first instance.

All other incidents should be reported as soon as possible, always within **24 hours** of the incident taking place or 24 hours of becoming aware of the incident.

6. What happens once an incident is reported?

- **Notification** - every incident report is automatically forwarded to those who need to know about it. As a minimum this will include:
 - Team/Ward manager
 - Consultant
 - Matron and Borough Nurse (in-patient)
 - Service manager (community)
 - Service Director
 - Clinical Director

It is vital that the correct information about people, ward/service, site, and consultant of the service user involved is included in the InPhase report.

In addition some categories of incident will be forwarded to Trust Leads in that area, or those with particular responsibility for following up or supporting people involved in certain types of incident, for example Health and Safety incidents are followed up by the Health, Safety and Security Manager, Infection control incidents are followed up by the Lead Nurse for Infection Control. It is therefore vital that incidents are categorised accurately so that this follow up and support can be delivered

- **Manager's sign off** – all incident reports require sign off by the manager of the service submitting the form. This sign off should take place within 20 working days of the incident being reported.

The sign off process ensures the quality, accuracy and completeness of incident reports. It also provides additional information about the causes and management of incidents that can then be used to learn, and to improve the quality and safety of services. The manager must save any corrections made to the form to enable resubmission to the LFPSE.

Sign off provides assurance that managers are aware of incidents that have taken place, and are in a position to ensure that the incident has been managed, those involved have been appropriately supported and appropriate action plans formulated. Managers should provide support and feedback to staff as necessary.

Managers should also use the incident reports to facilitate learning at local governance or reflective practice groups.

- **Governance** – Data and information collected from incident reports and subsequent reviews feed into the Trust's Governance processes to help monitor and improve the quality and safety of our services.

All staff are involved in the governance process, and learning from incidents takes place at all levels across the Trust. Individuals, teams and Directorates review and draw learning and actions for improvement from incidents that take place in their locality.

Trust incident reporting data is analysed by the Governance & Risk Department and disseminated to key Trust Groups and Committees. Directorates should manage their own incident reporting data via dashboards and portals.

All Patient Safety Incident reports will, where appropriate, identify areas of learning and have an associated action plan for addressing those issues. As well as feedback to individuals/teams involved in serious incidents, all SI reviews are reviewed by senior staff from across the Trust to ensure that issues are shared where appropriate, across the Trust. Issues arising from SI reviews are analysed by the

Governance & Risk Management Department to identify key themes to help identify priorities and co-ordinate improvement work.

The Trust runs quarterly learning seminars to share some of the important lessons learnt from Serious Incident Reviews and promote discussion of the issues.

7. Additional information

For more incident reporting data, feedback and information around learning from incidents please speak to your local governance lead or go to the Governance & Risk Management pages of the intranet.

The Governance & Risk Management Department is available to support all aspects of the incident process; reporting, review and learning. Please do not hesitate to contact them by phone or email if you would like to discuss any part of the process, or need any practical support, help or guidance. Email incident.reporting@elft.nhs.uk

Further incident training and guidance information is available from the Trusts Intranet site

Appendix B

Guidance on completing and reviewing 72-Hour Reports

Introduction

This guidance outlines the procedure for creating, submitting, reviewing, and utilising 72-hour reports in our incident response system. These reports serve as preliminary reviews to understand incidents, their immediate impacts, and the initial actions taken to ensure safety and service continuity.

Scope

This procedure applies to all senior staff members (Band 7 and above) within clinical, and non-clinical areas, or service areas, tasked with completing 72-hour reports upon request.

Definitions

- **72-Hour Report:** A preliminary report compiled within 72 hours of an incident to gather essential information, assess initial impacts, and outline immediate corrective actions.
- **Daily InPhase Panel:** one of the oversight panels implemented as part of PSIRF. A daily incident review panel/meeting that meets daily to discuss incidents that have been identified for potential further review.
- **Decision-Making Panel:** A Corporate's panel responsible for reviewing completed 72hrs reports and deciding on further actions or investigations.

Identification of Need

72-Hour Reports Identified via Daily Incident Panel

The primary mechanism for identifying the need for 72-hour reports is through the daily incident huddle. During these meetings, the corporate team, reviews all reported incidents and determines which ones warrant further investigation and a 72-hour report.

When the corporate team identifies an incident that requires a 72-hour report, they will communicate this request directly to the relevant directorates. This communication will outline the details of the incident and the rationale for the 72-hour report, ensuring the directorate has a clear understanding of the requirements.

Directorate-Identified 72-Hour Reports

In contrast to the standard reporting process, where the need for a 72-hour report is identified by the corporate team, there may be instances where a directorate recognises the requirement for such a report due to specific incidents or issues requiring further clarification. In these cases, the directorate must communicate with the Governance and Risk Team via email to ensure the incident is appropriately logged and managed through the correct channel.

Report Compilation

- Designated senior staff members within the relevant directorates or teams are responsible for compiling the 72-hour incident report.
- Report Content Requirements: The 72-hour incident report must include the following comprehensive contextual information:
 - Detailed patient history, including medical, physical, mental, and social background
 - Relevant risk assessments and care plans
 - Documentation of any inter-service involvement or coordination
 - Where appropriate the Action section is completed

Support from Governance and Risk Team with report writing

- If the directorate requires assistance in writing the 72-hour report, they can contact the Governance and Risk team for guidance.
- A member of the Governance and Risk team will be available to help the directorate in navigating the report template and ensuring the report meets the required standards.
- The Governance and Risk team can provide training sessions for the directorate staff on how to properly complete the 72-hour report template and meet the necessary standards.
- They will offer drop-in sessions or one-on-one support to walk through the report writing process and address any questions or concerns the directorate may have.
- The team will develop comprehensive guidance documents, checklists, and templates to assist the directorate in preparing the 72-hour reports.
- Staff can access training materials, videos/recorded sessions, on the intranet at: <https://www.elft.nhs.uk/intranet/teams-support-me/governance-and-risk-management>

Timely Submission: The completed 72-hour report must be submitted to the Governance & Risk Team within the specified 72-hour timeframe.

- Before submission to the Governance & Risk Team, the 72-hour report must be reviewed by an operational lead or a senior equivalent within the relevant directorate.

Ownership and Quality Assurance of the 72-Hour Report

Ownership and Accountability:

- The Directorate and the author retain ownership of the 72-hour report throughout the process. This ensures consistency and accountability in its handling and modification.
- Upon reception of the completed 72-hour report by the Governance & Risk team, the report will undergo a quality assurance check. This process ensures that the report contains detailed information necessary to support informed decision-making. The QA process should be completed within 48 hours to prepare the report for presentation at the next panel, which occurs every Tuesday.
- Reports that need to be submitted to the Care Quality Commission (CQC) should be prioritised accordingly.
- Any gaps or inconsistencies in the information are addressed through direct collaboration with the report's author(s). Clear communication channels should be established to facilitate this process.

Report Presentation and Decision-Making

- The author of the 72-hour report, or a suitable representative, is expected to present the report at the weekly Decision-Making Panel.
- At the panel, a decision will be made to either close the incident or escalate it to a PSII (Patient Safety Incident Investigation) or request an AAR (After Action Review).
- The author may be required to take comments from the panel and update the report accordingly before final closure.

Revisions Post-Decision Making Panel:

- If revisions are necessary following the report's presentation at the Decision Making Panel, the Directorate and the author are responsible for implementing these changes and bringing the revised report to the next panel the following week.
- The same timeline applies to Patient Safety Lead Reviewers (PSLRs) supporting the Directorate.

Governance & Risk Management of 72-Hour Reports

- A standard 72-hour report template is provided with each request to ensure consistency and completeness across all reports.
- A redacted and completed 72-hour sample report is sent with every request to provide additional guidance on the expected content and format. The sample report serves as a reference point, illustrating the level of detail and quality expected in the final submission.
- The Governance and Risk team will ensure that all sections of the 72-hour report, and where appropriate, ensure SMART Action Plan, are fully completed.
- No report will be considered complete unless it includes a clearly defined SMART Action Plan addressing each identified gap or area for improvement.

Record Keeping

- Finalised 72-hour reports are stored in the designated folder on the K drive and included in the next Decision-Making Panel's agenda.
- Feedback from the reviews of 72hrs reports and decision-making process is used to refine and enhance the 72-hour reporting and review procedures.
- Action plans resulting from the 72hrs reports must be followed through by the Directorates, with evidence of their implementation tracked on the InPhase system.

Introduction

As part of our response to Patient Safety Incident Response Framework (PSIRF), we have established a comprehensive oversight mechanism known as the Oversight Panels to ensure thorough and systematic review of all safety incidents. These panels are designed to provide a structured approach to incident review, decision-making, and accountability, fostering a culture of continuous improvement and learning.

The Oversight Panels consist of three distinct meetings:

- **Daily Incident Review Panel**
- **Decision-Making Panel**
- **Sign-Off Panel**

1. Daily Incident Review Panel

Overview

The Daily Incident Review Huddle is a crucial component of our Patient Safety Incident Response Framework (PSIRF) oversight process, designed to standardise the daily assessment of incidents recorded on InPhase. Patient Safety Lead Reviewers conduct daily evaluations to identify incidents that require further scrutiny for panel discussions. The identification of these incidents is guided by local and national priorities in line with PSIRF guidance. For more detailed information, please refer to the PSIRF plan.

Participants

- **Director-Led Safety Grader:** The chair, brings clinical expertise and oversight to the session. This role ensures that decisions made incorporate comprehensive clinical implications, risk management, and public interest.
- **Patient Safety Lead Reviewers:** Completes the initial assessments of all Incidents logged on InPhase, identifying incidents needing clarity.
- **Incident Assistants and Coordinators:** Handle the logistical aspects of the meeting, ensuring efficient workflow and documentation.
- **Head of Incident Management:** provides guidance and procedural support related to the Patient Safety Incident Review Framework (PSIRF), ensuring decisions align with the Patient Safety Incident Review Plan (PSIRP). This role ensures the quality and timely submission of reports to the decision-making and sign-off panels and manages day-to-day logistics, ensuring procedural requirements are met.
- **Associate Director of Governance and Risk:** The Associate Director of Governance and Risk holds overarching accountability for governance and risk management processes. This role ensures all actions comply with established standards and support the overall safety and quality objectives of the organisation.

Process

Pre-Session Review of Incident reported on InPhase by Patient Safety Lead Reviewer (PSLR):

- Review all incidents reported on InPhase against set criteria.
 - Assess compliance, completeness and reported harm levels.
 - Identify incidents requiring escalation (e.g. 72-hour report, AAR, PSIR, CRTs).
 - Prepare agenda for daily incident review panel.
 - Ensure comprehensive evaluation, considering multi-service patient engagement.
- **Electronic Systems Review:** As part of their daily review, where applicable, Patient Safety Reviewers will access electronic systems like Rio, SystemOne, and EMIS to resolve ambiguities and support informed decision-making. This ensures that all available information is considered when categorising and deciding on next steps for incidents.
 - **Documentation and Agenda Setting:** The "Daily InPhase Template" is completed for incidents selected for discussion, providing rationale and suggested next steps. This forms the session's agenda.
 - **Session Conduct:** Chaired by the Director-Led Grader, the session discusses each case flagged for discussion on the agenda.
 - The huddle ensures that decisions align with the PSIRF framework, focusing on systemic learning and efficient dissemination of lessons learned, avoiding regression to previous SI (Serious Incident) framework practices.
 - Incidents that required Duty of Candour will be flagged and recorded on the InPhase Reporting template for the Incident assistants to action.
 - **Timing:** Sessions last 30 minutes, with an extension to 45 minutes on Mondays to cover increased caseloads from the weekend.

Post-Session Follow-Up

- Incident Assistants relay decisions and actions to the relevant directorate personnel, ensuring uniformity and centralised coordination.
- Responses are required within 72 hours to affirm patient safety assurances.
- Unresolved issues after 72 hours are addressed in the next huddle. This will be presented by the Incident Assistants.
- Records are archived systematically on the K://drive for future reference and accountability.

Violence and Aggression Incidents

- **Local Team Ownership:** Local teams ensure that violence and aggression incidents are managed in accordance with policies, and affected staff are supported and directed to necessary support services.
- **Health & Safety Team Review:** Reviews significant cases, racially aggravated incidents, or where RIDDOR (Reporting of Injuries, Diseases and Dangerous Occurrences Regulations) escalation is needed. Reviewing these cases again in the huddle would be redundant unless new information is presented.

Review and Continuous Improvement

The protocol will be regularly updated to integrate new insights, address challenges, and comply with current standards, ensuring the Daily Incident Review Huddle remains relevant to our PSIRF process.

PSIRF Decision Making Panel Procedure

Introduction

The Decision-Making Panel (DMP) serves as the second oversight panel. Its primary purpose is to review completed 72-hour reports and make informed decisions regarding the need and level of further investigation. The panel evaluates these reports in line with PSIRF, focusing on identifying learning opportunities, system issues, and trust-wide concerns to enhance patient safety and care quality. Additionally, the panel ensures that reports are prepared to a standard suitable for external scrutiny if required.

Panel Composition: The DMP consists of the following key members, whose presence is mandatory for the meeting to proceed:

- **Medical Director- Grader (Chairperson):** Responsible for overseeing the meeting, guiding discussions, and inputting into the decision-making process. This role is fulfilled by the Medical Director.
- **Director of Nursing:** co-chairs the meeting.
- **Head of Incident Management:** provides guidance and procedural support related to the Patient Safety Incident Review Framework (PSIRF), ensuring decisions align with the Patient Safety Incident Review Plan (PSIRP). This role ensures the quality and timely submission of reports to the decision-making and sign-off panels and manages day-to-day logistics, ensuring procedural requirements are met.
- **Associate Director of Governance and Risk:** The Associate Director of Governance and Risk holds overarching accountability for governance and risk management processes. This role ensures all actions comply with established standards and support the overall safety and quality objectives of the organisation.
- **Incident Coordinator:** Provides administrative support to the meeting, prepares the agenda, ensures the attendance of the authors of the 72-hour reports, and manages follow-up actions.
- **Authors of 72-Hour Reports:** Provide detailed accounts and insights into the incidents under review, offer contextual information, and take back comments and actions, responding where appropriate.

