NHS
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NHS Foundation Trust

Engaging and Involving Patients, Families and Staff following a Patient Safety Incident Policy and Procedure (N-074)

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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 (e.g., 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
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

PSIA	Patient Safety Incident Analysis is undertaken when an incident requires further investigation, involving the patient, families / carer, using the SWARM methodology. A Swarm meeting will 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).
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 are 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.

1. Introduction

National published reports clearly articulate the importance of engaging with patients, families, and staff appropriately after a patient safety incident and involving them in any subsequent investigation.

While healthcare organisations have undoubtedly increased their focus on engagement with and involvement of patients, families and staff, the way they do this in patient safety incident investigations remains varied. Many of those affected still feel excluded from the process.

"The Patient Safety Incident Response Framework promotes systematic, compassionate, and proportionate responses to patient safety incidents, anchored in the principles of openness, fair accountability, learning and continuous improvement – and with the aim of learning how to reduce risk and associated harm. The PSIRF recognises that meaningful learning and improvement following a patient safety incident can only be achieved if supportive systems and processes are in place. The PSIRF supports development of a patient safety incident response system that prioritises compassionate engagement and involvement of those affected by patient safety incidents." (NHS England 2022)

'Those affected' include staff and families in the broadest sense; that is: the person or patient (the individual) to whom the incident occurred, their family and close relations. Family and close relations may include parents, partners, siblings, children, guardians, carers, and others who have a direct and close relationship with the individual to whom the incident occurred.

This policy and procedure aims to reflect the guidance developed and published by the National Patient Safety Team, the Healthcare Safety Investigation Branch and the Learn Together research team and will be built on the following 9 engagement principles as described in Engaging-and-involving (england.nhs.uk) and described as part of this policy.

2. Purpose

This policy and procedure set out the expectations within Humber Teaching NHS Foundation Trust for compassionate engagement and involvement with those affected by patient safety incidents. This should be read alongside the Duty of Candour Policy and Procedure.

Engagement and involvement are terms that are often used interchangeably, and this can be confusing. Engagement refers to everything the trust do to communicate and work with patients, families and staff within the processes that follow a patient safety incident, usually this will involve being open through the duty of candour process. Involvement refers to the activity that is specific to the investigation, such as speaking to patients and families about the patient safety incident and seeking their feedback on the draft report. Whilst the term engagement covers all activity to engage and communicate with patients and families following a patient safety incident, involvement relates to a smaller subset of engagement and specifically to activity that directly supports the investigation. (Learn-together, 2023) Humber Teaching NHS Foundation Trust understand that involving patients, families and staff in the investigation:

- Supports organisational learning, research has shown that involving those affected by an incident helps join different sources of evidence together.
- Supports patient, family and staff healing, how an incident is dealt with can on some occasions cause patients and families to mistrust healthcare services. Rebuilding trust is particularly important as patients and families will require support from health

services in the future. Patient safety incidents are not always preventable, but how you support those involved in ways that they feel valued and respected can have a huge impact on their lives now and in the future.

First, those affected by a patient safety incident may have a range of needs (including clinical needs) as a result and these must be met where possible. This is part of our duty of care. Meeting people's needs not only helps alleviate the harm experienced, but also helps avoid **compounding** that harm (compound harm is the harm that can be created after a safety incident due to the process that is followed). While we cannot change the fact that an incident has happened, it is always within our gift to compassionately engage with those affected, listen to, and answer their questions and try to meet their needs.

Second, engaging with those affected by a patient safety incident substantially improves our understanding of what happened, and potentially how to prevent a similar incident in future. Patients, their family members, and carers may be the only people with insight into what occurred at every stage of a person's journey through the healthcare system. Not including those insights could mean an incomplete picture of what happened is created. Similarly, staff have important contributions to make about their experience of the incident and the working environment at the time and should be supported to share their account.

3. How to use this Policy/Procedure

This document has two parts:

- **Part A: Creating the right foundations** describes the systems and processes that establish strong foundations on which an effective involvement process can be built. This policy / procedure is for those responsible for PSIRF implementation within Humber Teaching NHS Foundation Trust and those in system oversight roles.

