Patient Safety Incident Response Policy

(N-075)

Version Number:	1.2
Author (name & job title)	Colette Conway, Assistant Director of Nursing Kate Baxendale, Deputy Director of Nursing, AHP and Social Work
Executive Lead (name & job title):	Hilary Gledhill, Executive director of Nursing, AHPs and Social Work Professionals
Name of approving body:	EMT
Date full policy approved:	11 September 2023
Date Ratified at Trust Board:	27 September 2023
Next Full Review date:	September 2026

Minor amendments made prior to full review date above (see appended document control sheet for details)	
Date approved by Lead Director:	*Hilary Gledhill - 25 March 2025*
Date EMT as approving body notified for information:	*March 2025*

Policies should be accessed via the Trust intranet to ensure the current version is used

Table of Contents

Glossary of Terms 3
1. Introduction 6
2. Purpose 6
3. Scope 7
4. Roles and Responsibilities (Oversight) 7
5. Our Patient Safety Culture 11
6. Patient Safety Partners 12
7. Addressing Health Inequalities 13
8. Engaging and Involving Patients, Families and Staff Following a Patient Safety Incident 13
8.1. Involving Patients & Families 14
8.2. Involving Staff, Colleagues and Partners 14
9. Patient Safety Incident Response Planning 15
10. Immediate Action to Take Following PSII Being Declared 15
11. Confidentiality 15
12. Resources and training to support patient safety incident response 16
13. Our patient safety incident response plan 16
14. Reviewing our patient safety incident response policy and plan 16
15. Responding to Patient Safety Incidents 17
15.1. Patient Safety Incident Reporting Arrangements 17
15.2. Patient Safety Incident Response Decision-Making 17
16. Homicides by Patients in Receipt of Mental Health Care 18
17. Safeguarding – Children 18
18. Safeguarding – Adult 19
19. Health Care Acquired Infections – MRSA Blood Stream Infections 19
20. Responding to cross-system incidents/issues 20
21. Timeframes for learning responses 20
22. Safety Action Development and Monitoring Improvement 21
23. Safety Improvement Plans 21
24. Complaints and Appeals 21
Appendix 1 - Incident Reporting Flowchart 22
Appendix 2 - Patient Safety Incident Analysis (PSIA) 23
Appendix 3 - Learning From Template 25
Appendix 4 - Patient Safety Incident Investigation (PSII) 26
Appendix 5 - Document Control Sheet 27
Appendix 6 - Equality Impact Assessment (EIA) Toolkit 28

Glossary of Terms

Term/Acronym	Definition
AAR	After Action Review (AAR) is a method of evaluation that is used when the outcomes of an activity or event, have been particularly successful or unsuccessful.
Clinical risk management group (CRMG)	This is a weekly group comprised of a range of senior clinical, operational and corporate leaders across a range of departments and discipline. The group reviews all initial incident reviews and completed Swarm huddles; identifies potential PSII's and escalates to the Director of Nursing/Medical Director and commissions Swarm huddles and mortality reviews.
CQC	Care Quality Commission - independent regulator of health and social care in *England*
Definitions of Harm	Unanticipated, unforeseen accidents (eg, patient injuries, care complications, or death) which are a direct result of the care dispensed rather than the patient's underlying disease
Division	A grouping of multi-disciplinary staff working together to provide care within a certain area.
Duty of Candour	Being open and honest with patients and families when treatment or care goes wrong.
Governance Structures	System that provides a framework for managing organisations
HFACS	Human Factors Analysis and Classification System a user-friendly, cost-effective and evidence-based approach to incident investigation, based on the goal of understanding organisational systems.
HSE	Health and Safety Executive
HSSIB	Health Services Safety Investigations Body
Human Error	A human error is an action or decision which was not intended that has negative consequences or fails to achieve the desired outcome
Inequalities data	Facts and statistics collected relating to health inequalities which are unfair and avoidable differences in health across the population, and between different groups within society.
Initial Incident Review (72 hr. report)	A staff debrief to ascertain rapid gathering of facts and areas of immediate safety actions and learning ensuring that urgent action is taken to address risks. A report is produced.
Integrated Care Board (ICB)	Statutory organisation that brings NHS and care organisations together locally to improve population health and establish shared strategic priorities within the NHS.
Just Culture Approach	The treating of staff involved in a patient safety incident in a consistent, constructive, and fair way.
MHRA	Medicines and Healthcare products Regulatory Agency

MNSI	Maternity and Newborn Safety Investigations
MDT	A Multidisciplinary (MDT) approach supports health and social care teams to learn from patient safety incidents that occurred in the significant past and/ or where it is more difficult to collect staff recollections of events either because of the passage of time or staff availability.
Near Miss	A near miss is defined as an unplanned event that did not result in injury, illness or harm but had the potential to do so. Only a fortunate break in the chain of events prevented an incident from occurring for example an injury or fatality. it is important that near misses are reported and appropriately investigated as the learning may prevent actual harm occurring to future patients, their families or staff.
Never Events	A nationally recognised category of incidents that could cause harm to people that should never happen and can be prevented.
NHSE	National Health Service England
Paradigm Shift	An important change that happens when the usual way of thinking about or doing something is replaced by a new and different way
Principles of Proportionality	The least intrusive response appropriate to the risk presented
PSII	A patient safety incident investigation (PSII) is undertaken when an incident or near-miss indicates significant patient safety risks and potential for new learning. Investigations explore decisions or actions as they relate to the situation. The method is based on the premise that actions or decisions are consequences, not causes, and is guided by the principle that people are well intentioned and strive to do the best they can. The goal is to understand why an action and/or decision was deemed appropriate by those involved at the time.
PSII Buddy Role	This is a role taken on by senior staff in the nursing and quality directorate. The buddy is responsible for ensuring that: • Advice and support is given to investigators/teams with regards the process of their investigations/reviews and the content of their reports • Provide ongoing support to the investigators to ensure that the investigation is progressing well and that the draft report will be completed within the agreed timescales. • Receiving and escalating as appropriate any matters that require an immediate improvement action to be undertaken during the course of the investigation; to ensure the investigators remain on track with the investigation and are not distracted by ensuring immediate improvement actions are undertaken.
RIDDOR	Reporting of Injuries, Diseases and Dangerous Occurrences Regulations
SEIPS	System Engineering Imitative for Patient Safety - a framework for understanding outcomes within complex socio-technical systems.

SOP	Standard Operating Procedures
Stakeholder	People or groups who have an interest in what an organisation does, and who are affected by its decisions and actions.
PSIA using Swarm Huddle methodology	Patient Safety Incident analysis is a review of care incorporating a meeting to explore an incident in a non-punitive way and deliver learning. It is a facilitated discussion on an incident or event to analyse what happened, how it happened and decide what needs to be done immediately to reduce risk. It enables understanding and expectations of all involved and allows for learning to be captured and shared more widely. It is a safe space, invitees only (those involved in incident, agreed by the Division/Patient Safety team). A report is produced to be shared with the patient / family / carer if requested.

1. Introduction

Humber Teaching NHS Foundation Trust is committed to providing high quality, safe services to its patients, service users and staff. The Trust recognises that, on occasions, patient safety incidents or near misses will occur and that it is important to identify causes and to ensure that lessons are learnt to prevent recurrence. Learning from incidents and embedding the learning in clinical practice is a fundamental quality priority for the Trust to ensure services are continually evolving and improving based on feedback from those who use and those who deliver our services.

