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Date	Version	Who made the changes	Summary of changes
31/10/2023	2.0	Jo Nicholls	Major revision following new reporting system and to bring in line with the new Patient Safety Incident Response Framework
14/08/2024	3.0	Jo Nicholls	Separation of non-clinical incident reporting from patient safety incident reporting Removal of terminology, 'Serious and Untoward Incident, now Patient Safety Incident. Replacement of 72 Hour review with Rapid review (ideally within 24 hours.

			Update in incident investigation timescales in line with National Guidance.
29/11/2024	3.1	Jo Nicholls	Minor revision to align with Trinity Hospice & Palliative Care Services (Trinity) Patient Safety Incident Response Plan (PSIRF)

Consultation / Acknowledgements with Stakeholders

Name	Version	Job Title	Date
David Kay	**2.0**	**Director of Clinical Services**	**10/11/2023**
Clinical Quality Improvement Group	**2.0**		**15/11/2023**
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David Kay	**3.1**	**Director of Clinical Services**	**29/11/2024**
Lancashire & South Cumbria ICB	**3.1**		**28/01/2025**

Policy Overview

This Policy & Procedure supports the requirements of the Patient Safety Incident Response Framework (PSIRF) and sets out Trinity Hospice & Palliative Care Services 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.

If you are reporting any incident that is not a patient safety incident please refer to the E08 Incident & Near Miss Reporting Policy & Procedure for guidance.

Related Policies & References

A09 Complaints Policy & Procedure
A13 Being Open (Including Duty of Candour) Policy Trinity Hospice & Palliative Care Services' Risk Management Policy and Strategy.
A46 Never Events Policy

B06 Disciplinary Policy & Procedure
E01 Trinity Risk Management Strategy and Policy
https://www.cqc.org.uk/guidance-providers/notifications
https://www.england.nhs.uk/patient-safety/incident-response-framework/
RIDDOR – Reporting of Injuries, Disease and Dangerous Occurrences Regulation 1995
https://www.hse.gov.uk/riddor/
Health and Safety at Work Act 1974 https://www.legislation.gov.uk/ukpga/1974/37/contents

Contents

Introduction to Patient Safety Incident Reporting

To comply with national legislation and guidance and bring Trinity Hospice & Palliative Care Services inc. Brian House (Trinity) in line with the new Patient Safety Incident Response Framework (PSIRF), Trinity requires all staff to record **ALL** patient safety incidents or near miss incidents (see definitions on page 3).

A patient safety incident can be described as **''an event or circumstances that *could* have resulted or did result in harm to a patient or patients.**''

Patient safety incidents may be observed, reported, and witnessed by staff and /or any person present including members of the general public. However, it is staff that are responsible for reporting a patient safety incident.

The hospice has in place systems for the reporting patient safety incidents. Incidents and near misses are regularly monitored at Safety Huddle meetings held weekly via Teams. This is attended by appropriate members of the Trinity Management Team (TMT) & staff. Patient safety incidents should also be discussed at departmental or team meetings. All patient safety incidents are reviewed by the Director of Clinical Services once they have been closed to ensure all appropriate recommendations and safety actions have been identified and actioned and to determine if any further thematic reviews are required. Lastly the Clinical Governance Committee have oversight of ALL patient safety incidents via the quarterly Governance Reports for wards to board oversight.

Trinity is committed to enhancing the workplace and patient/service user care standards. All patient safety incident reports underpin risk management systems and procedures helping to:

- Promote a positive, open and non-punitive approach to managing risk and integrated governance.
- Ensure a 'no blame culture' within the organisation.
- Ensure that we learn from our mistakes.
- Ensure family & patient engagement in all patient safety incidents.

Policy & Procedure Aims and Objectives

Trinity's approach to incident management is designed to achieve the following objectives:

- A standardised approach to patient safety incident management across the organisation.
- To ensure that learning from incidents is an integral part of the organisations culture.
- Analysis of trends which may identify the further need for intervention, i.e. a thematic review.
- To improve patient and staff safety by addressing systemic errors.
- To promote a culture of accountability with 'no blame'.

This policy describes the arrangements for reporting near misses and Patient Safety Incidents within the organisation. It aims to:

- Provide guidance to staff, encouraging timely and full reporting of near misses and patient safety incidents.
- Ensure the organisation complies with all Health and Safety, and other relevant legislation.
- Ensure that the organisation complies with the Care Quality Commission, NHS and Medicines & Healthcare Products Regulatory Agency requirements and standards for incident reporting in line with the Patient Safety Incident Response Framework.

The benefits of patient safety incident reporting include:

- Identifying trends across the organisation.
- Making sure areas of concern are acted on.

- Targeting resources more effectively.
- Increasing awareness and responsiveness.
- Increased family inclusion and engagement.

Outcomes will be monitored by identifying:

- The actual impact on the individual / organisation.
- The potential impact on the individual / organisation.
- The likelihood of recurrence.
- The potential future consequences to the individual /organisation of a recurrence.
- Facilitate proactive improvements and safety actions from incidents.
- Minimise, and where possible prevent, incidents from recurring by undertaking a system wide view of causes.