Attendance Requirements

- Both the Medical Director and the Director of Nursing must be present for the meeting to proceed. If either is absent, the meeting will not go ahead. The Medical Director and Director of Nursing are responsible for ensuring their attendance. If unable to attend, the Medical Director and Director of Nursing must allocate a suitable deputy or replacement to ensure the continuity of the meeting.
- All attendees must read the 72-hour reports prior to the meeting to positively engage with the process and provide informed input.

Meeting Procedure

Review of 72-Hour Reports:

- Each 72-hour report will be quality assured by the designated Patient Safety Lead Reviewer to ensure that relevant and key information are included before presentation.
- Each 72-hour report is reviewed in detail by the panel. Discussions focus on the content, context, and Findings of each report and actions to address areas for improvement identified in the report.

Decision-Making:

- Evaluate if the incident requires further investigation (e.g., PSII, AAR). Ensure that the decision to escalate to a PSII aligns with the PSIRF framework, focusing on the significance of the incident and the potential for organisational learning.
- Identify learning opportunities and determine the best methods for team learning and improvement.
- Determine if an after-action review (AAR) is required to augment learning and improvement for the team.
- Agreed scope and Terms of reference of reviews.

Closure of Incidents:

- If, on review of the 72-hour report, the panel is satisfied with the content and there are no omissions in care, or all learning from the incident has been identified, and the team or directorates have provided evidence or assured the panel that learning has been taken, then the incident can be closed.
- Where deemed necessary, the panel can also recommend an AAR to enhance learning and improvement for the team.
- If the 72-hour report has been reviewed and there are no care omissions that contributed to the fatality, but the report is needed for an inquest, specific actions will follow.

Administration of the Meeting

The administration of the Decision-Making Panel will be managed by the Incident Coordinators within the Governance and Risk Team. Their responsibilities include:

- Preparing the agenda and ensuring all documents are up-to-date and accurate and circulated 48hrs before the meeting.

- Ensuring the authors of the 72-hour reports are invited to the meeting and are aware of their reports.
- Ensure that the scope of the incident, terms of reference for cases that escalate to a PSII investigation, and follow-up actions are recorded.
- Managing the administrative aspects, ensuring that incidents come back to the panel for sign-off if additional comments are required and they are not allocated to a lead reviewer.
- Linking with the Head of Incident Management for direction if any concerns arise.
- Submitting closed cases that need to go to the legal team within 24 – 48 hours and keeping the legal team updated on progress, especially for cases requiring additional work.
- Updating the directorate on any additional actions required for cases where the author was not present at the time.

PSIRF Sign-Off Panel for Patient Safety Incident Reviews Procedure

Purpose

The Sign-Off Panel aims to finalise learning responses and reviews conducted under the Patient Safety Incident Response Framework (PSIRF). This includes Patient Safety Incident Investigations (PSII), Care Review Tools (CRT), Thematic, and Cluster Reviews. The panel ensures reports meet required standards, identifies all relevant learning, and adheres to the terms of reference and scope.

Panel Composition

- Chair: Medical Director
- Director- Level Safety Graders (minimum two in attendance for any panel to be quorate)
- Investigation authors (Patient Safety Lead Reviewers and Co-reviewers)
- Incident Team Coordinators
- Associate Director of Governance & Risk
- Head of Incident Management
- Director of Patient Safety

Process

- The incident team schedules and manages the meeting, held weekly.
- All reports must undergo a quality assurance process by the Head of Incident Management or the Associate Director of Governance and Risk to ensure they meet standards and identify all learning.
- The panel reviews up to 8 reports per session, ensuring they meet required standards and all learning is identified.
- Participants must review reports prior to the meeting.
- Participants make suggestions, corrections, and identify gaps, ensuring a diverse perspective by involving experts from different areas.

Approval: Once the panel is satisfied with the content, the Chair approves the report on behalf of the Chief Medical Officer.

Amendments: Any post-approval changes or suggestions from external stakeholders must be brought back to the panel. The external stakeholder, the author, and the head of incident management must coordinate and present these to the panel for consideration.

The external stakeholders must provide feedback within **one to two weeks** of the report's final approval to ensure timely consideration. For urgent changes required after approval but before the next meeting, the Chair **may** take action outside the meeting in extreme cases, although this will be generally avoided.

Follow-Up Actions: The implementation of approved reports and action plans is tracked and monitored by the directorate.

Additional Procedures

- New panel members receive orientation from the Associate Director of Governance and Risk.
- Refer to subject matter experts when necessary
- Record all proceedings, decisions, and action plans on the K/drive
- Final reports and amendments sent to legal team and Integrated Care Board

Appendix D

After Action Review (AAR) Procedure

Introduction

An After Action Review (AAR) is a facilitated group discussion, which seeks to rapidly identify and reinvest learning for improvement. It originated in the military, and was introduced to the NHS in 2009, where it has since been widely adopted across acute and mental health trusts.

An AAR follows a specific incident or event, close to the frontline. Discussion focuses on four questions which seek to ascertain what staff expected would happen, what actually happened, why was there a difference between expected and actual and what can be learned from the event.

The outcome of this discussion enables the individuals involved in the event to understand for themselves what went well and why, what did not go well and why. This allows them to agree on what they would do differently in the future and apply this to inform improvement. AAR's used in this way creates both individual and team opportunities to improve personal, team and organisational effectiveness, to deliver safer, better patient care and improved service user and staff experience.

Purpose

The AAR is a reflective practice tool that is recommended not mandated. It is used to strengthen prompt and collaborative learning from any incidents that present clear opportunities for internal learning and practice improvement where there is potential for teams to introspect and enhance their practices.

Notification

An AAR may be identified by the team/s involved in the incident. In these circumstances, it is helpful if the reporter of the incident completes the relevant section on Inphase stating that an AAR will be conducted or where this is not possible (i.e. after the incident has been reported), the incident team must be notified via email for central oversight.

An AAR may be recommended centrally during the Daily Incident Review Huddle or during the weekly Decision-Making Panel, and ideally in collaboration with the Directorate.

In some circumstances, particularly where there may be a more in depth review on the horizon, an AAR may be requested and upon completion, the summary shared at the next Decision-Making Panel.

The incident team will notify the Directorate, along with guidance supporting documentation.

Organising and Completing an AAR

An AAR should be completed as soon as is practicably possible, whilst it remains fresh in people's minds. Guidance suggests ideally within one to two weeks, and no more than six weeks.

An AAR should be completed by a trained conductor who was not involved in the incident and who is impartial. The conductor has the option of seeking support from a scribe to capture themes and actions as they arise during the AAR.

A number of conductors are trained across the Trust and governance leads have access to an up to date list. Alternatively, the incident team can provide this information.

The conductor will benefit from administrative support from within the team where the incident took place.

A pre-meet at the earliest opportunity between the conductor and local lead/or team is recommended, in order to establish a basic understanding of what happened and agree the following:

- Scope (which elements of the incident the AAR will and will not focus on)
- Who (as few as three people can carry out an AAR, and ideally no more than eight. Diverse viewpoints are sought and so all staff should be involved from any domestic, admin, clinicians (including bank, part-time staff) through to members of the management team. The patient/carer/family may also be invited, where appropriate).
- When and Where (within six weeks of the incident, online or face-to-face [hybrid is not recommended], in a neutral environment - if practical).
- Duration (no more than two hours).
- To maintain a psychologically safe environment, we discourage documenting detailed accounts of who said what to maintain this supportive atmosphere and encourage honest, constructive dialogue. Detailed notes of the AAR proceeding are not kept. Instead, learning themes and outcomes should be summarised using the SEIPS (Systems Engineering Initiative for Patient Safety) framework and logged on InPhase under the relevant incident. This ensures insights are actionable and integrated into broader safety strategies.
- Introduce the session
- Outline and then keep people to the ground rules
- Maintain time boundary
- Maintain a non-judgmental position/atmosphere
- Ask the four questions
- Ask curious, neutral questions to help people learn/reflect

After an AAR

There is a mechanism within the toolkit to seek feedback from those attending AARs. This is particularly valuable as we continue to refine the process and continue to improve the experience of those involved.

The AAR summary must be written up as soon as possible, using the AAR template. They should then be saved on Inphase (if the AAR arose from an incident) and the patient's record (where it involved patient/s), and a copy emailed to the incident team for central oversight.

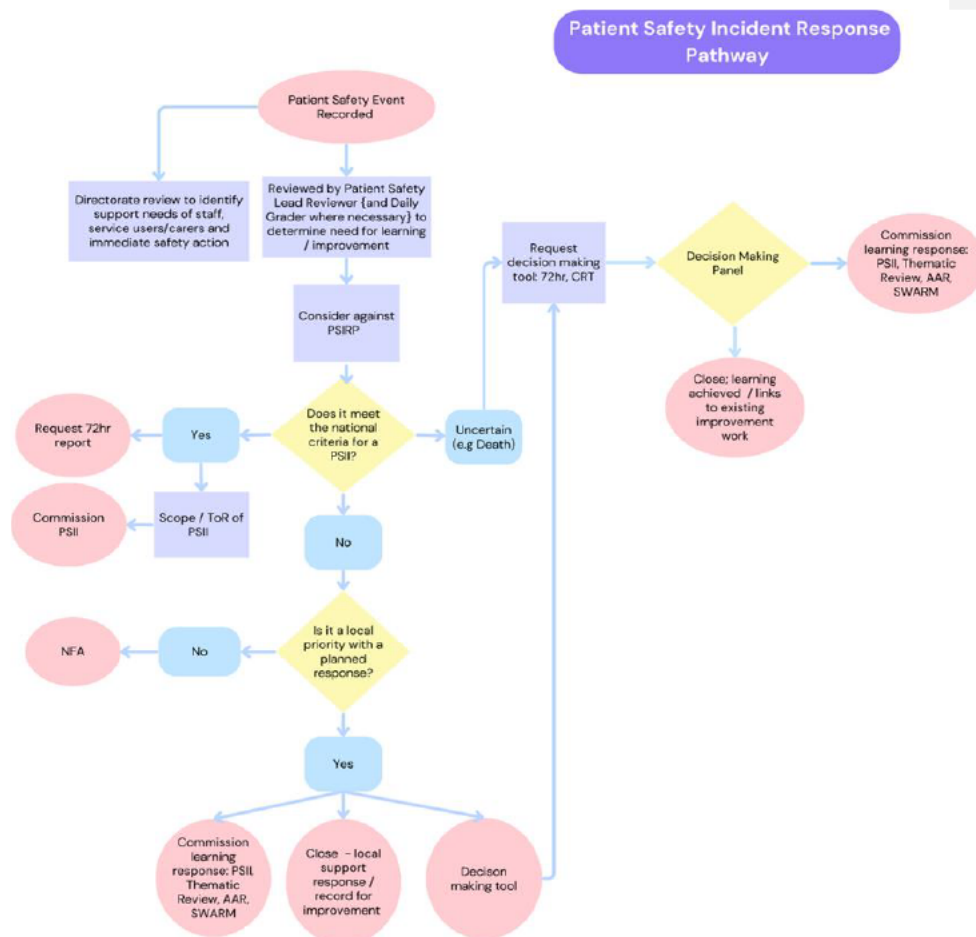
A sample of AARs will be brought to the Trust's Patient Safety Learning Committee, and also reported on as part of the Trust's wider patient safety learning.

Learning from the AAR should be shared across the team/s involved as soon as possible and ideally across the Directorate, and Trustwide where applicable. Further advice can be sought from the DMT/governance lead and the central incident team/Director of Patient Safety for Trustwide learning.

For up to date and further information including training, guidance and AAR toolkit (including the ground rules) visit the AAR page on the Trust's intranet.

Appendix E:

Patient Safety Incident Response Pathway



Appendix F

Patient Safety Incident Investigation (PSII) Procedure

Introduction

A Patient Safety Incident Investigation (PSII) is a structured, systems-based approach to examining patient safety incidents within the NHS. It forms a crucial part of the Patient Safety Incident Response Framework (PSIRF) and replaces the previous root cause analysis methodology.

The primary aim of a PSII is to identify learning opportunities and drive sustainable improvements in patient safety. Unlike traditional investigative methods, PSIIs focus on understanding how and why incidents occur, rather than attributing blame to individuals. PSIIs involve a thorough examination of the systems, processes, and contributing factors surrounding an incident. They require specially trained personnel to conduct and oversee the investigations, ensuring a high standard of analysis and reporting.

Key features of a PSII include:

- Compassionate engagement with those affected by the incident, including patients, families, and staff
- A systematic approach to gathering and analysing evidence
- Identification of safety actions and recommendations
- Development of SMART improvement plans

PSIIs are typically reserved for more complex or serious incidents, as determined by our Patient Safety Incident Response Plan (PSIRP). They form part of a proportionate response strategy, which may also include other methods such as After-Action Reviews or local learning responses.

The ultimate goal of a PSII is to generate actionable insights that lead to meaningful changes in practice, policies, or systems, thereby enhancing patient safety and reducing the likelihood of similar incidents occurring in the future.

Administrative Process

- **Incident Identification:** Incidents reported on InPhase will be reviewed by Patient Safety Lead Reviewers (PSLR) daily. This ensures that any incidents with potential for further investigation and learning are promptly identified and escalated.
- **Daily Incident Review Huddle:** Incidents identified by the PSLR that may require further information or clarity will be escalated to the daily session. This session serves as a platform for further discussion and decision making on the incidents in question. If necessary, a 72-hour Report, After-Action Review (AAR) or Care Review Tool (CRT) may be requested from the Directorate and taken to the decision-making panel to provide an overview of the incident, immediate learning and actions taken and form the basis for a decision to be made about whether the decision making tool i.e. 72 hour report, AAR or CRT is sufficient or whether a further investigation such as a PSII, Cluster or Thematic review is necessary to identify further learning and associated actions to be taken.