From the outset of a patient safety incident or a near miss the Trust is committed to supporting and working with those involved to understand what has happened and why, and to understand the impact of this on the patient and/or their family. Responses to patient safety incidents under this policy follow a systems-based approach which o looks at failures in the system rather than individual fault. The Trust will work with staff, the individual and/or their family/carers to identify learning and explore how practice can be changed to maximise safety.

This policy outlines the way in which patient safety incidents or near misses will be managed to ensure immediate actions are taken to ensure patient safety, support for staff and those affected by the incident is provided and learning is embedded across the organisation; with changes to practice and or systems and processes to prevent reoccurrence.

This policy replaces the Trusts Serious Incidents and Significant Events Policy and Procedure (N-031)

2. Purpose

This policy supports the requirements of the Patient Safety Incident Response Framework (PSIRF) and sets out Humber Teaching NHS Foundation Trust's approach to developing and maintaining effective systems and processes for responding to patient safety incidents and issues for the purpose of learning and improving patient safety.

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

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

- Compassionate engagement and involvement of those affected by patient safety incidents
- Application of a range of system-based approaches to learning from patient safety incidents
- Considered and proportionate responses to patient safety incidents and safety issues
- Supportive oversight focused on strengthening response system functioning and improvement.

3. Scope

This policy is specific to patient safety incident responses conducted solely for the purpose of learning and improvement across Humber Teaching NHS Foundation Trust.

This policy applies to all permanent (clinical and non-clinical staff), locum, agency, bank and voluntary staff and students working within the Trust.

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

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

Information from a patient safety response process can be shared with those leading other types of responses, but other processes should not influence the remit of a patient safety incident response.

4. Roles and Responsibilities (Oversight)

Chief Executive and Trust Board
The Chief Executive and the Trust board hold ultimate accountability for ensuring the provision of high quality, safe and effective services within the Trust, ensuring robust systems and processes are in place when serious incidents, serious near misses and or significant events occur. The Chief Executive and Trust board are also accountable for ensuring compliance with the duty of candour and ensuring learning to prevent reoccurrence.

The Trust board will receive a monthly report Integrated Board Report (IBR) in relation to incidents and mortality.

Director of Nursing, Allied Health & Social Care Professionals (DON)
The Director of Nursing (DoN) has responsibility for the strategic implementation and monitoring of this policy and evaluation of organisational learning, holding the responsibility for decision making of declaring Patient Safety Incident Investigations (PSII).

The Director of Nursing and Medical Director and Chief Operating Officer sign off all Patient Safety Incident Investigation reports prior to final release to the patient and or family and submission to the coroner if required.

Medical Director (MD)
The Medical Director (MD)works with the DoN holding joint responsibility for the decision making in relation to the declaration and sign off of Patient Safety Incidents (PSII)

Chief Operating Officer (COO)
The Chief Operating Officer is responsible for ensuring all learning from patient safety incidents is shared via the divisional governance structures and that the learning is embedded across the teams/organisation.
The COO is also responsible for the commissioning of the communication and media handling strategy where required.

Divisional General Managers
The divisional operational lead has responsibility for the operational implementation of this policy across their respective division and will ensure:

- All incidents resulting in harm, an unexpected death, near miss, or never event are reported via Datix. The Datix system is the Trust system for the reporting of all incidents.
- All initial incident reviews requested by the patient safety team are completed and returned within 72 hours of the request being made.
- Agreeing who will make the initial contact with those involved, or their family/carers in complex situations to ensure compliance with the requirements for duty of candour. There are appropriate numbers of people from within the divisions trained in appropriate incident investigation methodology.
- They, or their nominated deputy attend PSIA swarm huddles.
- All PSIA swarm huddle reports are completed in the required timeframe following the meeting and submitted to the patient safety team.
- Confirming the people undertaking the lead for a PSII, are allocated considering the person with the most appropriate skills, alongside allocation on a rota basis from the list of those trained in a system-based approach to incident investigations.
- Staff within their sphere of responsibility are aware when an incident has been reported and a PSII or PSIA using Swarm huddle methodology has been commissioned.
- All staff follow the principles of openness and honesty as outlined within duty of candour Policy.
- Staff are supported following the occurrence of a patient safety incident and have been given or have access to the Navigating difficult events booklet.

Divisional Clinical Leads
The divisional clinical leads have the responsibility for the operational implementation of this policy across their respective division and will ensure:

- They or their nominated deputy attend the PSIA using swarm huddle methodology.
- They or their nominated deputy identify a lead for the PSIA and notify the Patient safety team within 48 hrs. of the need for a PSIA being identified.
- Ensure action plans from the PSIA using swarm huddle methodology and PSII's are developed jointly by staff within the division with budgetary responsibility and an understanding of the wider issues/competing priorities and the investigator of the patient safety incident.
- Reports for PSII's and PSIA's are reviewed and agreed prior to submission to either the Director of Nursing or executive directors, depending on the investigation.
- Ensure reports and learning arising from patient safety investigations is disseminated through the divisions.
- Action plans are monitored on a monthly basis within the division's clinical governance structure to ensure that they are completed in the timescales agreed.
- They or their nominated deputy attend the closing the loop group to present evidence for closure of action plans and discuss ways to ensure embedding of actions such as clinical audit.
- Learning and or changes needed to practice as identified from any patient safety investigation are led from within the division, shared within CRMG and across the Trust.

Deputy Director of Nursing

- Responsible for the review of all incidents reported within Datix, via the daily (Monday-Friday) corporate safety huddle meeting.
- Responsible for the commissioning of initial incident reviews (72-hour reports)
- Responsible for escalating incidents potentially meeting the PSII or PSIA using swarm huddle methodology threshold to the director of nursing and/or the medical director.
- Facilitation of swarm huddle when required.
- Responsible for ensuring all initial review reports are reviewed by CRMG for decisions regarding potential further review.

Assistant Director of Nursing

- Responsible for the review of all incidents reported within Datix, via the daily (Monday-Friday) corporate safety huddle meeting.
- Responsible for the commissioning of initial incident reviews (72-hour reports)
- Responsible for escalating incidents potentially meeting the PSII or PSIA using swarm huddle methodology threshold to the director of nursing and/or the medical director.
- Responsible for ensuring that all external legal processes are in place and for coordinating information/notification to external bodies, e.g., police, CQC, NHSI, local authority to meet the Trusts statutory duties.
- Facilitation of swarm huddle when required.
- Responsible for capturing learning for all patient safety incidents.
- Responsible for theming of all incidents within the Trust to include patient safety incidents, complaints, freedom to speak up, review of deaths by medical examiners, safeguarding reviews and any other investigations.