Trinity Hospice follows 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 an investigation conducted for the purpose of learning and improvement.

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.

Trinity shares the ethos of the NHS 'Just Culture' which encourages accountability and responsibility. Where staff have made a mistake, error or a misjudgement, truthfulness and admission is fundamental. **(See Appendix 1)**

Compassionate Engagement Following an Incident

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.
See Appendix 2 on how to achieve compassionate engagement and involvement.

Definitions

- **Hazard:** Anything which has the potential to cause harm.
- **Risk:** the likelihood of the harm (e.g. injury, loss of equipment) actually occurring and the severity of the injury, loss etc (e.g. first aid, fatality) that would result.
- **Patient Safety Incident:** An incident is defined as an untoward event which has happened to, or occurred with a patient(s), the result of which might be harmful or potentially harmful, or which does cause or lead to injury/harm.
- **Accident:** An unplanned, uncontrolled event which has led to injury to a patient.
- **Adverse Event:** Any untoward occurrence which can be unfavourable and has an unintended outcome associated with an incident.

- **Near Miss:** is an unplanned event that did not result in injury or illness – but has the potential to do so. The difference between a near miss and a patient safety incident or accident is often a fraction of a second. Near misses are warnings of accidents or situations in the making. By accepting these warnings and looking for their cause, we can prevent these situations recurring.
- **Unexpected Deterioration in a Patient's Health:** where a healthcare professional is of the opinion that, given the care and treatment the patient is receiving, a sudden deterioration in the patient's health was not to be expected.
- **Reportable Diseases:** any outbreak of infectious disease notifiable under the Public Health Regulations 1988.
- **RIDDOR 2013 Regulations:** Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013. These Regulations require employers, the self-employed and those in control of premises to report specified workplace incidents.

Responsibilities (Ownership & Accountability)

Trinity's Board of Trustees

Has overall legal responsibility for effective organisational risk management and compliance with statutory obligations.

Chief Executive

Ensures Trinity has adequate systems and processes for the reporting and the investigation of all patient safety incidents.

Is ultimately responsible for ensuring the effectiveness of this policy and that the organisation remains compliant with the Health and safety at Work Act 1974 and is the appointed person in respect of Health and Safety.

Finance Director

Has executive responsibility for Trinity's – 'Risk Management Policy and Strategy'.

Director of Clinical Services

Has the lead role for patient safety incident investigation and management.

Has weekly oversight of completed patient safety incidents to ensure if any further action is required and/or request thematic reviews.

Have oversight over patient safety incidents and be the main escalation point for patient safety incidents where the investigation and closure of incidents exceeds 20 days, in line with Trinity's agreed internal incident investigation suggested timescales.

Authorised named person who be responsible for deciding if an incident triggers either a Rapid Review, an After Incident Review (AIR) or a 'PATIENT SAFETY INCIDENT INVESTIGATION (PSII)'.

Ensures that Trinity's Board are appraised of all patient safety incidents and by presenting incident reports as necessary.

Reviews high-level performance reports in relation to incident and investigation management.

Ensures organisational learning, patient safety action plans & areas for improvement following the investigation into reported patient safety incidents are implemented and communicated effectively.

Is responsible for presenting a quarterly report, to the TMT, with a bi–monthly report to the board of Trustees, and providing annual clinical governance report to the Clinical Governance Committee and reporting to outside bodies where required.

Medical Director

The Medical Director will participate in the patient safety incident process and any reviews (where appropriate), to ensure support for the Accountable Officer and any changes in clinical/medical practice.

Members of the Trinity Management Team Executive (TMTE)

Ensure that all staff in their area of responsibility are fully aware of and compliant with this policy, to ensure the timely and effective reporting and investigation of all patient safety incidents.

Ensure that compassionate engagement is for patients and/or families and/or staff when a patient safety incident has occurred.

Ensure that any equipment that may have been involved in the patient safety incident is isolated and/or decommissioned. In the case of patient safety incidents, to ensure any danger areas or areas that may need to be preserved are isolated.

Ensure any patient safety incidents or Never Event is escalated to all members of the TMT Team as soon as possible.

Ensure effective mechanisms and processes are in place to ensure timely reporting and management of patient safety incidents and investigations, against national and local standards, including strict compliance with Duty of Candour & the Patient Safety Incident Response Framework.

Ensure that incident investigation reports are completed comprehensively to a high-quality standard (including patient safety action plans) by no less than 2 working days in advance of any scheduled Trinity patient safety incident meeting. Ensure that recommendations and safety actions resulting from incident investigations are implemented against agreed internal timescales and impact is audited to provide assurance to the Board that learning has taken / is taking place.

Develop mechanisms within their Department(s) for sharing learning effectively within the Department(s), across the wider organisation or, where appropriate, outside the organisation, in a timely manner.

Ensure that trends or themes arising from incidents are reviewed, risk assessed and responded to, by implementing processes that mitigate ongoing risk and/or, where appropriate to do so, manage these via the Clinical Risk Register.