- **Part B: Engagement and involvement process** describes a process for engaging those affected by patient safety incidents and supportively involving them throughout a learning response, and while it focuses on patient safety investigation's (PSII and PSIA) it can be applied to other learning response methods. This practical procedure is aimed at those working directly with people affected by patient safety incidents (eg learning response leads and family liaison officers).

4. Scope

The focus of this policy / procedure is to achieve **compassionate engagement and involvement** by

- providing practical advice to support compassionate engagement with those affected by patient safety incidents.

- providing practical advice to enable meaningful involvement as part of a patient safety investigation (PSII and PSIA), although the principles and approaches described can be applied to any type of patient safety incident and/or response method.

5. Engagement principles

Nine principles should be followed for engaging and involving those affected by patient safety incidents.

1. Apologies are meaningful.
Apologies need to demonstrate understanding of the potential impact of the incident on those involved, and a commitment to address their questions and concerns. Ideally, an apology communicates a sense of accountability for the harm experienced, but not responsibility for it ahead of investigation. Getting an apology right is important – it sets the tone for everything that follows. Apologising is also a crucial part of the Duty of Candour Policy and Procedure

2. Approach is individualised.
Engagement and involvement should be flexible and adapt to individual and changing needs. These needs could be practical, physical, or emotional. Engagement leads should recognise that every response might need to be different, based on an understanding of the different needs and circumstances of those affected by an incident.

3. Timing is sensitive.
Some people can feel they are being engaged and involved too slowly or too quickly, or at insensitive times. Engagement leads need to talk to those affected about the timing and structure of engagement and involvement, and any key dates to avoid (e.g., birthdays, funeral dates, anniversaries), particularly where someone has lost a loved one.

4. Those affected are treated with respect and compassion.
Everyone involved in a learning response should be treated respectfully. There should be a duty of care to everyone involved in the patient safety incident and subsequent response, and opportunities provided for open communication and support through the process. Overlooking the relational elements of a learning response can lead to a breakdown of trust between those involved (including patients, families, and healthcare staff) and the organisation.

5. Guidance and clarity are provided.
Patients, families, and healthcare staff can find the processes that follow a patient safety incident confusing. Those outside the health service, and even some within it, may not know what a patient safety incident is, why the incident they were involved in is being investigated or what the learning response entails. Patients, families, and healthcare staff can feel powerless and ill-equipped for the processes following a patient safety incident.

6. Those affected are 'heard'.
Everyone affected by a patient safety incident should have the opportunity to be listened to and share their experience. They will all have their individual perspective on what happened and each one is valid in building a comprehensive picture to support learning. Importantly, the opportunity to be listened to is also part of restoring trust and repairing relationships between organisations and staff, patients, and families.

7. Approach is collaborative and open.
An investigation process that is collaborative and open with information, and provides answers, can reduce the chance litigation will be used as a route for being heard. The decision to litigate is a difficult one. Organisations must not assume that litigation is always about establishing blame – some feel it is the only way to get answers to their questions.

8. Subjectivity is accepted.
Everyone will experience the same incident in different ways. No one truth should be prioritised over others. Engagement leads should ensure that patients, families, and healthcare staff are all viewed as credible sources of information in response to a patient safety incident.

9. Strive for equity.
The opportunity for learning should be weighed against the needs of those affected by the incident.

Engagement leads need to understand and seek information on the impact of how they choose response types on those affected by incidents and be aware of the risk of introducing inequity into the process of safety responses.

6. Part A: Creating the right foundations.

These are the foundations for effective and compassionate engagement:

Leadership
Managers and leaders should demonstrate their commitment to compassionate engagement and involvement in their words and actions.

Training and competencies
PSIRF sets specific expectations regarding training required for engaging and involving those affected by patient safety incidents.

Support systems
Families and staff may need to be signposted to support at any point during engagement or involvement in a learning response.

Ensuring inclusivity
Engagement and involvement must take into account individual needs. Organisations should consider this in the design and delivery of their service.