Quality and Patient Safety team

- Responsible for ensuring all initial review reports are reviewed by CRMG for decisions regarding potential further review through PSII, PSIA or mortality review.
- Meet with PSIA leads to confirm attendance at PSIA / Swarm huddle meeting and set time scales.
- Facilitates the sending out of Duty of Candour letters or condolence letters to all patients, families and carers when an incident requires further investigation.
- Responsible for ensuring that reports meet the required standards and are submitted within the agreed timescales or escalate with reasons for apse in timescales.
- Work collaboratively with the division on the completion of actions arising from patient safety incidents to ensure they are completed within the required timescales.
- Reviewing of actions ready for closing the loop group and identifying areas for further audits/checks to evidence change is embedded in practice.
- Provide advice, support, and training on the new patient safety processes.
- Facilitate the setting up and chairing of PSIA using swarm huddle methodology.
- Ensure all staff attending PSIA meetings have been sent invite and appropriate documentation (as stated in Swarm huddle SOP).
- Circulate completed patient safety incident investigations, IIRs, Swarm huddles to MD/ DON and the Clinical Director and the appropriate Divisional General Manager and Clinical leads and that the report is sent for inclusion on the next CRMG meeting.
- Facilitate the sending of a final letter to patients, carers and families following the completion of the investigation.
- Coordinate and disseminate learning from patient safety incidents events to ensure learning from all investigations are shared with staff corporately and across the divisions.
- Theming of all incidents within the Trust to include patient safety incidents, complaints, freedom to speak up, review of deaths by medical examiners, safeguarding reviews and any other investigations.

Service Managers/Matrons/Team Leaders/Charge Nurses/Ward Managers

- All staff within their sphere of responsibility are aware of the contents of this policy and follow the guidance.
- Staff are fully supported in the reporting of all incidents including those that may be an PSII, near miss or never event.
- Staff involved in the incident should be given a copy of Navigating Difficult Events at Work Trust booklet.
- Staff complete a Datix as soon as possible following any patient safety event.
- Staff complete a datix when they are notified there has been an unexpected death within services.
- Staff complete initial incident reviews within 72 hours of being requested to do so by the patient safety team.
- Staff are open and honest with the person and or their family when a patient safety incident has occurred. Staff should acknowledge and offer a sincere expression of sorrow or regret for the harm that has occurred, explaining the facts, as they understand them at the time of sharing the incident.
- Staff are fully aware of the statutory duty of candour where potential harm has occurred, informing the person and or their family and providing feedback on the outcome of the investigation or review.
- Contact with the family to offer condolences where a patient has died unexpectedly whilst using services.
- The offer of the Trust document 'Help is at Hand' (which is available from the patient safety team) to family members when a relative has unexpectedly died.
- Staff within their sphere of responsibility are aware when an incident has been declared as an PSII or a PSIA using swarm huddle methodology is commissioned from the initial incident report discussed at CRMG.
- Attend the PSII review panel when invited to do so, in order to contribute to the learning and actions arising from the investigation.
- Attend the PSIA swarm huddle when invited to do so in order to contribute to the learning and actions arising from the investigation.
- Ensure staff are released to attend any meetings to participate in investigation or learning for patient safety incidents.
- Receive feedback on the outcome of any patient safety investigation.
- Support for staff during and following a patient safety incident, near miss or never event. Where staff experience particular difficulties associated with a patient safety incident, that referrals are made to the occupational health department in a timely manner in order to support staff or in the case of junior doctors, referrals are made to the medical director.
- Managers revisit the health and wellbeing of individuals or all staff members when there has been more than one PSII or PSIA using swarm huddle methodology in any one area in any quarter or consecutive quarters.
- Staff are supported with writing statements for coroner's court.
- Staff are made aware that they may be called to provide evidence to the coroner's court.
- Ensuring recommendations and actions required following investigation are progressed within the agreed timescale and evidence of change being embedded in practice is available.
- Ensure the evidence to close actions is submitted to the closing the loop group, and attend the group as required to present evidence and discuss monitoring and embedding of actions.
- Ensure learning elicited from patient safety incidents is shared across sphere of responsibility.

Other Trust Staff

- All staff, both clinical and non-clinical, are responsible for raising and escalating concerns regarding any incident which may be reportable as a patient safety incident or near miss to the person in charge of a unit or team.
- All staff have a responsibility to engage fully where required in incident investigations/reviews.
- All staff are required to complete Level 1- patient safety training available on ESR.

5. Our Patient Safety Culture

Humber Teaching NHS Foundation Trust promotes a just culture approach (in line with the NHS Just Culture Guide) to any work planned or underway to improve safety culture. Research into organisational safety has repeatedly found that an open and transparent culture, where colleagues feel able to report incidents and raise concerns without fear of recrimination, is essential to improving safety.

Humber Teaching NHS Foundation Trust encourages and supports incident reporting where any member of staff feels something has happened, or may happen, which has led to, or may lead to, harm to patients (or staff).

Humber Teaching NHS Foundation Trust is committed to these key steps in shifting towards a Safety II culture:

- Don't ask who is responsible, ask what is responsible. Human factors show that people's actions and assessments make sense once we understand critical features of the world in which they work. There are well-known cases in NHS history (and indeed recently, in the case of Countess of Chester Hospital) of individuals who have deliberately set out to cause harm to patients. These are incomprehensible and rightly cause the public anxiety. They represent, however, a minute proportion of the overall care delivered by the NHS and should not set the overall context of how we review poor care.
- Understand the difference between work as imagined and work as takes place. People are too often judged by those who do not understand the work that they do. They do not know the messy detail, they lack technical knowledge, and misunderstand the subtleties of what it is like working in a health system.
- People do not come to work to do a bad job. It is important to understand the importance of restorative vs retributive justice; retributive justice focuses on error and violation of individuals. It suggests that if error or violation has hurt someone then the response should hurt as well. This can provide some comfort to those who have been harmed, as well as to their loved ones. Restorative justice, on the other hand, suggests that if error and violations cause hurt then the response should heal. Restorative justice fosters a dialogue between the individuals and communities involved, rather than a break in relationships through sanction and punishment.
- People are not the problem to control but the solution to harness. Backward accountability means blaming people for past events, 'holding people to account' for what has already happened. This approach doesn't change what has happened and only achieves a sense of anxiety in others. This does not work to improve safety, and what actually happens is that people are motivated to be more careful about reporting and disclosure. Forward accountability changes the question being asked to "what should be done about the problem, and who should be accountable for implementing those changes and assessing whether they are working in future?"

- Supporting second victims and reducing the negative consequences and creating personal and organisational resilience. Second victims are those who have been involved in error or violations where people have been harmed. Strong social and organisational support systems have proven critical to contain the negative consequences of safety incidents. The opportunity to recount the experiences first hand can be healing, if taken seriously and not linked to retribution. The lived experience of second victims represents a treasure trove of data about how safety is made and broken at the very heart of an organisation.
- Improving communication and the development of a mature safety culture, encouraging a positive approach to the reporting and investigation of patient safety incidents.
- Openness in the handling of patient safety incidents and the application of Duty of Candour.
- The NHS Improvement Just Culture guide should be used to determine a fair and consistent course of action towards staff (see appendix).
- Senior leaders across Humber Teaching NHS Foundation Trust are required to proactively embrace this approach.

Humber Teaching NHS Foundation Trust encourages and supports incident reporting where any member of staff feels something may have happened, or may happen, which has led to, or may led to, harm to patients or staff.

Please refer to the Trusts' *Incident management policy* available on the Intranet for more information on how incidents are reported and managed in an open and transparent manner.

Humber Teaching NHS Foundation Trust are also committed to embedding a Patient Safety II inspired approach to learn from everyday work as described in *NHS England Safety culture: learning from best practice guidance (2022).*

Humber Teaching NHS Foundation Trust encourage staff to share and celebrate good practice via the GREATix process where individuals and teams can be nominated by their peers, managers, patients, or other services for work they have undertaken which demonstrates excellence in patient safety, empowerment and engagement with patients and their carers and families which has led to a positive difference for patients and their families/carers.