Have overall responsibility for ensuring staff understand the need to report all patient safety incidents, near misses as explained in this policy, to ensure compliances with the organisation's legal obligations.

Quality & Clinical Governance Team

To ensure that the investigation and closure of incidents is done within the agreed internal timescales as specified in this policy and escalate appropriately when any incident is taking in excess of 20 days to

complete. Any patient safety incident investigation involving the family or patient should be completed within agreed timescales following consultation with the patient and/or family.

To ensure that a contemporaneous investigation log containing all open and ongoing investigations is kept up to date and that all closed investigations are archived, and readily available for inspection by internal and external stakeholders.

To ensure a contemporaneous safety action log is maintained and proactively managed, to provide assurance that actions following investigations are managed and closed within agreed timescales. The Action Log is required to be readily available for inspection by internal and external stakeholders.

Ensure that trends or themes arising from incidents are reviewed, risk assessed and responded to, by implementing processes that mitigate ongoing risk and/or, where appropriate to do so, manage these via the Clinical Risk Register.

For reviewing all incidents reported on the Incident Reporting system daily. Any incidents that occur at weekend or bank holidays should be reviewed on the next available working day. This process includes a review of the patient details, cause, group, department, initial severity of harm, never event.

For ensuring that incidents are notified to the correct departments and for escalating, all moderate or above harms are immediately investigated via a rapid review and escalated incidents of concern, for review by the Director of Clinical Services or an appropriate Director.

For reviewing and escalating all rapid reviews for appropriate further investigation. All patient safety incidents should be reported via the Learn from Patient Safety Events (LFPSE) service (i.e. the NHS England national NHS system for the recording and analysis of patient safety events that occur in healthcare).

For notifying relevant managers of agreement for downgrade of harm on the basis of the rapid review, or local initial investigation.

For monitoring and tracking patient safety incident investigations and closures and for providing weekly updates to the Safety Huddle.

For collating both learning from incidents and safety actions resulting from incidents.

Members of the Trinity Management Team (TMT)

Are responsible for ensuring their service or department reports patient safety incidents as soon as possible after the event.

Must ensure their staff and patients are safe.

Must take immediate actions to ensure after reviewing patient safety incident reports within their area of responsibility that they take appropriate action to reduce the risk of re-occurrence or further injury.

Provide support to staff following a stressful or traumatic incident.

Review and confirm the level of harm on the incident report form.

Escalate patient safety incidents, as appropriate, to their Line Manager or the senior management team.

Carry out a risk assessment as appropriate and identify safety actions that would minimise ongoing risk to patients, staff, other persons.

Carry out a timely investigation for all patient safety incidents and update and close incidents as soon as possible after the incident has occurred, ideally within 20 working days (or sooner) of the incident having being submitted, or in line with agreed timescales with the patient and or family where applicable.

On the request of their Line Manager or Senior Management Team, carry out a rapid review, After Incident Review (AIR) or PSII incident investigation, or otherwise support such formal investigations where appropriate to do so.

Ensure learning from incidents and safety actions are shared with their staff.

Support staff to complete patient safety incident forms and provide them with feedback from any investigation or remedial actions that results.

All Staff

Must ensure they report incidents accurately and responsibly through Trinity's Reporting Systems and ensure that all relevant information is included within the report with regards to any incident they have been involved in or witnessed.

Make sure they, patients and other persons are safe.

Must, whilst ensuring their own, patients' and other persons' safety, take immediate reasonable actions to prevent further incidents from happening.

To provide initial care, treatment and support to those affected by the incident.

Inform their manager of the incident straight away and submit an incident report as soon as possible but within 24 hours of the incident occurring.

Seek support as necessary following a stressful or traumatic incident.

Must pro-actively engage with investigations into incidents and promptly provide data and/or information that support the investigations, including providing open, honest and transparent witness statements where required.

Reporting to Outside Agencies

Care Quality Commission

- The Health and Social Care Act 2008 (Regulated Activities) Regulations 2010 requires registered persons to formally notify the Care Quality Commission, about a number of specified events. These are known as statutory notifications and are detailed on the Care Quality Commission Website www.cqc.og.uk . Regulation 28 provides for the notification of events or incidents which may have directly affected the safety of patients.

LIN – Local Intelligence Network

- The Accountable Officer for the organisation is responsible for submitting a quarterly occurrence report to the Local Intelligence Network. The Local Intelligence Network looks at information that is provided to

them around Controlled Drug issues. This is part of the recommendations following the Shipman Inquiry, and the role of the Accountable Officer.

RIDDOR

For how to report and more detailed information about what must be reported (and by when) follow this LINK and select RIDDOR on the left hand side for the most up to date guidance and a link to the HSE website.

NPSA – National Patient Safety Agency

- The NPSA is part of the Department of Health and aims to improve the quality and safety of patients care by informing, supporting and influencing healthcare organisations and individuals working in health.