- **Decision-Making Panel:** The panel's primary function is to review and discuss completed 72-hour reports and agree the final decision on the next steps of the investigation. The panel will discuss and the scope of the review for each investigation. The panel will decide on the appropriate level of professional or disciplinary input required for the investigation.
- The Decision Making Panel reviews and assesses cases to determine appropriate next steps, aligning with local and national priorities and identifying opportunities for learning. This process ensures a consistent and proportionate response, maximising potential for improvement. For further details on trust priorities, please refer to the Patient Safety Incident Response Plan (PSIRP).

Outcomes from this panel include:

- **No Further Action:** The panel may determine that no further action is required, and the investigation can be closed.
- **Escalation to a PSII:** The panel may decide that the incident requires escalation to a PSII. PSII's are mandated under specific conditions as outlined in the Trust's Patient Safety Incident Response Plan (PSIRP). A PSII is required in the following scenarios:
 - When an incident meets the criteria for local priorities as defined in the PSIRP.
 - For all incidents that are nationally mandated for investigation.

The PSIRP is the main document that specifies when a PSII must be conducted. It is essential that the Decision Making panel is familiar with the PSIRP to ensure adherence to both local and national requirements for patient safety incident investigations.

- **Completion of an AAR:** The panel may recommend that an After-Action Review (AAR) be completed to identify lessons learned and areas for improvement. In certain instances, the review panel may determine that conducting an After-Action Review (AAR) would significantly enhance the team's learning and development. In such cases, the panel has the authority to require sight of the AAR summary in order to decide whether any further learning review is required.
- **Completion of a Care Review Tool (CRT):** In certain cases of unexpected death, the panel may require the completion of a CRT by a PSLR to thoroughly examine the incident and develop appropriate corrective actions alongside the Directorates.

PSII Investigation Process

Lead Investigator Appointment and Timeline:

- The Incident Coordinators will inform the Directorate Lead of the decision to escalate an incident that occurred in their service to a PSII.

- The Head of Incident Management will appoint a suitable Patient Safety Lead Reviewer to lead the PSII review and agree on a suitable timeframe for completion.
- Depending on the complexity of the case, either a single co-reviewer (Clinicians) or a panel of co-reviewers will be assigned to support the investigation. The decision to constitute a panel. (The Panel may include Service User and Carer Representative where available).
- Incident Coordinators will liaise with the Clinical Director of each Directorate to nominate an appropriate co-reviewer. The selection process will adhere to the Co-Reviewer Guide, emphasising the necessity for independence to mitigate potential biases. Where applicable, this may entail selecting reviewers from different departments outside the Directorates or even outside the organisation to ensure impartiality and objectivity in the investigation.

Communication with Affected Parties:

- In cases resulting in an inpatient death, a session explaining the PSII investigation process will be conducted by the Associate Director of Governance & Risk with the relevant team.
- The Patient Safety Lead Reviewer, once appointed, will contact the family to further fulfil Duty of Candour requirements, inviting them to participate in the investigation process and to voice any queries or concerns they may have if they wish. Where appropriate, these concerns / requests for explanations will be addressed within the PSII Review.

Engagement with Former Staff in Investigative Processes

The Patient Safety Lead Reviewer bears responsibility for ensuring the involvement of all pertinent staff, including those who have left the organisation, in patient safety incident reviews. This section delineates the procedures for engaging former staff to maintain a comprehensive and equitable investigative process.

Identifying and Contacting Relevant Former Staff

At the outset of the investigation, the Patient Safety Lead Reviewer shall determine which former staff members are crucial to the review. They shall then liaise with Human Resources and previous line managers to obtain current contact details for these individuals.

The reviewer shall make proportionate efforts to contact identified former staff, weighing the significance of their input against potential delays to the investigation timeline. All contact attempts must be meticulously documented, including methods employed, dates, times, and responses received.

Participation and Reporting

Should former staff agree to participate, their contributions shall be judiciously incorporated into the investigation. Any additional lines of enquiry arising from their input shall be pursued as appropriate.

All interactions with former staff, including contact attempts and subsequent communications, shall be succinctly documented within the investigation reports. This documentation exemplifies the organisation's commitment to a thorough and impartial investigative process.

Comprehensive Data Collection and Multidisciplinary Engagement

The Patient Safety Lead Reviewer shall orchestrate a meticulous and inclusive information-gathering process to ensure a thorough and balanced investigation:

- **Chronology Development:** Construct a precise and comprehensive chronology of events preceding and including the incident, to be presented to the investigation panel and Co-Reviewer(s).
- **Holistic Record Review:** Conduct an exhaustive examination of all pertinent records across all services the patient engaged with, ensuring a complete and nuanced understanding for the investigative process.
- **Inclusive Staff Consultation:** Engage systematically with all staff members involved in the incident, facilitating a multifaceted understanding of events from diverse perspectives within the care team.
- **Policy and Guideline Scrutiny:** Meticulously review relevant policies, standard operating procedures (SOPs), and both local and national guidelines to ensure compliance and identify potential systemic gaps.
- **Patient and Family Collaboration:** Proactively seek and meaningfully integrate the concerns, insights, and lived experiences of the service user/patient, family, or next of kin. This approach aligns with the collaborative ethos of the Patient Safety Incident Response Framework (PSIRF), ensuring that patients' and families' voices are not only heard but also valued and incorporated into the investigation.
- **External Stakeholder Consultation:** Where appropriate, consult external stakeholders such as local authorities, GPs, safeguarding teams, and police services to enhance the depth, context, and robustness of the investigation.
- **Patient Safety Partner Inclusion:** Nominate and involve a dedicated Patient Safety Partner to bring invaluable service user and/or carer perspectives to the investigation, ensuring a balanced and patient-centred approach.
- **Specialist Expertise Integration:** Incorporate relevant subject matter experts as supplementary co-reviewers, such as safeguarding leads, Mental Capacity Act/Mental Health Act experts, and Medicines Safety Officers, to provide specialised insights and ensure a comprehensive analysis of all aspects of the incident.

This multifaceted and inclusive approach ensures a thorough, multi-perspective investigation that captures all relevant information, expertise, and viewpoints.

Expanding the Investigation Lens:

- PSLR are to look beyond individual errors or failures, to consider how various elements of the healthcare system (work system design, processes, organisational culture) interact and contribute to safety incidents.

Multi-Faceted Methodology and Analysis:

- Employing the Systems Engineering Initiative for Patient Safety (SEIPS) to map out the broader system interactions and dependencies that may have played a role in the incident.
- **Incorporating Human Factors:** Recognising the importance of human factors and ergonomics in the design of safer healthcare systems and processes and integrating this perspective into SEIPS analyses.
- **Learning from Everyday Work:** Involving frontline observation methodologies within the safety review in order to understand the system factors and context and to learn from "work-as-done".

Guidance on Requesting Statements under PSIRF

Under (PSIRF), the preferred approach is to engage compassionately with patients, families, and staff affected by patient safety incidents, rather than requesting formal written statements. The PSIRF emphasises understanding how incidents happen through techniques like interviews and observations, rather than attributing blame. Reviewers should treat those involved seriously and with compassion, focusing on learning and improvement rather than a punitive approach.

Fostering an Environment of Trust and Transparency

In the event of an in-patient fatality, it is important to approach the situation with sensitivity and professionalism. While formal written statements should generally be avoided in favour of open, non-judgmental dialogue, there are certain circumstances where documentation may be necessary to support staff and the legal process.

Recollection of Events

When an in-patient fatality occurs, the ward manager should request that staff members provide a recollection of the events. This serves two important purposes:

- **Contemporaneous Documentation:** Capturing the staff's recollection of events as soon as possible helps to ensure accurate and detailed information is available, should it be required for any subsequent inquests, Police or legal proceedings.
- **Staff Support:** The process of recollecting and documenting the events can also provide an opportunity for staff to receive support and guidance, particularly in the face of a potentially traumatic incident.

Promoting a Culture of Openness

The overarching goal is to create an environment of trust and transparency, where staff feel safe to report and discuss patient safety issues without fear of repercussions. By fostering this culture, organisations can encourage open communication, facilitate learning, and ultimately improve patient care.

Feedback Meetings and Engagement

- **Directorate Feedback Meetings:** The Patient Safety Lead Reviewer (PSLR) and the investigation panel will engage with the relevant leads and subject matter experts throughout the process. Then, a feedback meeting will be held with the Directorate, presenting the draft PSII report. Attendees, including the Clinical Director and or Operational Lead, review the report, ensuring accuracy, and collaborate on the development of SMART action plans, with the Directorate assuming action ownership.
- **Family Engagement Meeting:** A dedicated meeting with the patient's family or service user is held where the draft report is shared and their input included. The PSLR ensures that this process is transparent and compassionate. Where the family cannot speak in English an interpreter will be engaged.

Quality Assurance

- **Peer and Secondary Reviews:** The PSLR will ensure the report is peer reviewed within the incident team by another PSLR colleague. A secondary review is completed by the Head of Incident Management and in their absence the Associate Director Governance and Risk. To ensure the reports quality, the Healthcare Safety Investigation Branch (HSIB) Safety Review Standards to guide the quality review;
 - People affected meaningfully involved?
 - Systems approach applied?
 - Human error as symptom of system problem
 - Blame language is avoided
 - Local rationality is considered
 - Counterfactual reasoning is avoided
 - Safety actions/recommendations are effective
 - Report concise, easy to read and anonymised

- **Sign off Panel**

The reviewed report is taken to the Trust's weekly Sign off Panel led by a minimum of two director level graders, attended by the Associate Director of Risk and Governance, Head of Incidents, PSLR and co-reviewer/s. The content of the report is reviewed and where appropriate signed off. Where a consensus cannot be reached, the chair will seek support from the Chief Medical Officer and Director of Patient Safety.

Final Report Finalisation and Distribution

- **Integrated Care Board (ICB) Submission:** Upon receiving final approval and sign-off from all relevant parties, the Incident Coordinator is responsible for sending the final investigation report to the Integrated Care Board (ICB), ensuring that the report's findings and recommendations are communicated to key oversight bodies.
- **Family Communication:** Concurrently, the Patient Safety Lead Reviewer (PSLR) is tasked with sharing the final report with the patient's family or next of kin. Prior to this step, it is imperative that the PSLR confirms that all involved parties, including the legal

team, agree with the contents of the report, ensuring that the version shared with the family is indeed the final and fully approved document.

- **Sharing with staff:** All staff involved in the PSII will have had the penultimate report shared with them during the feedback meeting and Action Plan Development. Once the report is completed, a final version will be shared with staff via Directorate Governance Leads.

Post-Investigation Administrative Review

Severity of Harm Assessment: As part of the post-investigation administrative duties, the Incident Coordinator conducts a thorough review of cases, particularly those with 'fatal' outcomes, to ascertain if any omissions in care were identified as contributing factors.

In instances where the investigation concludes that no omissions of care contributed to the outcome, the Incident Coordinator must update the incident management system InPhase to accurately reflect this finding.

This may involve downgrading the severity of harm classification based on the investigation's findings, ensuring that the incident record accurately reflects the nature and outcomes of the incident.

Communication and Survey

- **Final Report Sharing:** The PSLR shares the finalised report with the patient's family. Where the family's first language is not English, and they can read in another language, the report will be translated.
- **Post-Investigation Survey:** Incident coordinators distribute a survey to Directorates to elicit their views on the PSII process. Responses will be used to refine future PSII processes where appropriate.

Learning

Integration of Learning from Patient Safety Incident Investigations

To ensure the continuous improvement of patient care and safety, it is imperative that learnings from PSII are effectively communicated and integrated into clinical practice. Upon the conclusion of a PSII, the resulting report shall be disseminated to the involved clinical team by directorate leadership to facilitate immediate reflection and assimilation of the findings. This dissemination process is crucial for fostering an environment of transparency, learning, and improvement.

Learning Lessons Seminar

The Trust commits to the broader sharing of PSII outcomes through structured forums such as the Trust-wide Learning Lessons Seminars. These forums are designed to transcend departmental boundaries, enabling a culture of shared learning and collective responsibility for patient safety.

Patient Safety Forum

The Patient Safety Forum serves as a collaborative space dedicated to enhancing patient safety within the Trust. It functions as a platform for healthcare professionals to discuss and share knowledge on themes related to patient safety improvements and learning from past incidents. The forum fosters an environment of open communication and continuous learning, where members can collectively identify safety concerns, discuss best practices, and implement strategies to mitigate risks and enhance patient care.

Actions from PSII: Ensuring Effective Action Following PSII Findings

Following the dissemination of findings from (PSII), the responsibility to lead the development and implementation of comprehensive action plans falls to the directorate. These plans are designed to address and rectify the issues uncovered during the PSII. It is the duty of the directorate to ensure that these actions are not only put into effect but also completed within designated timeframes.

Appendix G:

Guidance for Selecting and Understanding the Role of Co-Reviewers in Patient Safety Incident Investigations (PSII)

Introduction

This document serves as a dual-purpose guide aimed at assisting Clinical Directors in the selection of appropriate Co-Reviewers for Patient Safety Incident Investigations (PSII), as well as providing prospective Co-Reviewers with a clear understanding of the role's expectations and responsibilities. It outlines the essential qualities, expertise, and multidisciplinary approaches required for effective participation in a PSII, ensuring a thorough and inclusive investigation process.

Definition

Co-Reviewer: A Co-Reviewer is a clinician who brings expert and specialist knowledge to the investigation process. The Co-Reviewer contributes valuable insights, viewpoints, and clinical understanding crucial for a comprehensive analysis of the incident. Their role encompasses evaluating the operational and clinical aspects of the service, ensuring alignment with established clinical protocols, and identifying deviations from standard and best practices. By integrating their clinical and service-oriented expertise, Co-Reviewers enhance the investigative process, ensuring a thorough understanding of the incident's context within the system in which it occurred including any human factors elements and their associated implications.