6. Patient Safety Partners

Humber Teaching NHS Foundation Trust has established roles for patient safety partners in line with the NHSE guidance Framework for involving patients in patient safety . Patient Safety Partners (PSP) will have an important role in supporting our PSIRF providing a patient perspective to developments and innovations to drive continuous improvement.

PSPs will use their lived experience as a patient, carer, family member or a member of the local community to support and advise on activities, policies and procedures that will improve patient safety and help us to deliver high quality care.

PSPs will offer support alongside our patients, families, and carers to influence and improve safety across our range of services. PSPs can be patients, carers, family members or other lay people (including NHS staff from another organisation) and offers great opportunities to share experiences and skills and provide a level of scrutiny. This exciting new role will evolve over time with the main purpose of the role to be the voice for our patients and

community who utilise our services, ensuring patient safety is at the forefront of all that we do.

Our PSPs have been pivotal in the organisations preparation, development and roll out for PSIRF. They have been an integral part of our PSIRF working group and members of our subgroups.

Further information can be found in the *Patient Safety Partner Involvement Policy* available on the Trust Intranet.

7. Addressing Health Inequalities

As a provider of Mental Health, Learning Disabilities, Forensic, Community services, Primary Care and Addictions Humber Teaching NHS Foundation Trust has a key role to play in tackling health inequalities in partnership with our local partner agencies and services. However, most of the fundamental factors driving inequalities in health are beyond the responsibility of the health care system, for example our education system; economic and community development in our most deprived neighbourhoods; employment levels; pay and conditions; and availability and quality of housing.

We will seek to utilise data and learning from investigations to identify actual and potential health inequalities and share with, and make recommendations, to our partner agencies and the Integrated care boards on how to tackle these.

Humber Teaching NHS Foundation Trust as a public authority 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 risk to patients from across the range of protected characteristics. We will work collaboratively with all our staff networks to ensure staff who share an affiliation with a protected characteristics voices on patient safety are heard. The networks include:

- Rainbow Alliance LGBTQ+ network (and Trans Alliance subgroup)
- The Disability Network
- Race Equality Network

Humber Teaching NHS Foundation Trust will work collaboratively with the patient experience and inclusivity agenda and ensure investigations and learning do not overlook these important aspects.

All safety improvements will consider health inequalities and any disproportionate risk to patients with specific characteristics.

Our engagement with patients, families and carers during and following a patient safety investigation will also recognise diverse needs and ensure inclusivity for all.

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

Our Key Principle is being Open and Transparent with all affected by the incident which includes patients, carers, families, and staff.

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

The principles of openness and honesty as outlined in the NHS Being Open guidance and the NHS contractual Duty of Candour will be applied in discussions with those involved. This includes staff, patients, victims and perpetrators and their families and carers. Further information can be found in the Trust's *Duty of Candour Policy and Procedure: Communicating with Patients and/or their Relatives/Carers following a Patient Safety Incident (N-053)*

8.1. Involving Patients & Families

The needs of those affected is the primary concern in a learning response to a patient safety incident. Patients and their families/carers and victims' families will be given the opportunity to be involved and will be supported throughout.

Humber Teaching NHS Foundation Trust recognises the importance of and is committed to involving patients and families following patient safety incidents, engaging them in the investigation process and to fulfil the duty of candour requirements. It is recognised from experience and research that patients and families often provide a unique, or different perspective to the circumstances around patient safety incidents, and/or may have different questions or needs to that of the organisation. This policy therefore reinforces existing guidance relating to the duty of candour and 'being open' and recognises the need to involve patients and families as soon as possible in all stages of any investigation, or improvement planning, unless they express a desire not to be involved.

The patient safety response team will offer to meet with those affected by the incident which will include the patient, their family and/or carers as appropriate. Through the meeting they will be given the opportunity to raise areas for consideration by the response team and will agree how they wish to be involved and supported going forward. A member of the Quality and Patient safety team will be the identified individual, independent from the investigation team and will be offered as a point of contact for the patient/families and or carers' who are affected by the patient safety incident. This will be explained in the initial being open letter or duty of candour letter where known harm has occurred letter sent by the Trust.

More information can be found in our *Patient and Family Engagement Policy* on the Trust Intranet

8.2. Involving Staff, Colleagues and Partners

Similarly, involvement of staff and colleagues (including partner agencies) is of paramount importance when responding to a patient safety incident to ensure a holistic, inclusive, restorative just culture approach from the outset. Again, this reinforces existing guidance such as our incident reporting and management policy, though it is recognised this approach must not be restricted to only those incidents that meet a threshold of harm or predefined categories. We will continue to promote, support and encourage our colleagues and partners to report any incident or near-misses, with a shift in focus to incidents, or groups of incidents, which provide the greatest opportunities for learning and improvement.
Staff that are involved in a patient safety incident that requires any level of investigation are sent a copy of the Trusts *Navigating Difficult events* booklet. Also, managers are asked to ensure this booklet is available to all staff in their teams and also it is available on the Trust Intranet.

9. Patient Safety Incident Response Planning

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

Humber Teaching NHS Foundation Trust welcomes this approach so we can focus our resources on incidents, or groups of incidents that provide the greatest opportunities for learning and improving safety. It is also recognised that our planning needs to account for other sources of feedback and intelligence such as complaints, risks, legal claims, mortality reviews and other forms of direct feedback from staff and patients.

PSIRF guidance specifies the following standards that our plans should reflect:

1. A thorough analysis of relevant organisational data
2. Collaborative stakeholder engagement
3. A clear rationale for the response to each identified patient safety incident type.

Our associated patient safety incident response plan (PSIRP) reflects these standards.

10. Immediate Action to Take Following PSII Being Declared

Agree who will make the initial contact with those involved, or their family/carer(s). Where an individual(s) has been harmed by the actions of a patient, particular thought should be given to who is best placed to contact the victim and/or their family. Those involved should have a single point of contact within the Trust.

The incident response team will offer to meet with those affected by the incident which will include the patient, their family and/or carers as appropriate. Through the meeting they will be given the opportunity to raise areas for consideration by the response team and will agree how they wish to be involved and supported going forward. A member of the Quality and Patient safety team will be the identified individual, independent from the incident response team and will be offered as a point of contact for the patient/families and or carers' who are affected by the patient safety incident. This will be explained in the initial being open letter or duty of candour letter where known harm has occurred letter sent by the Trust.

Where there is police involvement contact must be made with the police and agreement made with them as to who will make the initial contact with the patient their family/carer(s) or in the case of a homicide the perpetrator's family. The legal team in the Trust will lead on any communications with the Police.

See Appendix 3

11. Confidentiality

Patient Safety investigation reports must be shared with key interested bodies including patients and their families. It is recommended that reports are drafted on the basis that they may become public, so issues concerning anonymity and consent for disclosure of personal information are important and should be considered at an early stage in the investigation process.

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

Humber Teaching NHS Foundation Trust is committed to ensuring that we fully embed PSIRF and meet the national training requirements.

An in-depth training needs analysis has been undertaken to ensure organisational compliance with the Patient Safety syllabus and the PSIRF standards. Essential training is:

- All Trust staff are required to complete Level 1 - Essentials for Patient Safety which is available through ESR.
- All Board members and Senior Leads must complete Patient Safety Level 1b delivered.
- All staff involved in undertaking Patient Safety Incident Investigations are required to completed Systems approach to learning from patient safety incidents 2 days course.