Information resources
Those affected by a patient safety incident must have clear information about the purpose of a learning response, and what to expect from the process.

Processes for seeking and acting on feedback
Organisations must assess the progression and outcome of engaging with those affected by a patient safety incident and their involvement in a learning response.

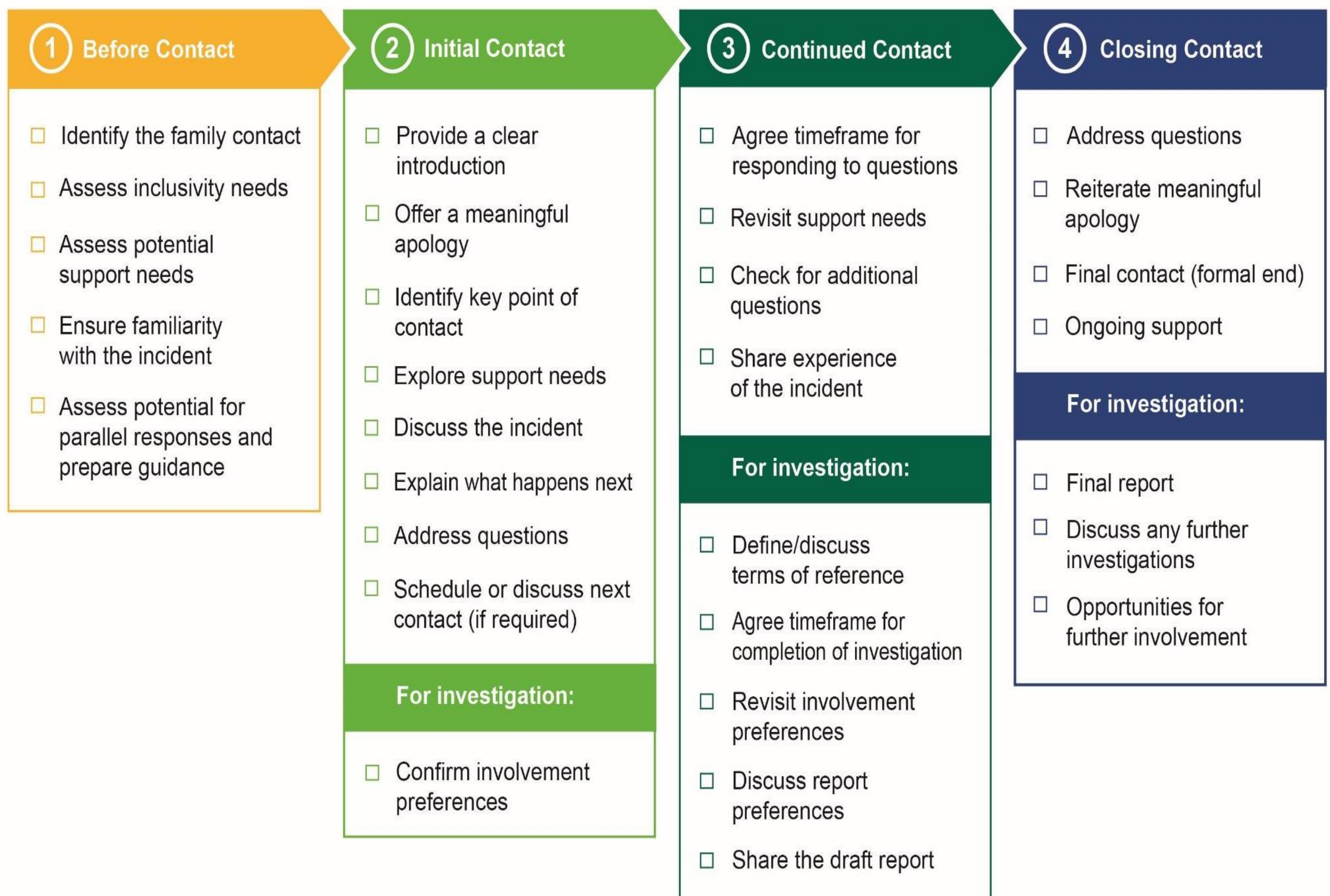
Processes for managing dissatisfaction
When the expectations of those affected are not met, families and staff must be given meaningful, truthful and clear explanations as to why this was not possible.