The Co-Reviewer's contribution is pivotal in maintaining objectivity throughout the investigation, ensuring that findings and recommendations are grounded in professional standards and aimed at enhancing patient care and safety.

The Co-Reviewer will work closely with the Patient Safety Lead Reviewer, who leads the investigation, ensuring a team-oriented approach. This collaboration allows the Co-Reviewer to contribute expert insights without the additional pressure of leading the inquiry.

The Director of Patient Safety, Director of Nursing and Clinical Director, provides additional support, guiding Co-Reviewers on expectations and standards, fostering a supportive environment.

Scenarios Requiring Multiple Co-Reviewers

While most PSII investigations will require only one Co-Reviewer, certain exceptional circumstances necessitate the involvement of more than one Co-Reviewer to ensure a thorough and multidisciplinary analysis. These scenarios include:

In-Patient Investigations of Homicides:

- **Co-Reviewer External to the Directorate:** To provide an independent and unbiased perspective.
- **Nurse Co-Reviewer:** To offer insights into the nursing aspects of patient care and safety.
- **Clinical Lead Co-Reviewer:** To provide expert medical analysis and understanding of the clinical aspects involved.

Community Homicides:

- **Co-Reviewer:** An external reviewer to ensure independence and objectivity in the investigation.

All In-Patient Deaths:

- **Medical Co-Reviewer:** To provide medical expertise and analysis of the clinical factors.
- **Nursing Co-Reviewer:** To contribute a nursing perspective, focusing on care delivery and patient safety dynamics.

Complex Clinical Incidents:

- **Multiple Specialists:** When an incident involves various clinical specialties, additional Co-Reviewers with relevant expertise (e.g., pharmacists, specialist nurses) may be required to provide comprehensive insights into the specific aspects of the incident.

Incidents Involving Systemic Failures:

- **Operational Leads or Borough Lead Nurses:** To provide strategic insights into operational processes and systemic factors influencing patient safety.

The selection of Co-Reviewers should adhere to the following principles:

- **Clinical Expertise:** Co-Reviewers should have the necessary clinical expertise and experience relevant to the incident under investigation.
- **Investigative Skills:** Co-Reviewers should be proficient in the use of investigative tools and techniques, such as SEIPS, and have a strong understanding of systems-based analysis.
- **Independence and Objectivity:** Co-Reviewers should be free from any conflicts of interest or potential biases that could compromise the integrity of the investigation.
- **Collaborative Approach:** Co-Reviewers should demonstrate a collaborative and inclusive mind-set, valuing the input of the PSLR, the directorate, and the affected family or service users. In more complex scenarios, it is important for Co-Reviewers to be prepared to collaborate effectively with service users involved in the panel and People Participation Leads (PPL), fostering a positive and inclusive environment for all participants.

The following clinician roles are identified as potentially suitable for Co-Reviewer appointments, subject to the specific requirements of the incident under investigation:

- **Consultant Psychiatrists:** Their extensive patient care experience and proficiency in handling complex cases equip them with the insight necessary for a nuanced understanding of medical clinical issues.
- **Senior Nurses or Nurse Practitioners:** Their direct patient care involvement and operational knowledge of the healthcare environment provide essential perspectives on

patient safety and care dynamics from a nursing perspective. (Band 7 nurses and above).

- **Patient Safety Experts:** Specialists in patient safety and quality improvement offer critical insights into systemic healthcare safety and human factors issues and best practices.
- **Pharmacists:** In incidents involving medication, pharmacists are invaluable for their analysis of pharmaceutical management and administration.
- **Consultant Nurses:** Bring high-level expertise and leadership in nursing practice, contributing strategic insights into nursing care and patient safety.
- **Specialists in Physical Health Medicine:** Physicians with expertise in general physical health, offering a broad perspective on the medical aspects of patient care relevant to the incident.
- **Specialist Nurses:** Including falls specialists and Tissue Viability Nurses (TVNs), who provide targeted knowledge in specific areas of patient care, offering valuable insights into incidents related to their specialties.
- **Operational Leads or Borough Lead Nurses:** Possessing extensive knowledge of operational processes and healthcare management within specific regions or services, providing strategic perspectives on systemic and procedural factors influencing patient safety.
- **Specialty and Associate Specialist Doctors:** They possess a deep understanding of the complexities and nuances of clinical practice within their respective specialties. Their frontline involvement in patient care also gives them unique insights into potential vulnerabilities, challenges, and areas for improvement.

Co-Reviewer Responsibilities

- **Independence and Objectivity:** As a Co-Reviewer, it is essential to maintain independence and objectivity throughout the investigation. This means avoiding any conflicts of interest or potential biases that could compromise the integrity of the review.
- **Incident Familiarisation:** Co-Reviewers will be expected to familiarise themselves with the details of the incident under investigation. This includes reviewing the chronology of events compiled by the Patient Safety Lead Reviewer (PSLR), as well as all relevant records, policies, and guidelines.
- **Multidisciplinary Collaboration:** Co-Reviewers will work closely with the Patient Safety Lead Reviewer (PSLR) and other members of the investigation panel to ensure a multifaceted understanding of the incident. This will involve consulting/interviewing with staff members who were involved in the care of the patient, as well as engaging with the affected family or service users.
- **Systems-Based Analysis:** Co-Reviewers should adopt a systems-based approach to the investigation, looking beyond individual errors or failures to consider how the interactions between the various elements of the healthcare system (e.g., work system design, processes, organisational culture) may have interacted / contributed to the outcome of the incident being investigated, with a focus on the following aims;

To understand “work-as-done” to help us learn from what happened and identify potential improvements to our systems. In some cases, this analysis will include Co-Reviewers working with the patient safety reviewer to undertake walkaround or observations of the workplace where the event happened, to add to the understanding of what happened.

- **Utilisation of Investigative Tools:** Co-Reviewers will be supported by PSLRs to make use of the Systems Engineering Initiative for Patient Safety (SEIPS) framework to identify the broader system interactions and dependencies that may have played a role in the incident.
- **Fair and Constructive Engagement:** Co-Reviewers and PSLR must treat all staff involved in incidents with fairness, focusing on understanding the systemic factors that contributed to the incident rather than attributing blame to individuals. This aligns with the guidance provided by NHS England and the NHS Resolution's Just and Learning Culture Charter, which advocate for a consistent, constructive, and fair approach towards staff involved in patient safety incidents¹.
- **Collaborative Investigation:** Co-Reviewers should work collaboratively with the PSLR, the investigation team, and relevant staff members. This includes actively participating in the formulation of questions, conducting interviews, and providing expert clinical insight to support the analysis of the incident.
- **Feedback and Engagement:** Co-Reviewers should attend feedback meetings with the PSLR to present the investigation findings to the directorate. They should also be involved in sharing the draft PSII report with the affected family or service users, inviting their input to ensure transparency and a collaborative approach.
- **Attendance at Sign-off Panel:** Co-Reviewers are encouraged to attend the sign-off panel alongside the PSLR to present the investigation findings and to learn from the panel suggestions for improvement.
- **Coroner's Inquest Participation:** Occasionally, Co-Reviewers may be called upon to present the PSII report and findings at a Coroner's Inquest.

Support and Training for Co-Reviewers

Co-Reviewers involved in (PSII) are entitled to a comprehensive suite of training opportunities to facilitate their continuous professional development (CPD). Co-Reviewers have access to patient safety training through the ELFT Learning Academy for their CPD.

Additionally, Co-Reviewers can access free NHS courses offered by the Health Services Safety Investigations Body (HSSIB), tailored specifically for NHS staff in England with roles in patient safety and investigations. The training includes a range of CPD-accredited courses, such as "A Systems Approach to Investigating and Learning from Patient Safety Incidents" among others, aimed at enhancing professional healthcare safety investigation skills²³.

¹ NHS England. (n.d.). A just culture guide. <https://www.england.nhs.uk>, NHS Resolution. (2023). Launch of Just and learning culture charter. <https://resolution.nhs.uk>, NHS Employers. (2021). Implementing a just and respo culture. <https://www.nhsemployers.org>

² <https://www.hssib.org.uk>

³ <https://www.hssib.org.uk/education/about-our-programme/>

Clinical Lead Support: Co-Reviewers' clinical leads should provide guidance and mentorship, ensuring they have a solid understanding of the PSII process, investigative techniques, and the application of systems-based analysis.

Line Manager Support: Co-Reviewers' line managers should allocate dedicated time and resources for Co-Reviewers to participate in the PSII process, including attendance at meetings, training, and the completion of investigation-related tasks.

Continuous Learning

Co-Reviewers should be encouraged to engage in ongoing professional development, staying up to date with the latest best practices and guidelines related to patient safety reviews.

Co-Reviewers are encouraged to participate in the Trust's Learning Lessons seminars, where they can present their cases together with the Patient Safety Lead reviewer and sharing the lessons learnt PSII reviews Trust wide. Co-Reviewers are also encouraged to attend the Trust's Patient Safety Forum, as this offers a platform for exchanging insights and experiences from their investigative work, further contributing to their professional development and the Trust's Patient Safety initiatives.

For Further Information -Please contact:

HOIM

AD Governance and Risk Management

Director of Nursing MH London

Director of Patient Safety

Appendix H:

Post investigation/feedback & Action Planning for PSII

Introduction

This appendix outlines the process for conducting post-investigation feedback meetings and developing robust and SMART action plans related to patient safety incidents. These meetings are crucial for promoting a culture of transparency, accountability, and continuous improvement in delivering safe, high-quality care. By adhering to this structured approach, the Trust aims to foster collaborative discussions, facilitate in-depth learning from incidents, and implement targeted, impactful improvements to prevent future occurrences. Staff active participation and commitment to this process are invaluable as we strive to enhance our incident investigation practices and create a safer environment for our patients.

Purpose and Objectives

The PSII Feedback Meeting serves as a pivotal platform to:

Purpose:

- Discuss the detailed findings and recommendations from the PSII report.
- Determine and agree on appropriate, data-driven actions for improvement.
- Create a continuous learning and improvement culture within the clinical directorate.
- Integrate key lessons learned into existing policies, procedures, and protocols.
- Develop a SMART and comprehensive action plan that will serve as a roadmap for implementing sustainable changes to enhance patient safety and the quality of care.

Objectives:

- Thoroughly review and validate the investigation report's findings and recommendations.
- Collaboratively analyse the identified systems issues, care management problems, trust-wide factors, and human errors.
- Explore contributing factors, and systemic/organisational issues related to the incident.
- Evaluate the adequacy of existing policies, procedures, and protocols to prevent similar incidents.
- Ensure the investigation process identifies potential gaps or deviations from established best practices.
- Pinpoint opportunities for improvement in processes, training, communication, and other areas to strengthen patient safety.
- Develop a comprehensive, data-driven action plan with clear responsibilities, timelines, and measurable outcomes.

Confidentiality and Anonymity

All discussions during the post-investigation review meeting will be treated with the utmost confidentiality. Participants are expected to maintain strict confidentiality and non-attribution regarding the details of the incident and the identities of the individuals involved. The focus should be on understanding and improving the systems, not assigning blame.

Meeting Guidelines

During the meeting, participants are required to maintain a high level of professionalism, treating all attendees with respect and courtesy, and refraining from derogatory or offensive language. Individuals are expected to approach the meeting with an open mind, remain receptive to diverse perspectives, and avoid defensiveness. The chairperson should actively encourage participation from all team members, fostering a constructive and solution-oriented atmosphere for the feedback discussion. They should also ensure that the meeting stays focused on the key objectives and that all voices are heard.

Quoracy and Attendance

It is essential that key stakeholders attend the Patient Safety Incident Investigation Feedback Meeting to ensure quoracy and effective decision-making.

The following individuals should be present, but not be limited to:

- Directorate Management Team (to be agreed locally if not already in place)
- Clinical Directors or Associate Clinical Directors (ideally one should be in attendance to co-chair the meeting).
- Borough Lead Nurses
- Consultant Responsible for Patient Care
- Directorate Governance Leads/Coordinators
- Patient Safety Lead Reviewer
- Investigation Co-reviewer/s
- Staff identified and agreed by the Patient Safety Lead Reviewer as crucial to the discussion.
- General Managers for directorates

The Patient Safety Lead Reviewer should work closely with the Governance & Risk Assistant to secure the attendance of key individuals necessary for the meeting, ensuring their availability from the outset of the investigation process.

Agenda and Meeting Structure

The agenda for the feedback review meeting shall include, but not be limited to, the following key elements:

- Welcome and introductions.
- Comprehensive presentation of the investigation report by the Patient Safety Investigator/Reviewer
- Detailed discussion of the report's findings, including themes, system factors, and contributing factors
- Open floor for questions, comments, and clarifications from attendees

- Identification of key lessons learned from the incident and recognition of good practices.
- In-depth analysis of existing processes, policies, and protocols to identify areas for improvement.
- Collaborative development of potential actions and recommendations to address gaps in care or issues raised.
- Allocation of clear responsibilities, realistic timelines, and measurable outcomes for the proposed actions
- Next steps, including follow-up actions and progress monitoring.

The chairperson should ensure that the meeting maintains a structured, yet flexible, approach to allow for meaningful dialogue and the exploration of all relevant aspects of the incident.

Timeliness and Meeting Arrangement

The post-investigation feedback meeting should be scheduled in a timely manner to ensure prompt feedback and resolution. Ideally, the meeting should be arranged as follows:

- Once the incident investigation is allocated to the Patient Safety Lead Reviewer (PSLR), the post-investigation meeting will be scheduled by the Governance & Risk Assistant in collaboration with the Directorate Governance Team. The date and time should be agreed at the start of the investigation, taking into consideration the report completion due date.
- The (PSLR), should work closely with the Governance & Risk Assistant to secure the attendance of the required key stakeholders, ensuring their availability from the onset.
- The meeting should be scheduled within a reasonable timeframe, considering the complexity and urgency of the incident. However, it is important to balance timeliness with the need for thorough investigation and preparation.