The Trust's PSIRP training needs analysis and this policy reflects these standards.

PSIRF recognises that resources and capacity to investigate and learn effectively from patient safety incidents is finite. It is therefore essential that as an organisation we evaluate our capacity and resources to deliver our plan. The PSIRP provides more specific details in relation to this including the number of comprehensive investigations that may be required for single or small groups of incidents that do not fall into one of the broader improvements workstreams/priorities.

Humber Teaching NHS Foundation Trust have governance arrangements in place to ensure patient safety learning responses are not led by Trust staff who were involved in the patient safety event itself.

13. Our patient safety incident response plan

Humber Teaching NHS Foundation Trust's Patient safety incident response plan (PSIRP) sets out how the Trusts intends to respond to patient safety incidents over a period of 12 to 18 months. The plan is not a permanent set of rules that cannot be changed. We will remain flexible and consider the specific circumstances in which each patient safety incident occurred and the needs of those affected, as well as the plan.

Humber Teaching NHS Foundation Trust's PSIRP is based on a thorough analysis of themes and trends from all incidents from 2019-2022 (including low harm, no harm and near misses), complaints and concerns, learning and recommendations from Serious Incidents (conducted under the previous framework), mortality reviews, legal claims and inquests, risks and risk registers and feedback from staff and patients. The priorities identified in the PSIRP will be regularly reviewed against quality governance reports and surveillance to ensure they are responsive to unforeseen or emerging risks.

Humber Teaching NHS Foundation Trust's PSIRP is available on the Trust's Intranet.

14. Reviewing our patient safety incident response policy and plan

Humber Teaching NHS Foundation Trust's patient safety incident response plan is a 'living document' that will be appropriately amended and updated as we use it to respond to patient safety incidents. We will review the plan every 12 to 18 months to ensure our focus remains up to date; with ongoing improvement work our patient safety incident profile is likely to

change. This will also provide an opportunity to re-engage with stakeholders to discuss and agree any changes made in the previous 12 to 18 months.

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

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

15. Responding to Patient Safety Incidents

15.1. Patient Safety Incident Reporting Arrangements

All permanent (clinical and non-clinical staff), locum, agency, bank and voluntary staff and students working within the Trust are responsible for recording and reporting potential or actual patient safety events on the trusts datix system in line with the Trusts *Incident Management policy* (see appendix 1 for Flowchart)

Initial incident reviews (IIR's) will be requested where there is concern about a level of harm identified via Datix which the corporate safety huddle identifies as needing further investigation or information gathering. This may then trigger a request for a further level of investigation.

The initial incident review can provide the opportunity for facilitated discussion, bringing together the people involved in the incident to review the incident. This may include members of the clinical team, admin staff, domestic/support staff, patients, +and families/carers. This process may allow those involved to take immediate actions to mitigate against identified risks and may also provide an opportunity to reflect and identify any learning for the team. This will preclude the need for further investigation and creates the opportunity for real time feedback and actions.

The Initial Incident Review should be undertaken and submitted to the patient safety team within 72 hours. They will then be reviewed at the weekly Clinical risk management group (CRMG) and any further action required identified.

More details can be found in the Trust's PSIRP on the Trusts Intranet.

15.2. Patient Safety Incident Response Decision-Making

Once the initial review is completed (within 72 hours) the patient safety team will ensure that it is circulated to the appropriate senior leaders which will include the director of nursing and medical director for immediate review. All initial reviews will also be added to the agenda for CRMG for further oversight.

There are several events where we must undertake a Patient Safety Incident Investigation or report through national reporting systems as follows:

Incident Type	Incident Response Method
Incidents that meet the Never Events list	Patient safety Incident Investigation
Death of a patient with a learning disability	Refer for LeDeR Consider for additional internal investigation

Incident Type	Incident Response Method
Adult and Children Safeguarding incidents	Refer to the local authority safeguarding lead Consider for internal investigation. Healthcare providers must contribute to any safeguarding investigations as requested by the local authority safeguarding leads ie safeguarding reviews/Domestic Homicide Review/joint targeted inspections
Child deaths	Contribute to joint agency review and child death overview panel. Consider internal investigation.
RIDDOR reportable incidents	Report to HSE and root cause analysis to be undertaken.
Information Governance Breach	Report to the Information Commissioners Office
Homicide committed by a patient in receipt of services or recently discharged.	Report to the Police and the ICS Complete a PSII Co-operate in any external investigation.
Death in Custody	Report to the Police. Undertake internal investigation. Co-operate in any external investigations.
National screening incidents	Report to the ICS. Undertake an internal investigation. Co-operate in any external investigation.
Hospital Associated Infections	After Action review

There are also other circumstances, as detailed below, where we need to follow defined processes.

16. Homicides by Patients in Receipt of Mental Health Care

Where patients in receipt of mental health services, or those who have been in receipt of services within previous months, commit a homicide, the Trust will complete an initial incident review report within 72 hours of the event and declare as an PSII, following which an investigation will commence, for conclusion within the identified time scales there will be some flexibility to incorporate the views of the patient, family and carers and the complexity of the investigation.

The Trust will work closely with the police and those affected during this process to ensure questions and concerns from those affected are responded to in the internal PSII investigation. Please refer to the Humber SOP - Working with the Police following a mental health homicide SOP. NHS England will consider and, if appropriate, commission an independent investigation. NHS England's Regional investigation teams oversee this process.

17. Safeguarding – Children

The local authority via the local safeguarding children partnership (LSCP) has a statutory duty to investigate certain types of safeguarding incidents/concerns.

Section 11 of the Children Act 2004 places a duty on a range of organisations and individuals (this includes NHS Trusts, commissioners, and NHS England) to ensure that their

functions, and any services that they contract out to others, are discharged having regard to the need to safeguard and promote the welfare of children.

As part of that duty they must have arrangements in place to identify, report, investigate and implement/manage any remedial action required, in situations where it is believed that an incident has occurred that could adversely affect the health or welfare of a child. In circumstances set out in *Working Together to Safeguard Children (2018),* the LSCP will commission safeguarding practice reviews. Where the threshold for a safeguarding practice review is not met the LSCP may commission another review such as a learning the lessons review. The timescales for a review to be completed will be agreed with the National Panel.

The safeguarding team will always review the reporting of a child death with the commissioners prior to reporting on the Strategic Executive Information System (StEIS) to determine which organisation will declare the incident as a patient safety incident investigation, if appropriate. When LFPSE becomes live, incident reporting will be automatic.

18. Safeguarding – Adult

Section 44 of the Care Act 2014 sets out the conditions in which the Local Safeguarding Adult Board (LSAB) will commission safeguarding adult reviews, the safeguarding team will be involved in this review if the person was known to the service. Where the threshold for a safeguarding adult review is not met the LSAB may commission another review such as a learning the lessons review.

The Local authority will also initiate safeguarding adult enquires or ask others to do so if they suspect that an adult is at risk of abuse or neglect, under Section 42 of the Care Act 2014. The section 42 enquiry should be normally undertaken within 20 working days of the initial alert.