MHRA – Medicines & Healthcare Products Regulatory Agency

- The Medicines and Healthcare products Regulatory Agency (MHRA) are responsible for protecting and promoting public health and patient safety by ensuring that medicines, healthcare products and medical equipment meet the appropriate standards of safety, quality, performance and effectiveness, and that they are used safely.
- Adverse incidents involving medical devices are reportable. Where the result of investigations of those incident reports has implications for patients or users, the agency will issue a Medical Device Alert (MDA) advising of hazardous products, potential safety issues or unsafe procedures. They should be reported as soon as possible, usually within 24 hours. Serious incidents should be reported by the fastest means available, preferably online or by fax or email and should be confirmed with a telephone call.
- If a relevant incident report is submitted to another body (such as the Health & safety Executive or the National Patient safety Agency), it is essential that a separate report is also sent to the MHRA.
- Examples of medical devices (this list is not exhaustive)
    - Catheters
    - Dressings
    - Examination gloves
    - Hospital beds
    - Hoists and slings
    - Wheelchairs
    - Pressure relief mattresses, cushions or pads
    - Commodes
    - Bathing and showering equipment
    - Blood glucose meters

Integrated Care Board

- As providers of End of Life Care (Specialist Palliative Care) we are required by the Integrated Care Board to report any Patient Safety Incidents to them in relation to their patients via LFPSE.

Levels of Harm

Ensuring the correct levels of harm caused by an incident is vital in ensuring appropriate and timely action is taken in response to any patient safety incident.

No Harm / Near Miss

No harm any incident that had the potential to cause harm but was prevented, resulting in no harm to a patient. This includes a 'near miss'.

Low Harm

Patient(s) required extra observation or minor treatment.

Any unexpected or unintended incident that required extra observation or minor treatment remedial action and caused minimal harm to one or more patients.

Moderate Harm

Patient(s) required further treatment or procedure.

Any unexpected or unintended incident that resulted in a moderate increase in treatment, possible surgical intervention and which caused significant but not permanent harm, to one or more patient.

a) harm that requires a moderate increase in treatment, and

b) significant, but not permanent, harm

"moderate increase in treatment" includes an unplanned return to surgery, an unplanned re-admission, a prolonged episode of care, extra time under care or as an outpatient, cancelling of treatment, or transfer to another treatment area (such as intensive care).

Severe Harm (Permanent or Long-Term Harm)

Any unexpected or unintended incident that appears to have resulted in permanent harm to one or more persons or property.

Severe harm means:

A permanent lessening of bodily, sensory, motor, physiologic or intellectual functions, including removal of the wrong limb or organ or brain damage, that is related directly to the incident and not related to the natural course of the service user's illness or underlying condition.

Unexpected death: Death (Caused by the Patient Safety Incident)

Any unexpected or unintended incident that directly resulted in the death of one or more patient.

Further descriptions of moderate harm and severe harm can be found on the Care Quality Commission (CQC) website:

https://www.cqc.org.uk/guidance-providers/regulations-enforcement/regulation-20-duty-candour#guidance

When attributing the level of harm to an incident, it is important to document the ACTUAL level of harm (based on a best assessment at time of the incident), not the potential level of harm.

For patient safety incidents with moderate or severe harm / unexpected death, Duty of Candour applies. See Duty of Candour Policy.

Never Events

Never Events are incidents that meet all the criteria given below and require full investigation.

Never Events are patient safety incidents that are wholly preventable where guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and have been implemented by healthcare providers. (See Never Events Policy for full details).

WHAT TO REPORT AS A NEAR MISS AND PATIENT SAFETY INCIDENTS

Trinity Hospice and Palliative Care Services welcome knowledge of adverse events as an opportunity to learn for the benefit of our patients and staff.

A patient safety incident can be described as **‘’ an event or circumstances which could have resulted or did result in unnecessary harm, damage or loss to a patient.**’’

A trigger factor is a prompt for staff to generate a patient safety incident report. The following general criteria must always trigger a patient safety incident report:

- Where it is suspected that any person was put at risk, was injured or died as a result of an action or lack of an action.
- Where a patient was injured or died as a result of any procedure, or instructions, lack of proper procedures or a failure to follow current procedures or instructions.
- Where a patient was put at risk , was injured or died due to faulty equipment, drugs or an unsafe environment.
- Where a patient harms him or herself or dies by suicide whilst in the organisations care or employment.
- A fire, flood, theft or other event, which endangers the safety of patients or causes injury or death.
- Any incident resulting in financial or material loss for a patient.
- An incident that had the potential to cause harm but was prevented through the barriers and control measures in place.

Some examples of the core Patient Safety incidents are:

- Tissue viability i.e. a pressure sore
- Falls
- Inappropriate treatment
- Poor, unsafe or inappropriate discharge /transfer
- Patient suicide or self-harm
- Patient record and record keeping issues
- Patient abuse
- Unexpected injury or death
- Patient absconding
- Incidence of MRSA Bacteraemia
- A medication error

Staff are reminded that near misses should also be reported as patient safety incidents. A near miss is a situation in which an event or incident fails to develop further. It is an incident that had the potential to cause harm but was prevented through barriers and control measures in place.