Follow-up and Implementation of Action Plans

- The clinical directorate will be responsible for implementing the comprehensive action plan and monitoring its progress.
- Regular updates on the implementation and any challenges encountered should be provided to the Governance & Risk Team, who may offer guidance or support as needed.
- Directorate Action Plan overall completion rates will be monitored at the monthly Governance and Risk Network Meeting and Quality Assurance Committee.
- The Directorate Governance teams will be expected to provide periodic progress reports/updates on the status and completion rate of their action plan at the Patient Safety Forum or Patient Safety Committee Meeting.
- The Governance & Risk Team will provide oversight and assistance to ensure the timely and effective implementation of the action plan.

Continuous Improvement and Organisational Learning

To foster a culture of continuous improvement, the organisation will:

- Conduct periodic reviews of the post-incident feedback and action planning process to identify opportunities for enhancement.
- Analyse trends and patterns across incident reviews to uncover systemic issues and develop organisation-wide improvement strategies.
- Share learnings and best practices from the post-incident feedback meetings across the organisation to promote cross-departmental collaboration and knowledge-sharing.
- Incorporate the insights and outcomes from the feedback meetings into the organisation's quality improvement initiatives and strategic planning.
- Recognise and celebrate successful implementation of action plans and the positive impact on patient safety and care quality.

By embracing this comprehensive approach, our organisation will strengthen its commitment to patient safety, enhance the effectiveness of our incident investigation and feedback processes, and drive sustainable improvements that benefit our patients, staff, and the broader healthcare community.

Appendix: I

Standard Operating Procedure for Conducting Thematic & Cluster Reviews

Introduction

The Trust utilises various strategies and Learning Responses to analyse and improve patient care, two of which are thematic reviews and cluster reviews. These methodologies play a crucial role in identifying patterns, underlying causes, and potential improvements in healthcare processes, though they differ in their focus, scope, and application. While thematic reviews drive broader, systemic improvements, cluster reviews address more immediate, localised concerns.

Definitions

Thematic Reviews: Addressing Systemic Challenges

Thematic reviews take a broad, strategic approach to identifying and addressing widespread issues across the NHS. By examining a range of incidents, practices, and outcomes related to a particular theme, these reviews provide valuable insights that can inform policy changes, training programmes, and systemic reforms. The goal is to enhance patient safety and care quality on an organisational level, tackling challenges that span multiple settings and services.

Cluster Reviews: Targeted Improvements

In contrast, Cluster reviews focus on more targeted, situational concerns. These reviews examine cases, incidents, or outcomes that are grouped within a specific department, service area, or patient demographic. This approach is used when there is a concentration of similar issues, suggesting that localised factors may be influencing patient outcomes. Cluster reviews aim to identify and address specific operational or clinical practices that require adjustment, in order to mitigate immediate risks within a defined scope.

Purpose

- The purpose of this Standard Operating Procedure (SOP) is to provide a structured approach for conducting Thematic and Cluster reviews within the Trust. This SOP outlines the key steps and responsibilities involved in planning, executing, and reporting on thematic reviews in the Trust.
- Thematic/Cluster reviews may be commissioned by the Executive Team, Medical Director, the Chief Nurse, the Associate Director of Governance and Risk, or at the Sign-off Panel, based on factors such as trends or patterns observed in incident reports, complaints, or other data sources, recommendations from previous reviews or investigations, or concerns raised by staff, service users, or external stakeholders.

Methodology and Process:

Utilise the following stages to conduct a Thematic Review⁴⁵.

- Identify the individual (reviews i.e. completed investigations/cases) which will be included in the thematic review.
- Describe the safety system via process mapping/narrative in which the incidents occurred i.e. what preventative safety measures were in place for each incident? Identify what safety systems worked well and which did not.
- Use Codes to classify the contributory factors identified either deductively or inductively (see below).
- Use Narrative Analysis inclusive, where appropriate, of the descriptors of the incident to identify the causative, contributory and preventative factors identified across the triangulated information obtained.
- Identify Safety Recommendations based on 'forcing' the system and not focused on individual person's being responsible.
- Decide whether a deductive or inductive approach best suits your needs.
- Deductive thematic analysis involves analysing the data according to pre-determined themes and categories. It is driven by your theoretical or analytical interest. It may provide a more detailed analysis of some aspects of the data than inductive thematic analysis that generates themes and categories directly from the data, but overall tends to produce a poorer description of the data. In the context of analysing patient safety data sources, a deductive thematic analysis might include a review of specific aspects/standards of care. Or it could be framed using a systems-based framework like Systems Engineering Initiative for Patient Safety (SEIPS) or a tool like the Human Factors Analysis and Classification System (HFACS), with data sorted into the different dimensions of these frameworks.
- Inductive thematic analysis involves coding qualitative data into clusters of similar entities or conceptual categories to identify consistent patterns and themes. An inductive approach involves deriving meaning and creating themes from data with fewer preconceptions than in a deductive thematic review.
- Use Multiple measures of safety to provide insights into Themed Reviews. Including; using observations (i.e. what is seen and heard should be considered at just as important as hard data).
- Seek evidence that challenges the initial review hypothesis.
- Identify 'Safety Clutter' i.e. stages in the safety system that are relied on 'but not actually contributing to overall safety.' (Machen, 2023)
- Remember, early assumptions can bias the Thematic Review findings.
- Conclusions should not be made too early in the review.
- The Thematic Review author must remain open to what the data is revealing.

⁴ <https://www.england.nhs.uk/wp-content/uploads/2022/08/B1465-Top-tips-for-thematic-reviews-v1-FINAL.pdf>

⁵ <https://bmjopenquality.bmj.com/content/bmjopen/12/2/e002020.full.pdf>

- The questions the Thematic Review is set to answer/respond to should be set in an initial Terms of Reference with a clearly defined scope agreed at the beginning of the Thematic Review. By starting with a clear set of questions the thematic review will have clear Terms of Reference set together with an associated scope to inform the review.
- Consideration should be given to what factors contributed to this incident or safety theme. From a deductive perspective, use either the SEIPs Framework or Yorkshire Contributory Factors Framework to identify relevant factors.
- Pay attention to those cluster factors which reveal themselves during the course of the factors identification exercise. This will constitute your Inductive approach where clusters of consistent themes are then identified for further analysis based on how their commonalities and differences within each contributory factor affected each case.(Machen, 2023)
- Always include the views and multiple perspectives of others in the review. This will assist in making the Thematic Review findings less subjective and introduce innovative ideas you might not have considered earlier.
- Consider Themed Reviews from other organisations' and previous internal approaches to thematic reviews.

Recap:

Once the above considerations have been made the process for conducting the Thematic Review should follow the following 5 stages.

- Identify the individual (reviews i.e completed investigations/cases) which will be included in the Thematic review.
- Describe the safety system in which the incident occurred.
- Include the classification of the Contributory Factors identified in the index cases Using either the SEIPS or the Yorkshire Contributory Factors Frameworks.
- Provide a narrative analysis of how these factors interplayed and together contributed to the safety outcome.
- Identify Safety Recommendations based on the Thematic Review with a focus on making these recommendations 'systems' focussed rather than 'individual person' focussed.

Roles and Responsibilities:

Incident Team

- Maintain oversight of the thematic/cluster review process
- Ensure the investigation/review is conducted within specified timeframes
- Manage the governance of the process and reporting
- Log the thematic/cluster review on Inphase and the Live MS Teams Tracker to maintain oversight
- The Associate Director of Risk & Governance will agree the terms of reference for the reviews

Patient Safety Lead Reviewer

- Lead the day-to-day conduct of the thematic/Cluster review
- Draft the report, investigate, and gather and analyse data
- Take ownership of the report

Co-Reviewer(s)

- Clinicians appointed by the directorate to work alongside the Patient Safety Lead Reviewer
- Contribute expertise and perspectives to the review

Reporting and Approval

- The Patient Safety Lead Reviewer, supported by Co-Reviewers, will compile a report on the thematic/cluster review findings using the agreed template and format.
- Utilise the Systems Engineering Initiative for Patient Safety (SEIPS) framework to analyse gathered data and information. The SEIPS framework, a systems-based approach with embedded human factors principles, will be used to analyse the data and information gathered during thematic and cluster reviews.
- This systems-oriented analysis allows the review team to identify the range of contributory factors leading to the patient safety issues or themes being investigated, beyond just individual human errors.
- Present the draft review at the Sign-Off Panel for deliberation and Trust approval.
- Present the completed thematic review at the Patient Safety Forum and Patient Safety & Learning Committee for discussion and sharing of the learning.

Continuous Improvement

- Conduct a post-implementation review to assess the effectiveness of the actions taken in response to the thematic review
- Document and share lessons learned and best practices from the thematic review process across the organisation to inform future reviews
- Review and update the SOP periodically to ensure it remains fit for purpose and aligned with the Trust's quality improvement priorities.

Post Thematic Review Feedback Meeting & Action Planning & Implementation

- A feedback/post-thematic review meeting will be conducted with the relevant directorates and stakeholders to share the findings of the review, ensure factual accuracy, and agree on the actions and recommendations.
- The action plan will assign clear responsibilities, timelines, and measures of success for each recommendation.

- The actions from the review will be managed and owned by the relevant Clinical Directors and Management Team, and their progress will be monitored at the Patient Safety & Learning Forum on a monthly/bi-monthly basis.
- The Clinical Directors and Management Team will present the progress on actions and their viability at the Patient Safety & Learning Forum.

Examples of Thematic Reviews conducted for reference and learning

- **Safe and Wellbeing Reviews (SWRs):** The NHS England commissioned a national review to check the safety and wellbeing of all people with a learning disability and autistic people who are being cared for in a mental health inpatient setting⁶.
- Thematic Review of Homicides Involving People Known to Services at Sussex Partnership NHS Foundation Trust⁷.
- Thematic Review of Care, Education, and Treatment Reviews (CETRs) and Care Programme Approach (CPA) Records⁸.
- **Thematic Reviews of Patient Safety Incidents:** Thematic reviews of patient safety incidents as a tool for systems thinking: a quality improvement report⁹.

⁶ <https://www.england.nhs.uk/long-read/safe-and-wellbeing-reviews-thematic-review-and-lessons-learned/>

⁷ <https://www.sussexpartnership.nhs.uk/about-us/how-our-trust-run/our-thematic-review>

⁸ <https://nhsproviders.org/media/695150/nhse-safe-and-wellbeing-reviews-february-2023.pdf>

⁹ <https://bmjopenquality.bmj.com/content/12/2/e002020>

Appendix J:

Local Incident Review Procedures

Local incidents are low level incidents that have been reported on InPhase that do not meet the criteria for a Patient Safety Incident Investigation review. Locally reviewed incidents are locally resolved within the team/service.

Learning from incidents

All teams/services should review their incidents and discuss them at their local governance forums as part of the learning process.

Review Procedures

1. Local reviews are undertaken at a team level and documented on InPhase.
2. All managers responsible for a team or a department have a InPhase login which enables them to access and view incident reports relating to their area.
3. The InPhase system will send an email notification to the manager's inbox when a member of their staff has submitted a InPhase report.
4. The manager will review incidents with the team, identify any root causes, undertake any necessary remedial action and record these on InPhase as part of the signing off process.
5. Where serious issues are identified, immediate escalation to relevant trust managers should take place.
6. The manager is responsible for making sure that the staff, patient, and relatives are supported in accordance with the Trust's Being Open Policy

Learning from Incidents

The Trust expects that all teams and directorates will regularly review their incidents and present them at relevant meetings and forum to promote shared learning.

Appendix K:

Protocol for the Coordination of Independent Reviews

1. Introduction

The PSIRF is designed to enhance the quality and effectiveness of local Patient Safety Incident Investigations (PSIIs). It focuses on fostering open, inclusive reviews that contribute to systemic learning and improvement. The framework aims to reduce the reliance on independent PSIIs and public inquiries, except in specific, predefined circumstances. The main objectives of the protocol are to ensure that:

- Independent Investigation Panels are properly supported in their role
- Trust staff receive appropriate support and advice
- Good communication takes place between all parties
- Recommendations are implemented in a timely and effective manner
- Risk to the Trust's reputation is minimised

The protocol is based on current Trust Incident Reporting and Management Policy. This protocol will be subject to regular review under the direction of the Quality Committee.

2. Responsibilities

- **Chief Medical Officer:** The Chief Medical Officer holds the primary responsibility for the strategic oversight of all Patient Safety Incident Reviews. This includes ensuring alignment with the Trust's overarching patient safety priorities and strategies. The CMO's role is crucial in maintaining patient safety as a central focus at the board level and ensuring compliance with the Patient Safety Incident Response Framework (PSIRF).
- **Associate Director of Governance & Risk Management:** The Associate Director of Governance & Risk Management is tasked with the primary coordination of independent Patient Safety Incident Investigations (PSIIs). This includes direct liaison with the Integrated Care Board delegates during the commissioning process of an independent PSII. The Associate Director is responsible for ensuring that the process complies with established standards and PSIRF guidelines, maintaining the integrity and efficacy of the reviews.
- **Head of Incident Management and Incident Coordinators:** In support of the Associate Director, the Head of Incident Management, along with the Incident Coordinators, will manage the operational aspects of the reviews. Their responsibilities encompass handling the day-to-day logistics, facilitating communication among all involved parties, and ensuring timely collection and processing of necessary data and documentation.
- **Role of the Patient Safety and Learning Committee:** The Quality Committee and the Patient Safety Committee collectively oversee the management and review of Patient Safety Investigations. The Quality Committee is responsible for ensuring that each incident leads to substantial learning and the implementation of improved practices. This includes reviewing and approving action plans that arise from investigation findings and monitoring their effective implementation.

Concurrently, the Patient Safety Committee plays a pivotal role in receiving and scrutinising reports from independent reviews. It provides summary reports and critical analyses to the Trust Board. This dual-layered oversight ensures that the Trust Board is well-informed about

the outcomes of reviews and that recommendations are practical, actionable, and effectively implemented within the Trust's operations.