19. Health Care Acquired Infections – MRSA Blood Stream Infections

Although a Post Infection Review (PIR) for all MRSA bloodstream infection (BSI) cases has formed part of the government strategy for achieving a “zero tolerance” to HCAI since 2013 the mandatory requirement to complete this has been modified in April 2018. https://improvement.nhs.uk/documents/2512/MRSA_post_infection_review_2018_changes.pdf.

The document states that formal reviews must now only be undertaken for organisations with the highest rates of infection. This change has been made to refocus trusts and ICB’s on infection prevention and control and to focus teams’ attention on gram-negative infections and antibiotic resistance.

Although the Trust is not reported to be an organisation with a high rate of infection a targeted patient safety reviews will continue to be undertaken on all cases to identify best practice and areas for improvement/learning. The existing national Post Infection Review Toolkit will continue to be utilised as outlined in annex 1 page 14 of the guidance on the reporting and monitoring arrangements and post infection review process for MRSA bloodstream infections April 2014 version 2 https://improvement.nhs.uk/documents/2513/MRSA_post-inf-guidance2.pdf.

Untoward incidents relating to infection prevention and control are reported and processed through the Trust Datix system.

An After Action Review will be undertaken for any other Trust apportioned HCAIs (currently MSSA and E. coli BSIs and *Clostridium difficile* infections). All the AAR's s will be reviewed by the director of nursing with the consideration of reporting as an PSIA or PSII where significant areas for learning are identified or the infection has contributed to a patient's death.

All MRSA bacteraemia will be managed in accordance with the updated Department of Health and Social Care guidance on the reporting and monitoring arrangements and post infection review process for MRSA bloodstream infections. MRSA post infection review 2018.

20. Responding to cross-system incidents/issues

The Patient safety team will assist in the coordination of these events identified to other providers directly, via each organisations reporting processes. Where required summary reporting can be utilised to share insights with other providers about their patient safety profile.

Humber Teaching NHS Foundation Trust will work with partner providers and relevant Integrated care boards (ICBs) to establish and maintain robust procedures to facilitate flow of information and minimise delays to joint working on cross-system events. The patient safety team will act as a single access point for such working arrangements and hold supportive procedures to ensure this is effectively managed.

Humber Teaching NHS Foundation Trust will refer to ICBs to assist with the co-ordination where a cross-system event is felt to be complex to be managed by a single provider, we anticipate the ICB will provide support and advice with identifying a suitable reviewer, should this circumstance arise.

21. 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.

Humber Teaching NHS Foundation Trust is aware the highly prescriptive timeframes for learning responses may not be helpful, so the following are included as a guideline only:

- Initial incident investigation – as soon as possible, within 72 hours of reporting.
- Further learning response (e.g., PSIA using Swarm huddle methodology) – within 12 weeks of reporting. – See Appendix 2
- Comprehensive Investigation- PSII – 16 weeks of reporting. – See Appendix 3

The timescales for any investigation will be flexible to incorporate the patient, family and carers involvement and the complexity of the case. If for any reason the timescales set are exceeded and more time is required to complete the investigation, then this needs to be escalated to the patient safety team to review.

A toolkit of learning response types is available from NHSE at:
https://www.england.nhs.uk/publication/patient-safety-learning-response-toolkit/

Under PSIRF arrangements the lead reviewer in conjunction with the Buddy will consider and agree the most appropriate tools to be used to gather information and engage staff in the process and eliciting learning. Mixed methods can be used e.g. Swarm Huddle, one to one interviews, that are suitable for the individual circumstances of the case for review.

In exceptional circumstances where there is an external investigation into a patient safety incident, the Trusts PSII will not commence until permission from the external agency has been granted.

22. Safety Action Development and Monitoring Improvement.

Patient Safety Learning Responses should not describe recommendations, as this can lead to premature attempts to devise a solution.

A Quality Improvement approach is valuable in this aspect of learning and improvement following a patient safety investigation. It will therefore be necessary to ensure close links are developed and maintained with the Quality Improvement Team so their expertise and guidance can be utilised when developing the learning response and safety actions. This approach is recognised within the Trust and considerable work has taken place to educate colleagues in the principles of QI methodology. PSIRF therefore provides an opportunity to strengthen this and for the QI and Patient Safety functions to work more closely together. Humber Teaching NHS Foundation Trusts has governance process in place, as details in our PSIRP, to monitor embedding of patient safety learning responses and that responses are completed in an agreed timescale.

23. Safety Improvement Plans

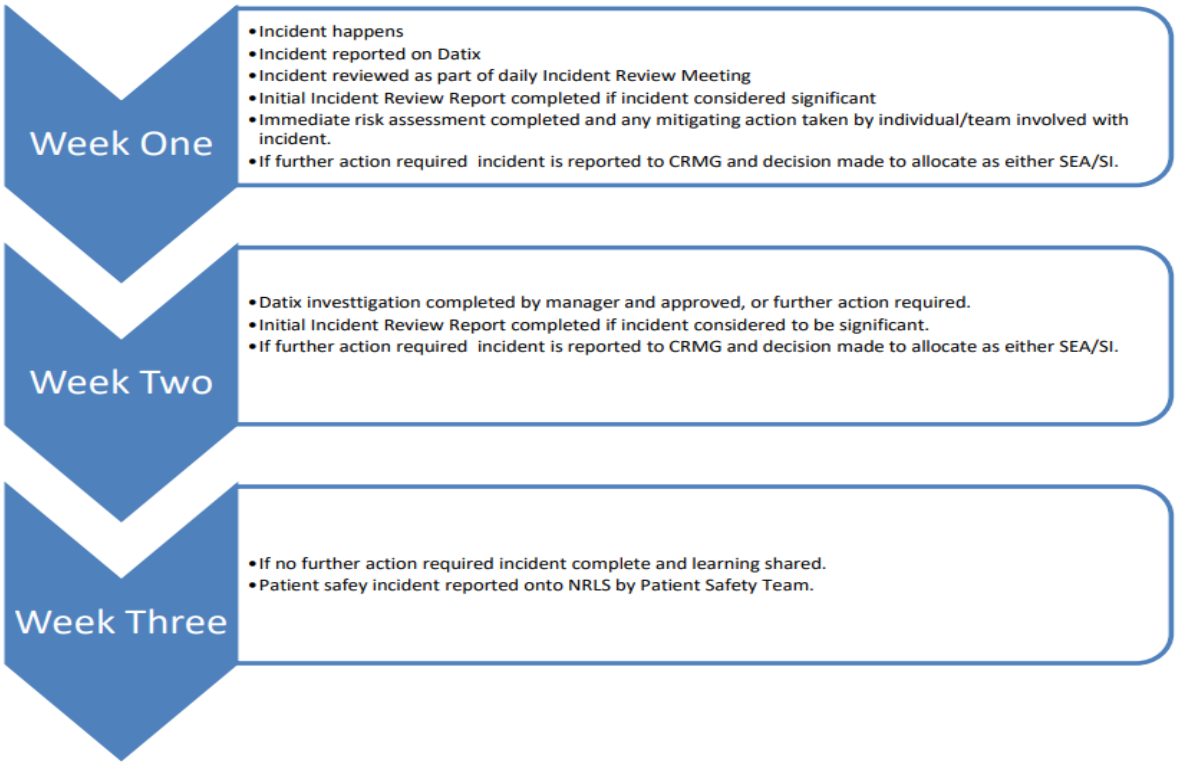
As referred to throughout the policy, Humber Teaching NHS Foundation Trust has developed a Patient Safety Incident Response Plan (PSIRP) that clarifies what our improvement priorities are. The PSIRP details how we will ensure patient safety incidents are investigated in a more holistic and inclusive way, to identify learning and safety actions which will reduce risk and improve safety and quality. All learning from PSII will be recorded on a safety action summary table in the PSII report.