7. Part B: Engagement and involvement process

Not all steps may be required, some steps may need to be repeated and the process may not be as linear as implied. Your approach must be adapted to meet the circumstances of each patient safety incident and the individuals affected. For example, careful consideration must be given to the sequence (including timing in relation to the incident, such as avoiding the anniversary of a death) and complexity of what is being asked of those being engaged and involved, remembering that this can be emotionally demanding for them.

Engagement and level of involvement must be in keeping with the wishes of those affected as far as possible.

Overview of the four steps of Engagement:



Step 1: Before Contact
Compassionate engagement and involvement of those affected by patient safety incidents is demanding but incredibly important. Engagement and involvement need to be tailored to the circumstances of a patient safety incident response and to everyone affected, so preparation for initial conversations with those involved is crucial.

Identify the family contact.
You need to identify the main family point of contact prior to commencement of any engagement. Note this contact may change.

Assess inclusivity needs.
Although the initial contact needs to be prompt, care and consideration should be given in its planning. The staff member making the initial contact with someone affected by a patient safety incident should ask themselves a series of questions, including:

- What is known about the people affected by and the circumstances of the incident?
- Do those affected have any specific communication needs?
- What engagement has occurred so far and have any specific needs been identified?

The nine protected characteristics of age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex and sexual orientation need to be considered and appropriate adjustments made if required (eg involvement of an interpreter; see also Using language services below). Wider health inequality variables (eg mental health conditions) that can affect care that people receive should also be considered.

Assess potential support needs.
Some patient safety incidents may leave people suddenly bereaved and/or experiencing complex trauma. Those affected may not be ready to participate in engagement activities for various emotional, psychological and/or physical reasons. In these circumstances the initial contact with them must be carefully planned so that support needs can be identified and met at the earliest opportunity.

Staff may have been involved in previous patient safety incidents or supported/witnessed other colleagues engaging with the learning response process, and this may heighten their anxiety about what to expect. The initial contact with such staff may need to be longer.

Ensure familiarity with the incident.
You should be familiar with the facts of the incident to date and know who you are talking about (the patient's name) and who you are talking to (eg patient, next of kin, staff member).

Assess potential for parallel responses and prepare guidance.
The patient safety incident may prompt responses that run in parallel to or affect the timeframe of your response, e.g., a coroner's inquest. If you know of any other processes that will run, you should prepare to inform those affected of this.

If a Patient Safety Investigation is required the Patient Safety team, in consultation with the relevant team/service will seek to identify who the initial contact letter should be sent to (often referred to as the Duty of Candour letter). This will be the person affected by the patient safety incident or in the event of a patient/services user death, their close family member; sometimes referred to as next of kin or significant other. In the event of a patient death, where a close family member cannot be identified, the Patient Safety team or delegated other may contact the Trust's legal team and seek this information from the coroner.

It would be best practice to contact those involved prior to the letter and support information is sent – see below for initial contact.

The initial contact letter will be sent from the Director of Nursing to the patient or relative within 10 working days of a Patient Safety Investigation being commissioned. The initial contact letter will include the name and contact details of the Patient Safety Engagement Lead / Investigator and details of how to contact the Patient Safety Team, support booklet will be provided with this letter. Supporting Families Carers and Loved Ones Following a PSI.pdf (humber.nhs.uk)

A copy of the initial contact letter will be sent to the lead investigator.

Support guidance will be sent to all staff involved in the patient safety incident for advice and support. Navigating difficult events at work (humber.nhs.uk)

Step 2: Initial Contact
The lead investigator is responsible for making the initial contact with those affected by a patient safety incident, this conversation sets the tone for any future interactions, establishing trust and respect from the outset is key.

Careful consideration needs to be made around the timing of the initial contact and where possible this needs to be done in person not via email or not at the end of an employee's shift.