PROCEDURE FOR REPORTING NEAR MISSES AND PATIENT SAFETY INCIDENTS

There is a system for reporting **ANY** patient safety near misses *and* incidents. **See the Reporting an Incident Flowchart in Appendix 3.**

ALL Patient Safety Incidents, should be reported via the incident reporting system that can be accessed via the Trintranet Home page.

Go to the Trintranet Home Page and select the 'Incident Reporting' icon on the right hand side... and follow the on-screen prompts.

Please complete all sections and provide as much detail as possible about what happened, including the names and roles of everyone involved in the incident and whether any harm was sustained (or could potentially have been please remember that it is important to report near misses).

THINK - If someone was reading your report would they know exactly what happened, where it happened, to whom and what harm was caused (or could have been).

If you think something would prevent this sort of incident happening again include this, as this helps us investigate and learn from incidents.

If you are not sure ask! You can contact Jo Nicholls, Clinical Quality & Governance Lead for further guidance or Katy Green Governance Administrator.

The incident must be reported as soon as possible following the incident or near miss.

You must only record facts and not include assumptions or make guesses.

If you have doubts as to whether a circumstance actually constitutes a near miss or incident and therefore needs reporting, check with your line manager or report it anyway and you will receive feedback and it will not be logged as an incident.

In addition to this **ALL patient safety incidents relating to a specific patient** should routinely be reported on the patients own EMIS record **unless**;

- As this information can be viewed by anyone involved in the patients clinical care, including GP's and District Nurses, if the incident involves an external agency or any sensitive information please consider if the patients record is the most appropriate place for this to be recorded. If you feel that there is sensitive information complete a summary on EMIS and then give details on the internal reporting system, ***(See reporting an incident section below).***

- We need to ensure transparency in all patient incidents so this should only be done where you feel there is a legitimate reason for not inputting the full details on EMIS. ***(See the Reporting an Incident on EMIS section below)***

1.0 Reporting an Incident

Important: Please consider if an incident requires **immediate attention** you will need to alert an appropriate manager or nurse in charge. Completing and submitting an incident form is important but you may need to take more immediate action. Make sure you have resolved/reduced the immediate risks involved in the near miss/ incident and document this on the incident report.

It is important that incident/near miss forms reduce the chances of the same incident happening again but do not replace the need for action to resolve the immediate problem.

Remember to log any Maintenance issues that require action in the Maintenance reporting system on the Trintranet Home page. If something needs urgent attention call the Maintenance Manager first (unless out of hours) and then log the Maintenance Task. (Refer to F02 Maintenance Policy for more details.)

1.1 ALL STAFF

Make sure you, patients and/or other persons are safe.

Where safe to do so, take immediate reasonable actions to ensure no further incidents can happen and/or minimise ongoing risk.

Provide initial care, treatment and support to those affected by the incident.

Report the incident via the Trintranet, (See above).

1.2 Reporting Patient Safety Incidents on EMIS

If a patient safety incident directly involves a specific patient: you should report the incident on EMIS directly using one of the EMIS Incident Reporting Templates (See reporting an Incident) .

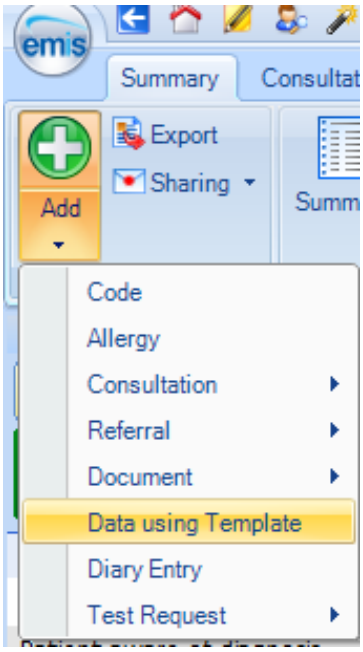
To alert the relevant TMT member automatically via an automatically generated email and allow for review please **also** follow the link on the Trintranet as above and record just basic information to show that you have reported it on EMIS. You only need to select the relevant 'incident category' and in the 'Incident Headline' record the NHS number.

All other patient safety incidents that do not involve a specific patient but could or did lead to the harm to patients: e.g. Pharmacy ONLY incident, should be reported via the Trintranet, See the ALL STAFF section above.

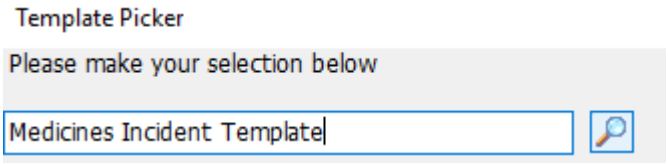
When an incident is reported on EMIS it will be visible to all staff involved in that patients care and everyone will be able to understand what has happened, making the process more transparent and allowing staff to act quickly and make any adjustments necessary to reduce the likelihood of the same thing happening again.