24. Complaints and Appeals

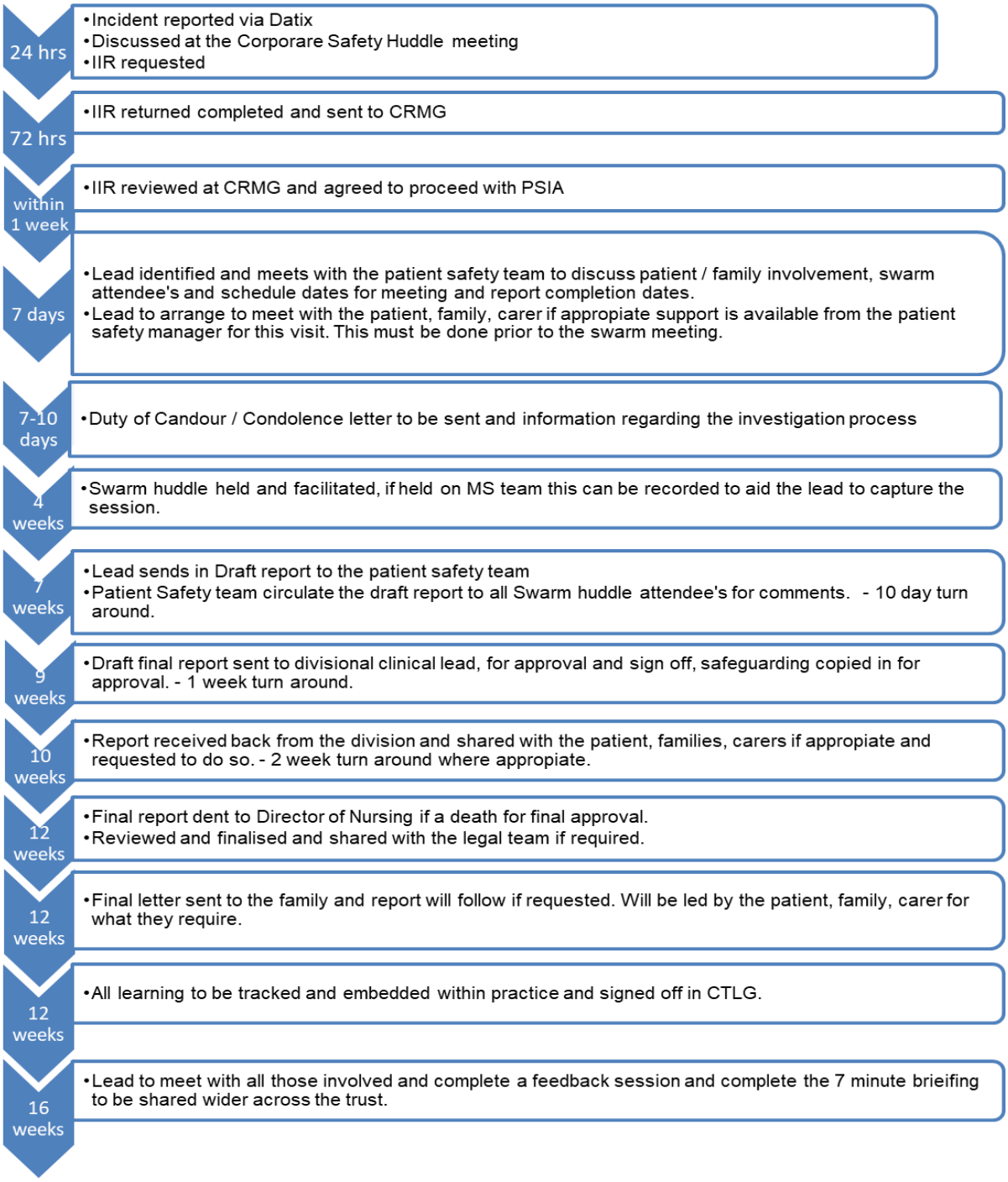
Any complaints relating to this document, its implementation or any of the processes within it can initially be raised with the Patient safety team or the Trusts Patient safety specialists, who will aim to resolve any concerns as appropriate.
Formal complaints from patients or families can be logged through the Trusts complaints procedure. Complaints can be made by letter, email or verbally.

Complaints and Feedback Manager
Humber NHS Foundation Trust
Willerby Hill
Beverley Road
Willerby
HU10 6ED
Tel: (01482) 303930 or email HNF-TR.complaints@nhs.net

Appendix 1 - Incident Reporting Flowchart



Appendix 2 - Patient Safety Incident Analysis (PSIA)



Appendix 3 - Learning From Template

PSIA/PSII/AAR/PSMDT XXXX- XX

NHS
Humber Teaching
NHS Foundation Trust

Brief summary of incident for example --- This is an account of what happened to insert name who XXXXX (name used is a pseudo name)