Provide a clear introduction: introduce yourself giving your full name and job title and work location. Explain what your role entails as part of the patient safety incident.

Offer a meaningful apology: You should give patients, their families, and carers a meaningful apology – one that sincerely expresses sorrow or regret for the harm that resulted from the patient safety incident. Apologising is the right thing to do; it is not an admission of liability. Patients have a right to expect openness in their healthcare.

Identify key point of contact: Ensure those affected know who their point of contact is within the organisation. The initial point of contact from the organisation may not be the same as the person who subsequently maintains contact throughout the engagement process.

Explore support needs: Everyone will respond differently to incidents, and some people will be more aware of their support needs than others. Not everyone will need support and needs may change over time. **Make sure they have received the support guide.**

Discuss the incident: Explain the patient safety incident clearly and in language appropriate to the person. Your description should be based solely on what is known at the time and you must not make any causal or outcome predictions.

Explain what happens next: Describe any immediate actions that have already been taken in response to the patient safety incident. Describe how the trust intends to respond to the incident in accordance with the patient safety incident response plan:

- Is a learning response planned?
- Is improvement work underway?
- Will a review be conducted to understand whether further learning is required?

If a patient safety investigation is planned, you should set out how this will happen. You should:

- Ask how they would like to receive information about the investigation process.
- Explain the process including any likely delays. You could talk generally about the trust's patient safety incident response policy, or more specifically about how the investigation will be completed. Timeframes for completion should be discussed and, if possible, mutually agreed.
- Explain anything that has already been done. If you have already started an investigation, explain what you have done and why it was necessary to begin the investigation before involving those affected in the process.
- Ask patient / family if they have any immediate questions about the investigation process.
- Ask what involvement they would like as part of the investigation and discuss with them how they would like to be kept up to date with the progress of the investigation, telephone call, email etc and the frequency of contact.

Address questions: you should make time to answer any initial questions and if you cannot answer any questions be honest and say you'll come back to them.

Schedule or discuss next contact: Plan to visit the patient / family /staff member face to face if appropriate and if they agree. This should realistically be planned within 2 weeks of the initial contact. Plan to visit with a colleague and the venue should be chosen by the patient / family or staff member this should be somewhere they feel comfortable talking in. This should be a supportive meeting and you should be able to get a clear picture/ understanding of the person involved in the investigation.

Step 3: Continued Contact

Although you may not always have something to update the patient / family about the investigation, you must reliably maintain contact with them as agreed. If communication cannot be maintained as agreed for any reason, you should let patient / family know as soon as possible and arrange another mutually convenient time to contact them. It is also important to be transparent about how much progress has been made since the last communication. By maintaining contact and being open, you will continue to build trust with the family and healthcare staff affected.

Agree timeframe for responding to questions: If further information gathering is required to address questions and concerns raised, you should agree with those affected when you will respond. The time needed will depend on the nature of the incident and the questions asked.

Revisit support needs: Support needs can change over time. You should raise and discuss potential support needs throughout continued contact.

Check for additional questions: Families and staff may lack the confidence to ask questions, particularly during the initial contact phase. You should check if they have any additional questions through the continued contact.

If questions lie outside the scope of understanding what happened and learning and improvement (e.g., are to do with culpability), you should support families to find people or organisations that could provide answers.

Share experience of the incident: Sharing experiences can be difficult, emotional, and daunting. If people feel comfortable, they are more likely to share everything they remember

about the incident and the events that surrounded it. You need to help them feel more comfortable by being transparent about how information will be recorded and used.

Consider the environment in which families and staff share their experience. The conversation should take place in a quiet, relaxed setting and for staff, if possible, away from their usual place of work and not where the patient safety incident occurred.

You should give people the time and space to share their experience with you in full. If you only have a set amount of time, be honest about this and offer to arrange a second conversation.

Continued contact: patient safety incident investigation
People will want different levels of involvement in a PSII or PSIA. Although their preferences might change as the investigation progresses, discussions at the initial contact will set clear expectations about how and when those affected would like to be involved. As the investigation progresses, you will need to enact the ways of working that enable involvement in the investigation process by those who want to be and remain flexible in your continued contact in case people change their mind about being involved.