The following are instructions on how to report incidents via EMIS and access the templates.

If you need to report a clinical incident that relates to an individual patient go into their patient record on EMIS and go onto the summary page. Then select Add Data using Template.



Type in the name of the template you want to use and click on the spy glass:



The name of the reporting templates available are:

Medicines Incident Template

Falls Incident Template

Pressure Ulcer Incident Template

Other Patient Incident Template – *To be used for any incident involving an individual patient which is not a Fall, Medication Incident or Pressure Ulcer.*

Duty of Candour Template – *To be used when this is done after an incident i.e. the following day due to the time of the day the incident occurs.*

Additional Specialist Templates to be used in specific circumstances include:

Medical Review Following Incident Template – *To be used by medical staff to record when a medical review of a patient has been requested following an incident.*

Pressure Ulcer Risk Assessment Review Template – *Can be used by a sister or senior member of staff when a patient is reviewed following the report of a Pressure Ulcer.*

Falls Risk Assessment Review Template – *Can be used by a sister or senior member of staff when a patient is reviewed following the report of a Patient Fall.*

Medicines Incident Risk Assessment Review Template - *Can be used by a sister or senior member of staff when a patient is reviewed following the report of a Medicines Incident.*

Other Patient Incident Risk Assessment Review Template - *Can be used by a sister or senior member of staff when a patient is reviewed following the report of an Other Patient Incident.*

Once selected complete the template in as much detail as possible.

Once you have used the template once it will appear automatically in your list of templates so you only need to search once for each template when you use it for the first time.

1.3 Patient Safety Incidents that Occur Out of Hours

If the patient safety incident occurs out of working hours (outside 09.00am to 17.00pm Monday to Friday), the Senior Nurse on Duty must be informed and an incident report & EMIS template completed and submitted as above.

Normal procedures as described above should also still be followed and actions taken in order to sufficiently control the situation and/or prevent the chance of a recurrence before working hours recommence.

For *emergency* out of hours Maintenance issues that cannot wait until working hours recommence (e.g. a leak) then consult the maintenance contractors list in the Nurses Useful Information Folder, located in the Nurses Office on the In-Patient Unit.

Escalating Concerns: In addition, if the Senior Nurse on Duty considers that it is not possible to sufficiently control the situation to a safe level and/or prevent the chance of an unacceptable recurrence before working hours recommence then they must notify the Manager on-call.

2.0 What happens once the incident form is submitted?

The trinity.governance@nhs.net mailbox will be checked each working day and any incidents submitted highlighted to the relevant staff, TMT member(s) and director(s) for consideration and investigation in line with PSIRF.

2.1 Procedure Following a Report of an Incident

Carry out an initial **patient safety incident review**.

When reviewing an incident review please remember; more often than not, there is a fellow human being at the centre of the incident, who may have been harmed.

Support patients, their families and colleagues affected by the incident.

Investigate incidents promptly and thoroughly.

Focus on learning and safety actions with the aim to preventing or minimising an incident of a similar kind from occurring again.

Seek advice and help – communicate with the Quality & Governance Team, who can provide help and support.

If indicated a rapid review and/or an After Incident Review (AIR) may be directed by the Director of Clinical Services or an appropriate Director.

See the Level of Investigation Flowcharts in Appendix 4.

A 'rapid review'

Following a patient safety incident, a rapid review may be required to be carried out by an appropriate member of staff appointed by the Director initiating the review. The Director or Clinical Services can request a rapid review on any incident where it is deemed necessary regardless of the level of harm caused, in line with PSIRF. This will typically be undertaken by a person with relevant expertise, but who is not involved in the care of the patient and was not involved in the incident. The purpose of the rapid review is to:

- Establish what happened, in context
- Establish the current condition of the patient or person(s) harmed
- Identify the immediate safety actions which have been taken to maintain safety
- Identify the initial areas of learning
- Confirm the level of harm to the patient
- Establish what further lines of enquiry are required, i.e., After Incident Review (AIR) or

- In case of some incidents, the rapid review may also be accepted as the conclusive investigation report.

It is essential that the rapid review is completed as soon as possible after the incident, ideally within 72 hours (3 working days) or sooner from the incident having been reported and has received Director sign-off prior to submission to the Quality & Governance Team. Compliance against this standard is monitored by the Trinity Executive Team with the assistance of the Quality & Governance Team.

Trinity's Rapid Review Template can be found in Appendix 8:

Duty of Candour

The statutory Duty of Candour is a legal duty to be open and honest with patients (or 'service users'), or their families, when something goes wrong that appears to have caused or could lead to significant harm in the future. It applies to all health and social care organisations registered with the regulator, the Care Quality Commission (CQC) in England. Please see Trinity's Duty of Candour Policy for full details.

Levels of Investigation

All patient safety incidents and near misses are reported on the Incident Reporting System and require a patient safety incident review by a member of the TMT to determine appropriate action and areas for improvement and safety actions and themes.