What happened to

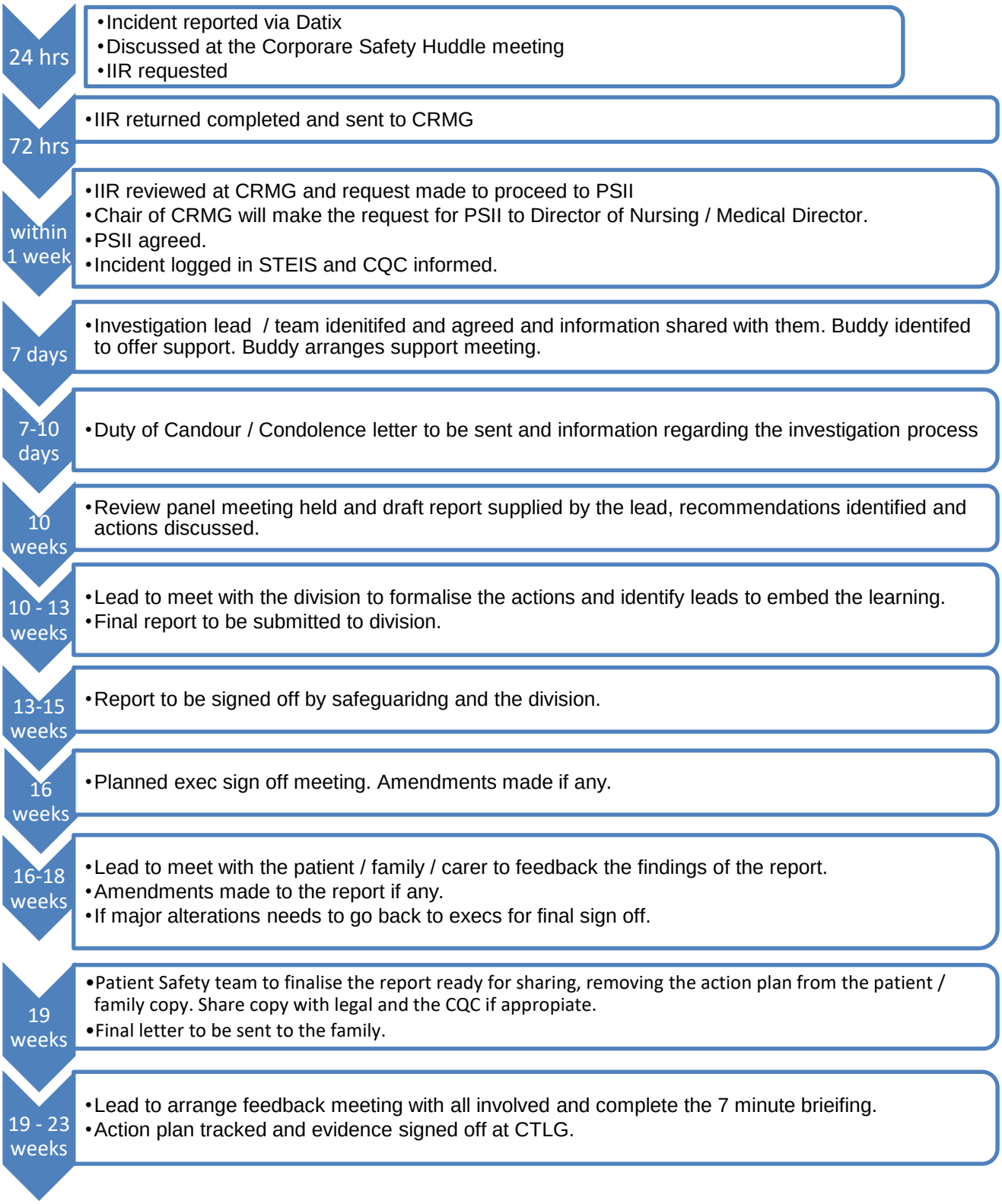
The voice of the XXXX

What we learnt

What went well

Our commitment to the young woman

Appendix 4 - Patient Safety Incident Investigation (PSII)



Appendix 5 - Document Control Sheet

This document control sheet, when presented to an approving committee must be completed in full to provide assurance to the approving committee.

Document Type	Policy		
Document Purpose	This policy supports the requirements of the Patient Safety Incident Response Framework (PSIRF) and sets out Humber Teaching NHS Foundation Trust's approach to developing and maintaining effective systems and processes for responding to patient safety incidents and issues for the purpose of learning and improving patient safety. The PSIRF advocates a co-ordinated and data-driven response to patient safety incidents. It embeds patient safety incident response within a wider system of improvement and prompts a significant cultural shift towards systematic patient safety management. This policy supports development and maintenance of an effective patient safety incident response system that integrates the four key aims of the PSIRF:		
Consultation/ Peer Review:	Date:	Group / Individual	
list in right hand columns consultation groups and dates -	Aug-23	PSIRF Working Group PSIRF Working Group	
		PSIRF Steering group	
	May 2024	QPaS	
Approving Body:	EMT (v1.0)	Date of Approval:	11 September 2023
Ratified at:	Trust Board (v1.0)	Date of Ratification:	27 September 2023
Training Needs Analysis: *(please indicate training required and the timescale for providing assurance to the approving committee that this has been delivered)*		Financial Resource Impact	
Equality Impact Assessment undertaken?	Yes [x]	No [ ]	N/A [ ] Rationale:
Publication and Dissemination	Intranet [ ]	Internet [ ]	Staff Email [ ]
Master version held by:	Author [ ]	InPhase [ ]	
Implementation:	*Describe implementation plans below - to be delivered by the Author:*		
	. . .		
Monitoring and Compliance:			

Document Change History:			
Version Number / Name of procedural document this supersedes	*Type of Change i.e. Review / Legislation*	*Date*	*Details of Change and approving group or Executive Lead (if done outside of the formal revision process)*
1.0	*New document*	*Sept-23*	*New Document required for the Patient Safety Incident Response Framework* *Approved at EMT – 11-Sept-23* *Ratified at Trust Board – 27-Sept-23*
1.1	*Minor changes*	*June 2024*	*Reviewed. Changed Swarm huddle to PSIA using swarm methodology. Removed reference to SEAs and SI. Added more clarity re safety II. Added incident reporting flowchart. Updated timescales for reviews. Approved at QPaS (27 June 2024).*
1.2	*Minor amends*	*25 March 2025*	*Appendix 3 "Learning From Template" added to policy. Approved by director sign-off (Hilary Gledhill - Executive director of Nursing, AHPs and Social Work Professionals – 25 March 2025).Date of next review unchanged.*

Appendix 6 - Equality Impact Assessment (EIA) Toolkit

For strategies, policies, procedures, processes, guidelines, protocols, tenders, services

1. Document or Process or Service Name:
2. EIA Reviewer (name, job title, base and contact details)
3. Is it a **Policy**, Strategy, Procedure, Process, Tender, Service or Other?

Main Aims of the Document, Process or Service To set out the requirements that must be met for approval, ratification and dissemination of all Humber Teaching FT policies.		
Please indicate in the table that follows whether the document or process has the potential to impact adversely, intentionally or unwittingly on the equality target groups contained in the pro forma		
Equality Target Group Age Disability Sex Marriage/Civil Partnership Pregnancy/Maternity Race Religion/Belief Sexual Orientation Gender re-assignment	Is the document or process likely to have a potential or actual differential impact with regards to the equality target groups listed? **Equality Impact Score** Low = Little or No evidence or concern (Green) Medium = some evidence or concern(Amber) High = significant evidence or concern (Red)	How have you arrived at the equality impact score? 1. who have you consulted with 2. what have they said 3. what information or data have you used 4. where are the gaps in your analysis 5. how will your document/process or service promote equality and diversity good practice

Equality Target Group	Definitions	Equality Impact Score	Evidence to support Equality Impact Score
Age	Including specific ages and age groups: Older people, Young people, Children, Early years	Low	No age group is adversely affected by this policy
Disability	Where the impairment has a substantial and long term adverse effect on the ability of the person to carry out their day to day activities: Sensory, Physical, Learning, Mental Health (and including cancer, HIV, multiple sclerosis)	Low	No group with a disability is adversely affected by this policy
Sex	Men/Male, Women/Female	Low	Review of the policy has taken place to ensure no group is adversely affected by the policy.
Married/Civil Partnership		Low	Review of the policy has taken place to ensure no group is adversely affected by the policy
Pregnancy/ Maternity		Low	Review of the policy has taken place to ensure no group is adversely affected by the policy
Race	Colour, Nationality, Ethnic/national origins	Low	Review of the policy has taken place to ensure no group is adversely affected by the policy
Religion or Belief	All Religions Including lack of religion or belief and where belief includes any religious or philosophical belief	Low	Review of the policy has taken place to ensure no group is adversely affected by the policy
Sexual Orientation	Lesbian, Gay Men, Bisexual	Low	Review of the policy has taken place to ensure no group is adversely affected by the policy
Gender re-assignment	Where people are proposing to undergo, or have undergone a process (or part of a process) for the purpose of reassigning the person's sex by changing physiological or other attribute of sex	Low	Review of the policy has taken place to ensure no group is adversely affected by the policy

Summary

Please describe the main points/actions arising from your assessment that supports your decision above			
The policy will be adopted system-wide within the Trust and is applicable to all members of staff. The procedures detailed within the policy will be applied unilaterally across the organisation.			
EIA Reviewer	Sadie Milner		
Date completed;	21/03/2024	Signature	S. K .Milner