3. Criteria for Independent PSIs and Special Cases Including Homicides:

- Cases where the Trust lacks the capacity for an objective investigation due to its size or potential bias.
- Incidents involving multiple agencies where no single entity is the clear lead.
- Situations where significant systemic learning opportunities exist for the wider healthcare system.
- Mental health-related homicides, particularly when the perpetrator has been under the care of specialist mental health services within six months prior to the event.
- Cases necessitating compliance with Article 2 of the European Convention on Human Rights, such as when state agents may be responsible for a death.
- Independent reviews should be completed within 6 months of them being commissioned.

4. Commissioning the investigation

The decision to commission an independent investigation by NHS London / East of England will normally be taken after receipt of the Trust's internal SI investigation report (and in the case of homicides, after the conclusion of criminal proceedings).

NHS London / East of England will consider the quality of the Trust's internal investigation when determining the scope and process for the independent investigation.

5. Trust internal/Local Reviews during External Independent PSIs:

- While an External Independent PSI is ongoing, the Trust should conduct its own internal investigation (PSI) to ensure continuous learning and to address immediate concerns. This parallel investigation allows for quicker implementation of necessary changes and provides support to the families involved. The local investigation should be designed to complement the broader independent investigation without overlapping or interfering with its process.

6. Support and communication systems

At the outset of the Trust's internal investigation, and on its conclusion, staff should be informed of the possibility of an independent investigation being commissioned, and given information to describe the process for independent reviews.

When the Trust is notified that an independent investigation is being commissioned, the Associate Director of Governance & Risk Management will inform all relevant staff/managers.

The Associate Director of Governance & Risk Management and the relevant Borough/Service & Clinical Director will discuss the support to be put in place for staff, including the need for specialist external advice. Advice will be taken from the Associate Director of Legal Affairs.

The exact nature of support to be put in place will vary according to the nature and scope of the independent investigation, and the circumstances of the particular incident. It may include some of the following:

- A briefing meeting at the outset of the investigation
- Provision of written information outlining the process

- Support in writing of recollection of events and at interviews
- Access to local managers/professional leads/executive directors
- Access to unions and professional bodies
- Access to the Employee Assistance Programme and occupational health services
- A meeting prior to publication of the report

The independent investigation team have responsibility for contacting the perpetrator, their family and the victim's family and involving them throughout their inquiry.

The progress of all independent reviews will be monitored by the Quality Committee and Trust Board on a monthly basis.

The Associate Director of Governance & Risk Management will keep all relevant parties informed of progress and developments throughout the duration of the process.

7. Initiating, conducting and supporting the investigation

At the outset of the investigation, NHS London / East of England will arrange a meeting with all stakeholders to agree timescales, ground rules, sharing of information and terms of reference.

The Associate Director of Governance & Risk Management will be the Trust's lead contact for the investigation manager, and will ensure that all requests for documentation, meetings and other evidence is supplied in a timely manner.

The investigation manager will be requested to send any correspondence to individual staff (i.e. requests for interviews) through the Associate Director of Governance & Risk Management, so that appropriate support can be put in place for staff.

8. Receipt of the draft report

The Trust will be provided with a copy of the draft report and asked to respond to matters of factual accuracy.

If there are any individual members of staff that are criticised in the report, they will be given warning letters and have the opportunity to respond to the investigation panel. As stated above, these letters should be sent via the Associate Director of Governance, who will ensure that they are communicated to the member of staff in an appropriate way (letters will be delivered in a sealed envelope). A meeting will normally be held with the member of staff to support them during this stage of the process.

The Trust will receive a final draft and will be requested to prepare an action plan in response to recommendations made (which are relevant to the Trust). This will be led by the Associate Director of Governance & Risk Management, in conjunction with the Chief Executive, Director of Nursing, Medical Director, Borough/Service and Clinical Director, and any other relevant staff.

The Trust's response will be approved by the Chief Medical Officer.

The final draft report and action plan will be submitted to the Quality Committee and SI Committee, and communicated to all members of staff interviewed during the investigation.

The role of the Quality Committee is a forum to highlight themes and trends within all SI reports, and a means of ensuring the Trust has an overview of those issues and that work is being done to address them, and to share and disseminate learning across the Trust. The role of the SI Committee is to receive independent investigation reports on behalf of the Trust Board.

The action plan will be incorporated into the Trust's register of action plans arising from independent reviews, which is maintained by the Incident Coordinator.

9. Publication

NHS London / East of England will determine how the report will be published. This is done by a grading system, and could include one or more of the following:

- Public launch event
- Press release
- Noted at NHS London / East of England Board meeting
- Placed on NHS London / East of England website

The Trust's Associate Director of Communications is responsible for developing and implementing a media strategy for each independent inquiry, including informing all relevant parties. This will normally be done in conjunction with NHS London / East of England, commissioners and other partners.

The Director of Governance is responsible for informing Monitor, the Care Quality Commission and other relevant agencies

The independent investigation report will be submitted to the Trust Board following its publication.

10. Implementing the action plan and monitoring implementation

The responsibility for monitoring the implementation of all action points lies with the Quality Committee.

The SI Committee will be provided with reports in order for it to scrutinise progress on behalf of the Trust Board.

11. Signing off the completed action plan

The completed action plan will be signed off by the Quality Committee and reported to the Patient Safety and Learning Committee.

12. Archiving

All documentation relating to independent reviews must be safely stored in order to comply with record keeping and information governance standards.

Electronic versions of all reports and action plans (and other documentation) should be linked to the relevant incident report on InPhase, with a backup stored in the Governance & Risk Management Department K drive.

Appendix L

Being Open Policy

The National Patient Safety Agency (NPSA) issued a [Safer Practice Notice Being Open When Patients Are Harmed September 2005](#) requiring all NHS Trusts in England to develop a [Being Open Policy](#) by June 2006, the Trust responded by developing a Statement in Support of Being Open March 2006. This policy replaces the Trust's Statement in Support of Being Open.

Being open simply means apologising and explaining what happened to service users and/or their carers who have been involved in a patient safety incident. Apologising and explaining what has happened does not in itself constitute an admission of liability.

It also refers to the open and timely reporting of all safety incidents including near misses (no-harm incidents).

More specifically the being open process refers to a systematic consistent approach to handling the communications with service users and/or carers after a patient safety incident. Generally this involves attempting to schedule a series of meetings to provide a sincere apology for the harm experienced by the service user, and to provide facts about exactly what happened and if possible why it happened. These communications also need to extend to detailing any actions to be taken by the organisation to minimise likelihood of recurrence and the outcome of these actions.

This open effective communication with service users and carers is central to the process of identifying and dealing with care issues. Evidence suggests that in taking this approach NHS organisations can mitigate the trauma suffered by service users and potentially reduce complaints and litigation. Being open also enables service/user and carer perspectives, and concerns to inform the direction and scope of any post incident investigation/review thereby assisting in the process of identifying, mitigating and where possible eliminating the root causes associated with a specific safety incidents.

In some cases harm to service user/service users may occur independent of any act or omission by healthcare staff or services. In the case of severe self-harming or suicide attempts these acts can sometimes be neither predictable nor preventable. However even in such cases the key principles of 'being open' can still be applied.

Following completion of Patient Safety Incident Investigation reviews, the investigators or locality managers will offer to meet with the patient, carers/family where appropriate to provide feedback on the findings of the review.

All actions carried out as part of the Being Open process should be documented and also incorporated into the incident report, 72Hour Report and the Patient Safety Incident Investigation Report.

Appendix M

Duty of Candour Policy

Introduction

The statutory duty of candour was introduced in England in 2014 in response to the Francis Inquiry into the Mid Staffordshire NHS Foundation Trust. The inquiry highlighted the need for healthcare providers to be open and transparent when things go wrong with patient care. The duty requires all health and social care providers registered with the Care Quality Commission (CQC) to be open and honest with service users when certain types of incidents occur that result in harm.

Purpose

This policy outlines the Trust's commitment to being open and transparent when things go wrong with a patient's care or treatment, in line with the statutory Duty of Candour. It details the responsibilities and processes for ensuring the Duty of Candour is upheld across the organisation.

Scope

This policy applies to all staff employed by the Trust, including permanent, temporary and agency workers. It covers the Duty of Candour requirements for all incidents that result in moderate or severe harm, or death, to a patient.

Principles

The Trust is committed to the following principles in relation to the Duty of Candour:

- **Openness and transparency:** We will be open and honest with patients, their families and carers when something goes wrong that appears to have caused harm or distress.
- **Patient-centred approach:** The needs and wellbeing of the patient will be the primary consideration when applying the Duty of Candour.
- **Timely communication:** We will initiate the Duty of Candour process within 10 working days of the incident being identified.
- **Compassionate support:** We will provide emotional support and a sincere apology to the patient and/or their family.
- **Continuous learning:** We will use Duty of Candour incidents as opportunities to learn and improve the quality and safety of our services.

Notifiable Incidents and Threshold

The statutory Duty of Candour applies when a "notifiable patient safety incident" has occurred. CQC regulation 20 defines this as an incident that appears to have resulted in:

- The death of the service user, where the death relates directly to the incident.

- An impairment of the sensory, motor or intellectual functions of the service user which has lasted, or is likely to last, for at least 28 days.
- Changes to the structure of the service user's body.
- The service user experiencing, or being at risk of, prolonged pain or prolonged psychological harm.
- The shortening of the service user's life expectancy.

When a notifiable safety incident occurs, the healthcare provider has a legal duty to inform the patient or their family, provide an apology, and follow a specific process of learning response and communication. This aims to promote a culture of honesty and continuous improvement.

Deaths and the Duty of Candour

Not all deaths are automatically notifiable under the Duty of Candour. The key determinant is whether there were any unexpected or unintended elements of the care provided (or not provided) that led to or could have led to harm. If an assessment reveals potential failings in care, such as missed opportunities to intervene or failure to follow protocols, then the incident is likely to be notifiable and trigger the Duty of Candour process. However, if a death occurs despite adherence to best practices, without identifiable gaps in care, it may not be considered a notifiable incident. In such cases, the incident would still be subject to internal review and potential external investigation.

Responsibilities

- The Chief Executive has overall accountability for ensuring the Duty of Candour is upheld.
- The Chief Medical officer and Chief Nurse oversee implementation of this policy.
- All staff have a duty to be open and honest when things go wrong.
- The Incident Review Team, Decision Making Panel and Daily Huddle identify Duty of Candour incidents.
- The patient's Consultant/Clinical Lead or Borough Lead Nurses leads the Duty of Candour discussion with the patient/family.

Duty of Candour Process

- **Incident Identification:** The Incident Review Team/Decision Making Panel/Daily Incident Huddle identify incidents meeting the Duty of Candour threshold.
- **Initial Notification:** Within 10 working days, the patient's Consultant notifies the patient/family that an incident has occurred and the Duty of Candour process is being initiated.
- **Duty of Candour Discussion:** The Consultant has a discussion with the patient/family to provide an apology, explain the incident, and outline the investigation.
- **Ongoing Communication:** where applicable, the Consultant or relevant clinical lead maintains regular contact, providing updates on the investigation and actions.
- **Final Disclosure:** Once the investigation is complete, the PSL meets with the patient/family to share findings and explain any improvements.
- **Support and Follow-up:** The Trust offers emotional support and monitors for ongoing concerns.

Documenting Duty of Candour Apologies

The Trust requires comprehensive documentation of all verbal and written apologies provided under the Duty of Candour.

Documentation Requirements

Staff must:

- Record the dates that verbal and written apologies were provided to the patient/family in the 'Additional Information' section of the corresponding incident report on the Trust's incident management system (InPhase).
- Also document the apologies in the patient's clinical record.
- Where it has not been possible to provide an apology to the patient/family, the reason must be recorded in the 'Additional Information' section of the InPhase incident report.
- A copy of any written apology provided to the patient/family must be attached to the corresponding incident report on InPhase. The written apology must also be filed in the patient's clinical record.

Monitoring and Reporting

Compliance is monitored through incident reporting and governance processes. Duty of Candour incidents and the Trust's response are reported quarterly to the Quality Assurance Committee.

Appendix N:

Safeguarding Adults and Children reporting

When a safeguarding concern or abuse is identified, practitioners must complete the referral to adult or children social care as soon as possible. Do not delay making a referral even if you do not have all the information available.

All ELFT staff must follow the ELFT Safeguarding Children and Adult policy when reporting safeguarding concerns. The Trust's Intranet safeguarding page has links that signpost you to the Local Authority process (referrals should be made to the local authority where the child resides).

Safeguarding Referrals to Adult or Children's Services must be recorded on patient's electronic record.

- When making an adult social care or children social care referral, the practitioner must upload the saved copy of the social care referral to the patient's electronic record.
- If a children services telephone referral is made, it must be followed up with an online referral within 24 hours.
- Children's Services should inform the practitioner of the outcome of referral within 72 hours of the referral being made and this must be documented in the patient's electronic record.
- Adult social care must inform the referrer of the outcome and this must be documented in the patient's electronic record.
- Where communication on referral outcome does not happen the person who made the referral has a duty to follow up.

Subsequent to making a safeguarding referral, an InPhase Incident Report should be generated in following situation:

- All incidents where there is an adult safeguarding implication involving our patients. This includes where our patient may be the source of harm.
- Any safeguarding escalation and professional disagreement
- Any significant event such as safeguarding adult and children concerns where complexity and high risk is indicated i.e cases of Fabricated and Induced illness, severe case of neglect and non-engagement
- Cases where trio of vulnerability is present
- CDOP notification for any child open to ELFT
- When a Child Protection Referral has been made,
- When a child goes missing,
- When a MARAC Referral is completed.
- Notification of Rapid Review for child open to ELFT
- Domestic abuse and harmful practice concerns
- All concerns radicalisation and extremism, including prevent referrals
- FGM referrals
- Forced marriage

This is not an exhaustive list

Any significant events listed above must be recorded on the RIO's alert triangle or patient's electronic record alert/flag.

Records should be clear, concise and reflect the Trust Clinical Record policy.