The following levels of investigation are to be carried out in the event of an incident:

Level 1 – Patient Safety Incident Review Investigation

Are carried out for:

- ALL patient safety incidents.

Level 2 - Rapid Review

Are carried out for:

- If requested by the Director of Clinical Services or on the direction of the appropriate Director for any incident when indicated.

Upon completion of the rapid review, should further investigation be required, the level of investigation is determined by the Director of Clinical Services or on the direction of the appropriate Director.

Level 3 - After Incident Review (AIR)

Are carried out for:

- Incidents confirmed as moderate harm that require further investigation.
- Incident trends / cluster reviews / thematic reviews.
- Some near miss incidents (on the direction of the appropriate Director).

Level 4 - Patient safety incident investigation (PSII)

Are carried out for:

- Severe harm / death incidents

• Moderate harm incidents or some serious near miss incidents (on the direction of the appropriate Director.)

In exceptional circumstances, an external / review investigation) may be carried out.

Incidents resulting in severe harm or unexpected death are to be submitted by the Director of Clinical Services to the Integrated care Board (ICB). For some incidents, direct contact may be made by a member of the senior leadership team with the ICB, and the Care Quality Commission (CQC). However, this timescale may be reasonably extended if the rapid review is expected to re-assign the level of harm. In such case, the local ICB and the CQC will be kept informed.

Managers should aim to have reviews completed as soon as possible following the incident but should aim to have them completed within the following timescales where possible:

• **20 working days** to close no harm / near miss / low harm patient safety incidents on the Incident Reporting System, from the date of the incident has been reported. (providing a more in-depth review hasn't been indicated.)

• **3 working days** for a rapid review to be carried out from the date of the incident has been reported and the requirement for a rapid review indicated by a relevant director.

• **30 working days** to undertake an After Incident Review for any incident requiring further investigation as directed, from the date of the incident has been reported.

• **6 Months** to complete a Patient safety incident investigation (PSII) investigation as directed, from the date of the incident having been reported. Timescales should always be agreed in consultation with the patient and/or family.

Trinity considers that prompt and thorough investigations into incidents demonstrate due respect, consideration and empathy to anyone involved and helps them to make sense of when something has gone wrong. It also helps Trinity to make swift improvements and safety action for everyone's benefit.

Thematic Reviews

There may be occasions where themes are identified in reported incidents. All patient safety incidents are reviewed and logged centrally by the Quality & Clinical Governance Team. All closed patient safety incidents are reviewed by the Director of Clinical Services and themes considered. If required a thematic review will be directed to be completed by a suitable member of staff. All thematic reviews will identify safety actions, where appropriate and this will form part of Trinity's annual audit programme and the outcome shared at board level and disseminated appropriately to all Clinical staff.

Equality & Inclusion

Trinity strives to reduce inequalities and improving access to all its services, tailoring our around the needs of the local population in an inclusive way.

Trinity is committed to delivering on the Equality Act, (2010) and will use data intelligently to assess any disproportionate patient safety risk to patients from across the range of protected characteristics.

We will address any features of an event which indicate health inequalities, that may have contributed to harm or demonstrate an ongoing risk to any population group, including all protected characteristics. When creating safety actions in our patient safety learning responses we will consider inequalities. Trinity will work to address health inequalities as part of our safety improvement work.

Engagement of those involved (patients, families/carers, and our people) following a patient safety event is crucial to our patient safety learning responses. We will ensure that we use available tools to include easy read, translation, and interpretation services alongside any other method appropriate to meet their needs and maximise the potential of being involved.

Information resources produced by Trinity can be made available in alternative formats, such as easy read or large print and may be interpreted upon request. These requests can be made to our Quality & Clinical Governance team.

Trinity adopts a zero tolerance of racism, discrimination, and unacceptable behaviours from and towards our staff, patients and their families.

The role of Lancashire & South Cumbria Integrated Care Board (L&SC ICB) in PSIRF

L&SC ICB have a responsibility to establish and maintain structures to support a co-ordinated approach to oversight of patient safety incident response in all the services within their system.

L&SC ICB have approved and signed off this patient safety incident response policy and plan ensuring they have been developed according to PSIRF guidance and meet (or demonstrate a plan to meet) the patient safety incident response standards.

L&SC ICB will assess whether the systems and processes put in place effectively respond to patient safety incidents for the purpose of learning and improvement by reviewing all patient Safety Incidents and associated action in response to them via the quarterly provider submission.

Reporting to the Learn From Patient Safety Events service (LFPSE)

All patient safety incidents must be reported to the Learn From Patient Safety Events service (LFPSE).

Appendix 1 – A Just Culture Guide

A just culture guide

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

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

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

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

Please note:

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

Start here - **Q1. deliberate harm test**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

if **No**

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

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

Appendix 2 - How to achieve compassionate engagement and involvement

This guidance is designed to ensure staff consider if the correct support mechanisms are available to anyone involved in a patient safety incident and, where necessary, signpost to other professionals, agencies or groups so that patients, families, carers and staff are 'supported' through an investigation process in accordance with their personal needs.