Continued contact means being open and clear about how the investigation is progressing. You need to recognise that it can be difficult for people to engage meaningfully with a system or process that they are unfamiliar with. Your continued contact with people provides them with both the opportunity and support to access those parts of the investigation process they want to be involved in, as well as updating them on the investigation's progress.

For people who want to be involved in the investigation, your continued contact with them will be very similar to your initial conversations: you will provide information, discuss experiences, answer their questions, and pay attention to support needs.

For people who do not want to be as involved, or involved at all, in your continued contact you may only need to give simple updates or basic information.

Define/ discuss scope of the investigation (terms of reference).
You or your team will draft the terms of reference for the investigation process. These need to be explained to those affected, as these guide what the investigation will cover and the questions that need to be answered.

If the scope of the investigation will not provide answers to their questions, support people to access different sources of information and types of investigation.

Agree timeframe for completion of investigation.
Timeframes for completion of an investigation are flexible and will depend on the nature of the incident and family and staff involvement. A response is usually completed within three months but in some circumstances this maybe longer, this should always be explained to those affected.

Revisit involvement preferences.
People may change their wishes on level of involvement as the investigation progresses. For people who initially did not want to be involved in the investigation, use your discretion when deciding how to revisit their preferences.

Discuss report preferences.
PSII and PSIA reports can include the name of the patient. Personalisation preferences should be discussed with the family and adopted in the draft before it is shared. It is

important to remember that family members may have different preferences; these should be resolved on a case-by-case basis.

Share the draft report.
Once the draft report has been through the divisional sign off process and been reviewed by the executives, then the draft report is ready to be shared with those affected this gives them a realistic opportunity to influence the content before it is finalised.

You will have a good idea of what the report will contain and of the safety actions you have identified. Involving those affected at this stage may feel daunting but they should have the chance to check for inaccuracies and to ask questions about the draft.

Could you have a conversation with those affected before sending them the draft report, and then arrange a time to discuss it? People will need time to read the draft report, and possibly support to access or discuss it.

Explain how you will use their comments to formalise the final report.

If you cannot change something, be honest and explain why not.

Step 4: Closing Contact
The end of engagement is a point of closure for everyone involved. This can be an emotional process for people, regardless of their level of engagement and involvement during the investigation process.

By this stage you should be more aware of individuals' needs and preferences, which should enable you to close contact with them respectfully, sensitively, and empathetically. This is important to minimise the likelihood of compounding any harm caused by the incident.

The engagement or investigation may have provided structure for people during a difficult time. It is important that closing contact is as positive an experience as it can be, and the potential impact of the end of the contact on everyone involved is recognised. A complaint or claim may still be ongoing.

Address questions.
At this stage you will have all the information to be able to answer any further questions. For questions that are not within scope, you should support families to find people or organisations who could provide answers.

Reiterate meaningful apology.
Reiterate the meaningful apology you gave at the beginning of the engagement process – a sincere expression of sorrow or regret for the effect the patient safety incident had on them, and that the trust is committed to learning and improving (even if a learning response method was not used in response to this incident).

Final contact (formal end)
For people with whom you have had regular contact, you can close communication at the last regular contact. You should thank them for their contributions.

Ongoing support
At the conclusion of engagement or an investigation, review the support you have signposted individuals to and consider they may need any extra support.

Closing contact: patient safety investigation

Final Report
Once all amendments have been made to the draft report and it has been signed off by the division and the executives, this is now ready to be shared and marks the end of the investigation process for everyone involved.

Ask those affected if and they want to see the final report, and if they do, what the easiest format is for them to receive it in. Make it clear when they can expect to receive a copy of the final report so that it does not arrive as a surprise.

When the final report has been published or shared with the family, acknowledge with the family the end of your 'relationship'. A final letter will be sent to the family from the patient safety team.