Safeguarding adult or children concerns should be routinely discussed as part of supervision and managerial or case management arrangements for all practitioners. Agreed action plans from the above should be recorded on patient's electronic record. Children who are subject to a Child Protection Plan, Child In Need plan and Children in Care must be discussed in the weekly MDT.

On occasion staff may be approached by a solicitor for information or be requested to provide a statement for court proceedings. In this event staff should seek advice and support from the Safeguarding Team, Named Doctor for Safeguarding and the Trust Legal team.

Domestic Abuse, MARACs and Mental Health Services

Staff should be aware of the interrelationship between domestic abuse, safeguarding children and mental health issues. Service users may be victims and/or perpetrators of domestic abuse.

If a service user alleges domestic abuse, checks must always be made if there are children in the household. Completion of a DASH risk assessment with the service user must be attempted following every new allegation of domestic abuse, if safe to do so.

A referral should be made to Children's Social Services if a child lives in the household where domestic abuse is believed to be a factor as this could indicate that a child is in need of support and protection.

Consideration should always be given to the use of the MARAC (Multi Agency Risk Assessment Conference) process alongside a safeguarding referral. Advice can be sought from the ELFT safeguarding team.

PREVENT/ Radicalisation

Prevent is part of the UK's counter-terrorism strategy, CONTEST. Its aim is to stop people becoming terrorists or supporting terrorism. Parents and children/young people are likely to be facing multiple challenges in their life, of which exposure to terrorist-related influences is just one. Safeguarding concerns generally should be dealt with via our procedures for identifying and responding to safeguarding concerns. In addition, where concerns have been highlighted the ELFT Prevent Lead, who is part of the safeguarding team, should also be contacted for specific advice and guidance.

ELFT Safeguarding Team can be contacted when practitioner requires an ad hoc safeguarding advice and guidance.

Safeguarding Children team: elft.safeguardingchildrenteam@nhs.net

Safeguarding Adult London team: elft.safeguardingadults@nhs.net

Safeguarding Adult Board (SAB)/Local Safeguarding Children Partnership (LSCP) requests for SI/PSII reports

1. Request received from SAB/LSCP for a copy of completed PSII report. This request will be made to the Corporate Safeguarding Team via the Named Professional (NP) for Safeguarding in the respective area.
2. The NP will discuss the request with incident team and determine if the request is reasonable and proportionate. If the NP determines that it is not reasonable and proportionate, they will share this decision with their respective Lead Professional (LP) for Safeguarding for their approval ahead of it being communicated to a SAB/LSCP. If NP for Safeguarding is not sure if the request is reasonable and proportionate they will seek the advice of their LP.
3. The NP will notify the respective Directors/Deputy Directors in the operational Directorate of the request received and their determination if the request is reasonable and proportionate.

4. If the NP is of the view that the request for the PSSI is reasonable and proportionate for the purposes of considering whether an SAR/CSPR is required then they will request a copy of the PSII and check with the incident team if there is any third party information in the report that should not be shared/redacted. If there is, request to be made to Information governance team to redact this information.
5. Report will be shared with the SAB/LSCP. Panel members at the SAR/LSCP will be subject a local information sharing agreement.

In terms of screening for Lead Professional's presence on PSII approval panel the following questions should be followed:

1. Was a Named Professional involved in the PSII working panel? If yes, please invite Lead Professional. If no, please consider question 2.
2. Is there reasonable cause for concern about how the ELFT or other agencies
 - worked together to safeguard the individual, and the individual has died or suffered serious harm, and
 - it is suspected that the serious harm or death resulted from abuse or neglect (it does not matter whether the abuse or neglect was known to ELFT). If yes, please invite Lead Professional. If no, please consider question 3.
3. Is there reasonable cause for concern about that neglect or acts of omissions* contributed or caused the incident? If yes, please invite Lead Professional. If no, please consider question 4.
4. Is there reasonable cause for concern that that the individual was experiencing abuse or neglect within the PSII review period? If yes, please invite Lead Professional. If no, please consider question 5.
5. Is there reasonable cause for concern that that the any informal carers (parents, family, friends etc.) were experiencing abuse or neglect from the individual within the PSII review period? If yes, please invite Lead Professional.

If answer to all of the above questions has been no and you think an adult or child safeguarding opinion is still required on the PSII panel, then please contact the Lead Professional to discuss further.

Types of abuse could include:

- Organisational or institutional abuse;
- Neglect or acts of omission;
- Self-neglect (including hoarding and unintentional overdose);
- Physical abuse;
- Domestic abuse;
- Sexual abuse;
- Psychological or emotional abuse;
- Financial or material abuse;
- Economic abuse;
- Cuckooing or mate crime;

- Modern slavery or human trafficking;
- Discriminatory abuse;
- Forced Marriage;
- Honour Based Abuse;
- Contextual safeguarding;
- Radicalisation;
- Abuse through position of trust (LADO and PiPOT concerns).

Neglect and acts of omission could include:

- Failure to provide or allow access to food, shelter, clothing, heating, stimulation and activity, personal or medical care;
- Providing care in a way that the person dislikes;
- Failure to administer medication as prescribed;
- Refusal of access to visitors;
- Not taking account of individuals' cultural, religious or ethnic needs;
- Not taking account of educational, social and recreational needs;
- Ignoring or isolating the person;
- Preventing the person from making their own decisions;
- Preventing access to glasses, hearing aids, dentures, etc.;
- Was not brought to appointment;
- Not meeting the child's education, health, developmental and social needs;
- Failure to ensure privacy and dignity.

Organisational or institutional abuse could include:

- Discouraging visits or the involvement of relatives or friends;
- Run-down or overcrowded establishment;
- Authoritarian management or rigid regimes;
- Lack of leadership and supervision;
- Insufficient staff or high turnover resulting in poor quality. care;
- Abusive and disrespectful attitudes towards people using the service;
- Inappropriate use of restraints;
- Lack of respect for dignity and privacy;
- Failure to manage residents with abusive behaviour;
- Not providing adequate food and drink, or assistance with eating;
- Not offering choice or promoting independence;
- Misuse of medication;
- Failure to provide care with dentures, spectacles or hearing aids;
- Not taking account of individuals' cultural, religious or ethnic needs;
- Failure to respond to abuse appropriately;
- Interference with personal correspondence or communication;
- Failure to respond to complaints.

Appendix O

Process for Handling Data Security Breaches

Introduction

A data security breach is one leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, personal data, transmitted, stored or otherwise processed - GDPR Article 4(12)

Personal data is 'any information relating to an identified or identifiable living individual'. Notifiable breaches to regulatory authorities are those likely to result in a high risk to the rights and freedoms of individuals.

These definitions apply irrespective of the media involved and include loss of electronic media and paper records.

Events / breaches which have a significant impact on the continuity of essential services under the Security of Network Information Systems (NIS) Directive are also reportable in the same way as any other data breach.

Breach reporting is mandatory for all organisations.

2.0 Purpose

This process ensures:

- The management of data security breaches conforms to the processes and procedures set out for managing Patient Safety Incident Investigations across the Trust
- There is a consistent approach to evaluating data security incidents
- All staff know how and to whom they should report and escalate suspected or actual data security breaches
- Early reports of data security breaches are sufficient to decide appropriate escalation, notification and communication to interested parties
- Appropriate action is taken to prevent damage to patients, staff and Trust reputation
- For those meeting the threshold of an investigation, all aspects of a data security breach are fully explored and 'lessons learned' identified, communicated and acted on. This process also applies in principle to 'near misses'.

Initial Reporting of Data Security Breaches

- All suspected breaches should be reported on InPhase as soon as they occur or when they become known.
- Breaches involving loss of ICT services (including loss of mobile phones, Smartcards etc) should be reported in the first instance to the Digital service desk for resolution.
- Individuals should seek the advice of the Data Protection Officer or information governance team prior to completion if clarity or advice is required on the type of incident.

4.0 Managing the Incident

- All confidentiality incidents will be managed in accordance with the high level confidentiality incidents flowchart attached at Appendix N.1.
- When the threshold initially appears met, or if further information is required to enable a decision, the DPO will seek a 48 hour report via the incident team. The DPO will also provide a clear list of questions based on information governance principles. Where there is no doubt the incident meets the severity for external reporting and time is crucial (ie weekends, bank holidays), the DPO or nominated delegate will report directly via the Data Security & Protection Toolkit to comply with the 72 timescale for reporting without waiting for the 48 hour report.
- On receipt of the 48 hour report, the DPO will make the decision regarding the need for a Patient Safety Incident Investigation, seeking the advice of the SIRO or Caldicott Guardian as appropriate.
- The decision will be dependent on the guidance provided by NHS Digital's 'Guidance to the notification of data security & protection incidents'. This establishes whether the confidentiality breach meets the threshold for reporting to the Information Commissioner's Office. This will depend on the adverse effect and likelihood values:
 - The significance of the breach, according to the impact on the individual, graded on a scale of one to five (one being the lowest and five the highest)
 - The likelihood of serious consequences occurring, according to the impact on the individual, graded on a scale of one to five (one being a non-occurrence and five indicating it has occurred)
 - The vulnerability of a group of individuals affected (automatically generating a score of two unless the incident is contained)
- The sensitivity of the information (if it is a special category of data)

4.5 Likelihood of an adverse effect

No.	Likelihood	Description
1	Not occurred	Absolute certainty there can be no adverse effect
2	Not likely or any incident involving vulnerable groups even if no adverse effect	Where there is no evidence to prove no adverse effect has occurred this must be selected
3	Likely	Likely there will be an adverse effect arising from the breach
4	Highly likely	Almost certain that at some point in the future an adverse effect will happen
5	Occurred	Reported occurrence of an adverse effect arising from the breach

4.6 Potential severity of an adverse effect

No.	Effect	Description
1	No adverse effect	Absolute certainty there can be no adverse effect
2	Potentially some minor adverse effect or any incident involving vulnerable groups even if no adverse effect occurred	Where there is no evidence to prove no adverse effect has occurred this must be selected

3	Potentially some adverse effect	Likely there will be some adverse effect arising from the breach
4	Potentially pain and suffering / financial loss	Reported suffering and decline in health, or financial detriment
5	Death / catastrophic event	Death or catastrophic occurrence

4.7 Breach assessment grid

Severity (Impact)	Catastrophic	5	5	10	15 20 25 DHSC & ICO		
	Serious	4	4	8	12 16 20		
	Adverse	3	3	6	9 12 15 ICO		
	Minor	2	2	4	6 8 10		
	No adverse effect	1	1	2	3	4	5
			1	2	3	4	5
			Not Occurred	Not Likely	Likely	Highly Likely	Occurred
			Likelihood that citizens' rights have been affected (harm)				

- Yellow breaches are reportable to the ICO whilst red breaches are reportable to the ICO and the NHS Digital Data Security Centre (the latter within 24 hours).
- Under the following circumstances notification to the Information Commissioner's Office may not be necessary:
 - Encryption – personal data protected by encryption
 - Trusted partner – there is a level of assurance that the recipient will not read / access the data, will comply with instructions to delete / return it, not take any further action with it etc
 - Cancelling the effect of a breach – where we can null the effect of the breach
- When the Trust is aware the threshold is met (i.e. this has been confirmed by the DPO) the breach will be reported via the Data Security & Protection Incident Reporting Tool to the Information Commissioner's Office (ICO) within 72 hours (this is taken to mean as soon as practicable during weekends and bank holidays). The NHS Digital Data Security Centre will also be informed where appropriate. See also 4.3 regarding incidents obviously meeting the threshold where the 72 hour framework is likely to be breached.
- The DPO will advise the SIRO when an incident is reported to the ICO.

- Concurrently the Incidents & Complaints Manager will set the process for investigation in motion following the national framework for managing Patient Safety Incident Investigations.
- The DPO will identify an information governance subject matter expert to support a confidentiality Patient Safety Incident Investigation.
- The DPO will send completed reviews to the ICO
- Completed reviews will be submitted to the Board.
- Lessons learned from data security incidents will be widely disseminated to mitigate against the recurrence of future incidents.

5.0 Communication of a personal data breach to the data subject

- Individuals must be advised when a data security breach occurs that is likely to result in a high risk to their rights and freedoms (ie their expectation to have their information kept safely and securely and used appropriately). This is the responsibility of the Directorate where the incident took place.
 - Individuals must be given:
 - A description of the breach
 - A description of the likely consequences
 - A description of the measures taken / proposed to be taken
 - Contact details of an individual from whom further information can be obtained
 - The Data Protection Officer will advise on a case by case basis when communication is necessary.

Appendix P:

Medical Examiner response to death

Since 2019, all NHS Trusts have had appointed medical examiners (MEs) to scrutinise most deaths in hospitals and some community settings on a non-statutory basis. From April 2024, scrutiny by MEs or a coroner's investigation has become a legal requirement for all deaths, whether they occur in healthcare settings or elsewhere.

This statutory medical examiner system, introduced through the Health and Care Act 2022 and Medical Certificate of Cause of Death Regulations 2024, aims to strengthen safeguards, ensure all deaths are reviewed, and provide bereaved families with more transparency regarding the circumstances surrounding the death.

The statutory ME system aims to improve poor practice, and ensure the right deaths are referred to coroners for further investigation. It provides a robust mechanism for identifying and addressing any concerns about the care provided, enabling organisational learning and enhancing patient safety.