Opportunities for further involvement.
Patients, family, and staff members can give valuable insight into how a trust could improve processes to reduce the likelihood of incidents happening again. If you think someone with whom you have engaged could support the trust with specific ideas for change or improvement, and may be interested in doing so, you could offer them an opportunity for further involvement. If they are interested in getting involved, you can contact the Patient and Carer Experience Team on telephone number: 01482 389167 or email: hnf-tr.patientandcarerexperience@nhs.net.

Additional considerations
Assessing risks throughout engagement
Engagement leads must ensure the personal safety of the patients, families, and staff with whom they engage.

Risk assessment needs to be a dynamic process throughout the engagement and investigation process. Risk should be considered in relation to:

- people (e.g. adverse behaviour of the people present)
- activity (e.g. risks associated with an action)
- location/environment (e.g. allergies, safeguarding concerns).

Details of any known or perceived risk should be recorded before contacting those affected and then be regularly reviewed. Any control measures that can be put in place (e.g. working in pairs if visiting someone at their home or another location external to the healthcare setting) and any action taken should be recorded.

Keeping good records
Every communication should be documented, even when attempts to make contact are unsuccessful, and what was discussed recorded. This ensures an accurate audit trail, demonstrates the efforts made and allows a thorough handover if ever required. Engagement leads can also refer to this log whenever they need to confirm the conversations that have taken place, which can be helpful to people who may be finding it hard to retain information due to their individual circumstances. Records should contain:

- date and time of all contacts, including any meetings
- method of contact (eg telephone, email)
- who was present during the contact
- purpose of contact and any information exchanged
- details of who initiated the contact
- details of non-family members or support present at any meeting all unsuccessful attempts to contact those affected or their representatives
- all contacts with those affected that were refused or declined, and any reasons given

Complaints
There is a statutory requirement to investigate and respond to complaints. This should never be put on hold without the complainant's permission. Where possible, and if the complainant agrees, the complaint investigation and patient safety incident investigation should be combined so that the patient/family get all the answers they are seeking together. Note, however, that the complaint may not limit itself to learning issues. When it is not possible to combine the two responses, how communication with those affected is best managed needs to be considered (see also PHSO Complaints Standards Framework). [Complaints and Feedback (humber.nhs.uk)]

8. Oversight Roles and Responsibilities

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.

Director of Nursing, Allied Health & Social Care Professionals (DON)
The director of nursing will ensure that this policy is acted on through delegation of responsibility for the development and implementation of the policy to the appropriate directors and committees.
The director of nursing will also ensure the policy and procedures are monitored and reviewed formally through the appropriate committees

Divisional Clinical Leads and Divisional General Managers
The divisional Clinical Leads and General Managers will ensure that this policy is acted on through a process of policy dissemination and implementation in collaboration with Trust senior managers.

- They will support their staff through making provision for appropriate training and in making adequate resources available to fulfil the requirements of this policy.
- Identify a lead for the investigation and liaise with the patient safety and compliance manager.
- 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. Liaising with the patient safety and compliance manager.
- 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.
- They, or their nominated deputy attend Patient Safety initial analysis / swarm huddles.

Senior Managers, Managers and Clinicians
Senior managers, managers and clinicians will ensure all staff within their area of responsibility are informed about the contents of this and other associated policies, procedures and will apply this policy and procedure in a fair and equitable manner.

- Staff are fully supported in the reporting of all incidents including those that may be an PSII, PSIA, near miss or never event.
- Staff involved in the incident should be given a copy of Navigating Difficult Events at Work Trust booklet.

- 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.
- Support for staff during and following a patient safety incident, near miss or never event. Where staff experience 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 swarm huddle 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.

Lead Investigator
- Arrange to meet with the patient safety and compliance manager to identify which staff / services need to be involved in the investigation.
- Work with the patient safety and compliance manager (Engagement lead) on how the patient / family / carers will be involved in the investigation.
- Liaise with the patient safety team regarding letters and access to clinical records.
- Prioritise and attend meetings associated with the investigation as and when required.
- Complete all the relevant documentation.
- Feedback to all those involved.

Quality and Patient Safety Team
- Assist in setting up all meetings relating to the investigations.
- Make sure all letters are produced and circulated as appropriate.
- Patient safety and compliance manager (engagement lead) to liaise with leads and assist in talking / visiting patients, families / carers involved in the investigation acting as an impartial member of the investigation team.
- Patient Safety and Compliance manager to assist the leads in feedback the findings of the investigation to the patient, families and carers involved.

Other Trust Staff
- 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.

9. Policy Consultation

- Patient Safety Incident Response Framework (PSIRF) Working Group
- Involving Patient and Families PSIRF sub-group
- Patient Safety Incident Response Framework Steering Group

10. Implementation

This policy will be disseminated as described in the Document Control Policy C-003.pdf (humber.nhs.uk). Implementation of this policy will be delivered and overseen by the Patient Safety Team reporting into the Quality and Patient Safety Group.

11. Training – can be accessed through ESR

Making every contact count
Care certificate standard 5: Work in a person-centred way
Negotiating and managing relationships
Handling difficult situations – Caring for yourself & others with compassion
How To hold Difficult conversations

12. References and supporting documents

- NHS England » Engaging and involving patients, families and staff following a patient safety incident NHS England » Framework for involving patients in patient safety
- NHS England » The NHS Patient Safety Strategy
- learn-together.org.uk – Serious Incident Investigation resources

Appendix 1 - Document Control Sheet

This document control sheet, when presented for approval/ratification must be completed in full to provide assurance. The master copy of the document is to be held by the Policy Management Team.

Document Type	Policy		
Document Purpose	Engaging and Involving Patients, Families and Staff following a Patient Safety Incident Policy and Procedure		
Consultation:	Date:	Group / Individual	
list in right hand columns consultation groups and dates -	August 2023	PSIRF Working Group PSIRF Steering Group	
	Sept-23	QPaS	
	Sept 24	QPaS	
Approving Body:	QPaS	Date of Approval:	*11 September 2024*
Date of Board Ratification:	29 November 2023 (v1.0)		
Training Impact Analysis:	None [✓]	Minor [ ]	Significant [ ]
Financial Impact Analysis:	None [✓]	Minor [ ]	Significant [ ]
Capacity Impact Analysis:	None [✓]	Minor [ ]	Significant [ ]
Equality Impact Assessment (EIA) undertaken?	Yes [✓]	No [ ]	N/A [ ] Rationale:

Document Change History:			
Version Number	*Type of Change (full/interim review, minor or significant change(s))*	*Date*	*Details of Change and approving group or Executive Director* ***(if very minor changes as per the document control policy)***
1.0	*New policy document*	*Sept-23*	*New policy required for the PSIRF process* *Taken through PSIRF Steering Group and QPaS* *Approved at EMT (Oct-23) and ratified at Trust Board (29-Nov-23)*
1.1	*Reviewed and updated*	*Sept-24*	*Updated to incorporate Patient Safety Incident Analysis and remove SIs. Approved at QPaS (11 September 2024).*

Appendix 2 - Equality Impact Assessment (EIA)

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

1. Document or Process or Service Name: **Engaging and Involving Patients, Families and Staff following a Patient Safety Incident Policy and Procedure**
2. EIA Reviewer (name) **Michelle Ireland**
3. Is it a **Policy**, Strategy, Procedure, Process, Tender, Service or Other? **Policy**

Main Aims of the Document, Process or Service
• The policy outlines how patient, their families and carers will be involved in learning lessons from patient safety incidents • The policy has been developed in line with national guidance and is a requirement of the Patient safety Incident response framework
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	Is the document or process likely to have a potential or actual differential impact with regards to the equality target groups listed?	How have you arrived at the equality impact score?
Age Disability Sex Marriage/Civil Partnership Pregnancy/Maternity Race Religion/Belief Sexual Orientation Gender re-assignment	**Equality Impact Score** Low = Little or No evidence or concern (Green) Medium = some evidence or concern(Amber) High = significant evidence or concern (Red)	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 outlines how patient, their families and carers will be involved in learning lessons from patient safety incidents			
EIA Reviewer	**Michelle Ireland**		
Date completed;	**4 September 2024**	Signature	**Michelle Ireland**