Core Functions:

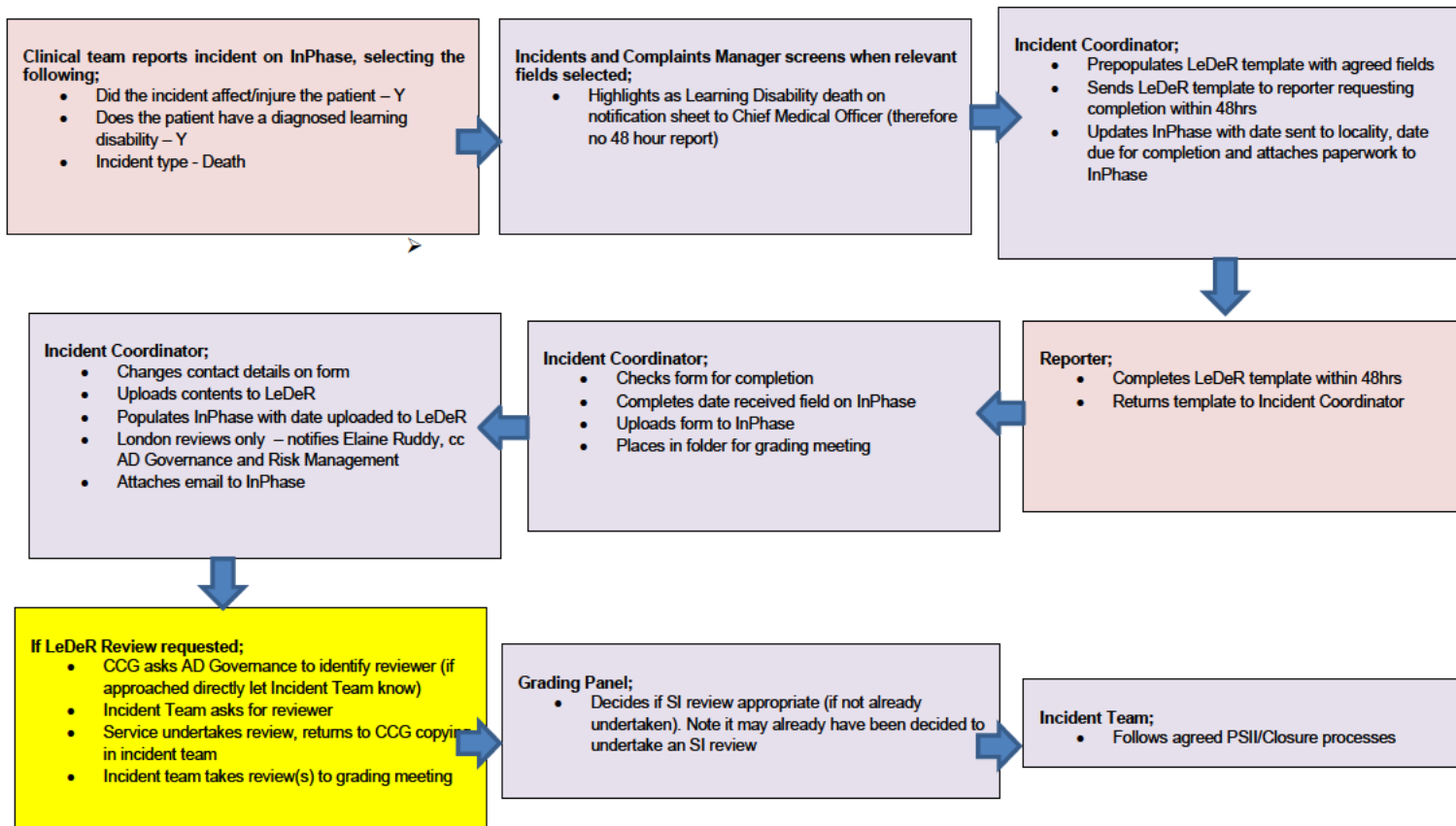
- Review medical records and discuss with the certifying doctor to determine the proposed cause of death
- Agree on the accuracy of the medical certificate of cause of death with the certifying doctor
- Offer a conversation to the bereaved, providing an opportunity to raise questions or concerns with a senior doctor not involved in the deceased's care
- Scrutinise all deaths and request a review if concerns are identified, either from the initial report, family, or services
- Notify the organisation/Trust if a review is required
- Act as a medical adviser to the local coroner on deaths that may require a coroner's investigation.
- MEs may delegate certain duties, such as speaking with bereaved families, to medical examiner officers under their supervision.

ELFT Linked Medical Examiners

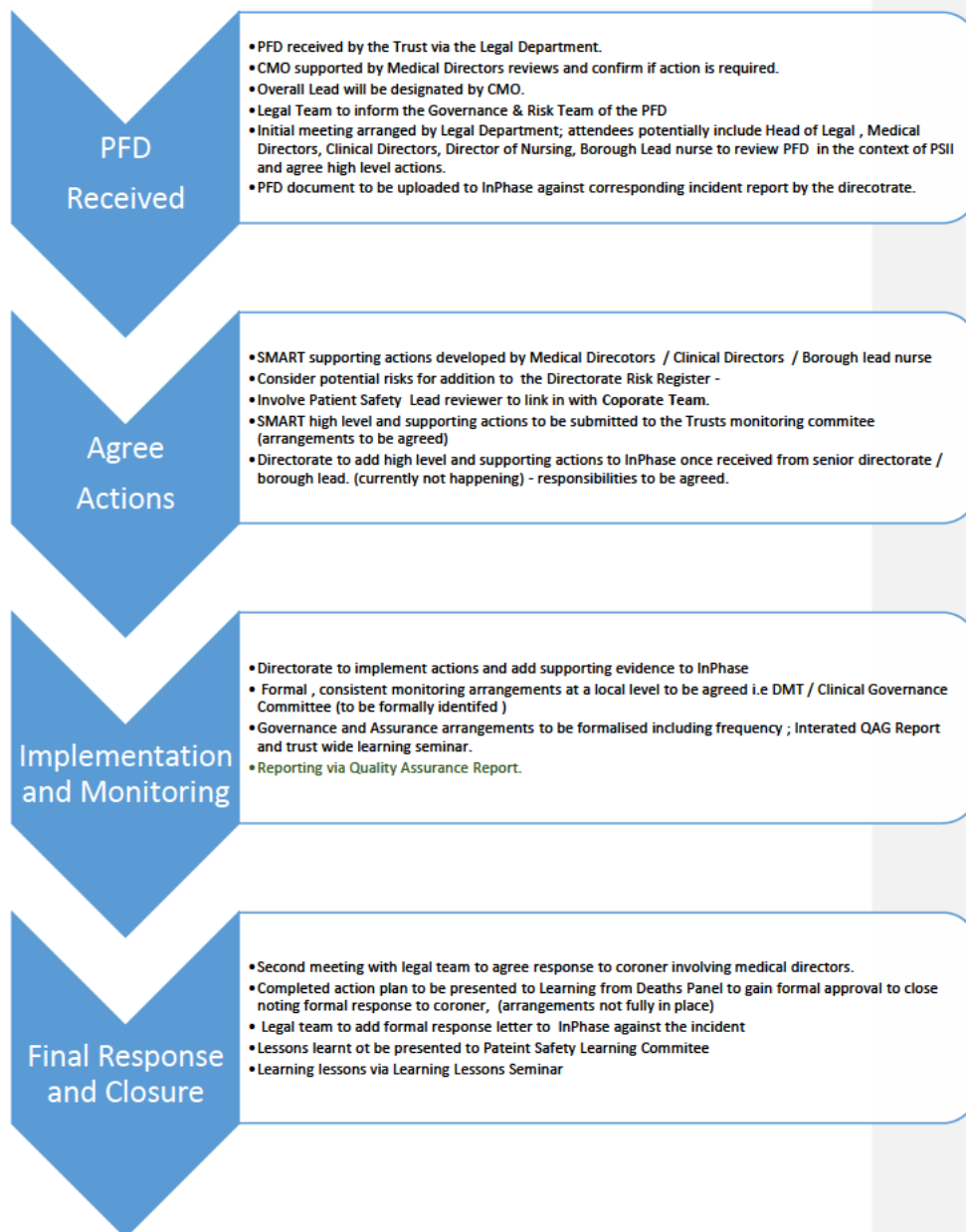
Each organisation/Trust will have access to one or more MEs. For ELFT, the linked ME services are:

- Bart's Health ME Service (covering: City of London, Tower Hamlets, Newham, and Waltham Forest): bartshealth.bhtmedicalexaminerservice@nhs.net
- Homerton ME Service (covering City & Hackney): Huh-tr.medicalexaminer@nhs.net
- Eastern Region MEs (covering Luton and Bedfordshire): ldhmeo@ldh.nhs.uk, mkmemo@mkuh.nhs.uk

Appendix Q. LeDeR Flowchart



Appendix R : Prevention of Future Deaths (PFD) Process



Appendix S: PSIRF Overview of Decision Making and Learning Response Tools

Commented [OF1]: Can we consider taking this out for now and update later as there has been updates to our process.

Report Type	Forum Identified	Lead	Guidance	Time-frame	Purpose	Examples	Methodology & Evidence	Quality Assurance (QA)	Discussion, Decision & Sign Off
72 hour	Daily Incident Review Huddle	Team/ Operational Lead/Ward Manager	Embedded within the template, Support from patient safety lead reviewer	72 hrs	A tool to swiftly gather initial information following a patient safety incident, enabling the Trust to quickly assess the level of harm, learning opportunities, and immediate next steps. It can be used as a decision making tool, or a learning response. A 72-hour report is also always requested in cases of PSII to provide immediate analysis and assurance around any remedial action and risk reduction.	❖ Anything that may meet the threshold for a PSII e.g. Unexpected deaths where ELFT is the foremost provider of care or service users have been discharged from Trust services within the last 6-8 months. ❖ Medication incidents ❖ Security breaches ❖ Information Governance (IG) breaches ❖ Sexual safety incidents ❖ Incidents likely to result in harm e.g. attempted suicide, slips, trips and falls on Trust premises,	Desktop by a senior manager within the service, with input from their team. Medical Records e.g. RiO Trust policy/process	Patient safety lead reviewer /)	Weekly Decision-Making Panel (DMP)

						violence and aggression (service user and staff).			
After Action Review (AAR)	Directorate; when incident occurs/reporting stage Daily Incident Review Huddle Decision-Making Panel (DMP)	Team/Operational Lead/Ward Manager	Trained facilitator Intranet material; webinar, template, Frequently Asked Questions FAQ document	Ideally within 2 – 8 weeks	A reflective practice tool that is recommended not mandated. It is used to strengthen prompt and collaborative learning from any incidents that present clear opportunities for internal learning and practice improvement where there is potential for teams to introspect and enhance their practices.	_____	Group Discussion { <i>Psychologically Safe</i> }	Quarterly sampling of 10 AARs	_____
Care Review Tool (CRT)	Daily Incident Review Huddle Decision-Making Panel (DMP)	Patient safety lead reviewer	_____	10 working days	CRT can be a decision making tool, a rapid learning response. It provides rapid assessment to ascertain the circumstances and care provided, with a higher level of independence than a 72-hour report, without necessitating a full Patient Safety	❖ A sub-set of unexpected deaths of mental health patients in the community, where the cause of death is likely due to a physical health issue, and where the degree of relationship between the care they received under ELFT and what happened is unclear.	Desktop Clinical input (for additional context or clarification, ensuring a robust and well-informed analysis and understanding 'work as done') Family/carer input _____ Medical Records e.g. RiO	_____	Weekly Decision-Making Panel (DMP)

					Incident Investigation (PSII). The report should provide key observations and recommendations for either immediate action or further investigation, potentially escalating to a PSII. There may be occasions where a 72-hour precedes a CRT.		Trust Policy/Process National Guidance		
Patient Safety Incident Investigation (PSII)	Daily Incident Review Huddle Decision-Making Panel (DMP)	Patient safety lead reviewer Co-reviewer/s	NHSE Patient safety response standards	2 - 5 months ideally and no longer than 6 months	A learning response tool using collaborative approaches, reserved for complex cases requiring detailed analysis, which emphasises recurrent or systemic issues with broad learning potential affecting organisational or policy level changes.	❖ Inpatient self-harm resulting in severe/life changing injuries ❖ Inpatient MH death ❖ Homicide by service user currently or under MH inpatient or MH community services in the last 6 months ❖ Trust acquired pressure ulcer where patient subsequently died. ❖ Serious assault causing significant	Systems Engineering Initiative for Patient Safety [SEIPS]. This involves understanding how five components of the work system (person, tasks, tools and technologies, physical environment, organizational conditions) interact with each other and influence each other. Joint/multi-organisational input where applicable e.g. primary, secondary, tertiary care providers, other organisations as required.	Head of Incidents Associate Director of Risk & Governance	Weekly Sign Off Panel

						injury to service user or staff	Medical Records e.g. RiO Staff interview Trust Policy/Process National Guidance e.g. National Institute for Health and Care Excellence (NICE) guidance Service user/ family/Carer input.		
Cluster Review	Can be proposed from anywhere in the Trust in liaison with Patient safety team / Director level Formally agreed either at PSF or by patient safety specialist/s	Patient safety lead reviewer Co-reviewer/s	_____	1-3 months	A learning response tool initiated when multiple (usually two or three) similar incidents occur within a specific service/locality in a relatively short period e.g. one month. The objective is to identify commonalities, emerging themes, or deviations in service delivery practices, aiming for alignment and improvement.	❖ Pattern of suspected suicide in the community in the same service with common attributes ❖ Pressure ulcer	Desktop Clinical Input _____ Medical Records e.g. RiO Trust Policy/Process National Guidance e.g. NICE guidance, Service user/family/Carer input	Head of Incidents Associate Director of Risk & Governance	Weekly Sign Off Panel
Thematic Review	Executive level	Patient safety lead reviewer Co-reviewer/s	_____	Up to 2-4 months	A learning response tool for extensive analyse involving common features to	❖ Transition in care e.g. Autism services	Systems Engineering Initiative for Patient Safety [SEIPS]	Head of Incidents	Weekly Sign Off Panel

				a number of incidents over a longer period e.g. 5 years. Unlike the cluster review, the theme is already identified e.g. similar location, similar means of harm, similar teams or services. The objective of a thematic review is to enable wider systemic learning from incidents, and to ensure that commonalities between individual incidents and reviews are identified for improvement.		Medical Records e.g. RiO, Staff Interview Trust Policy/Process National Guidance e.g. NICE guidance Service user/family/carer input.	Associate Director of Risk & Governance Director of Nursing	
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