It tries to prevent compounded harm during the investigation process. A 'Learn Together' study found that those affected by patient safety incidents overwhelmingly felt that a compassionate approach to investigation would help them feel supported and reduce any additional harm, such as erosion of trust in the organisation and feelings that duty of care had been removed.

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

The PSIRF supports development of a patient safety incident response system that prioritises compassionate engagement and involvement of those affected by patient safety incidents.

'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 document uses the term 'engagement lead' to refer to anyone who leads on engaging with and involving those affected by a patient safety incident.

There are compelling moral and logical arguments for engaging with those affected by a patient safety incident and involving them in a learning response.

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 harm4. 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.

Due to the range of incidents that can occur, and the different needs of individuals affected, the principles should be flexibly applied when engaging with or involving those affected by patient safety incidents in an investigation.

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.

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 (eg 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. Therefore, all communications and materials need to clearly describe the process and its purpose, and not assume any prior understanding.

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.

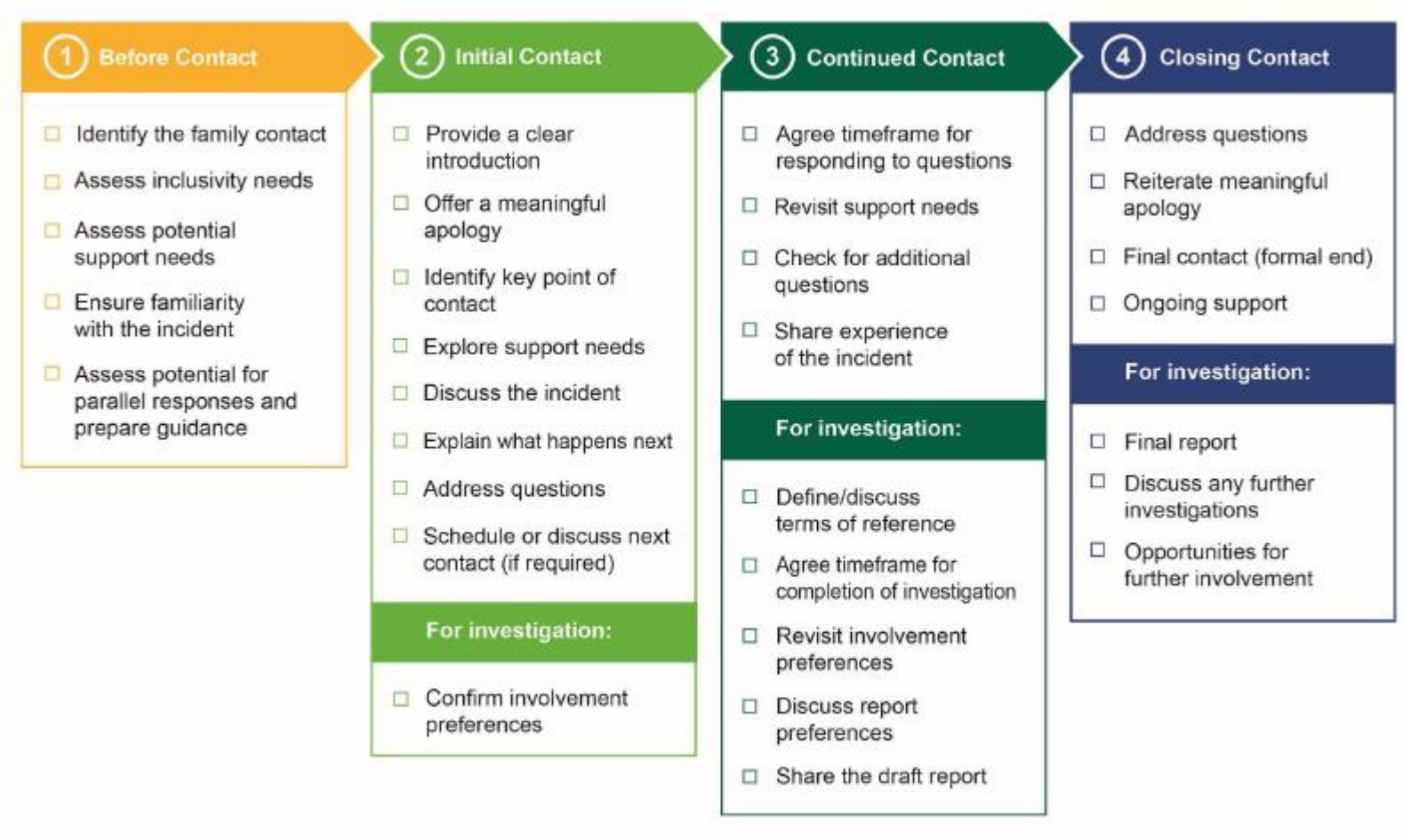
7. Approach is collaborative and open an investigation process that is collaborative and open with information, and provides answers, can reduce the chance litigation will be used as a route for being heard. The decision to litigate is a difficult one. Organisations must not assume that litigation is 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.

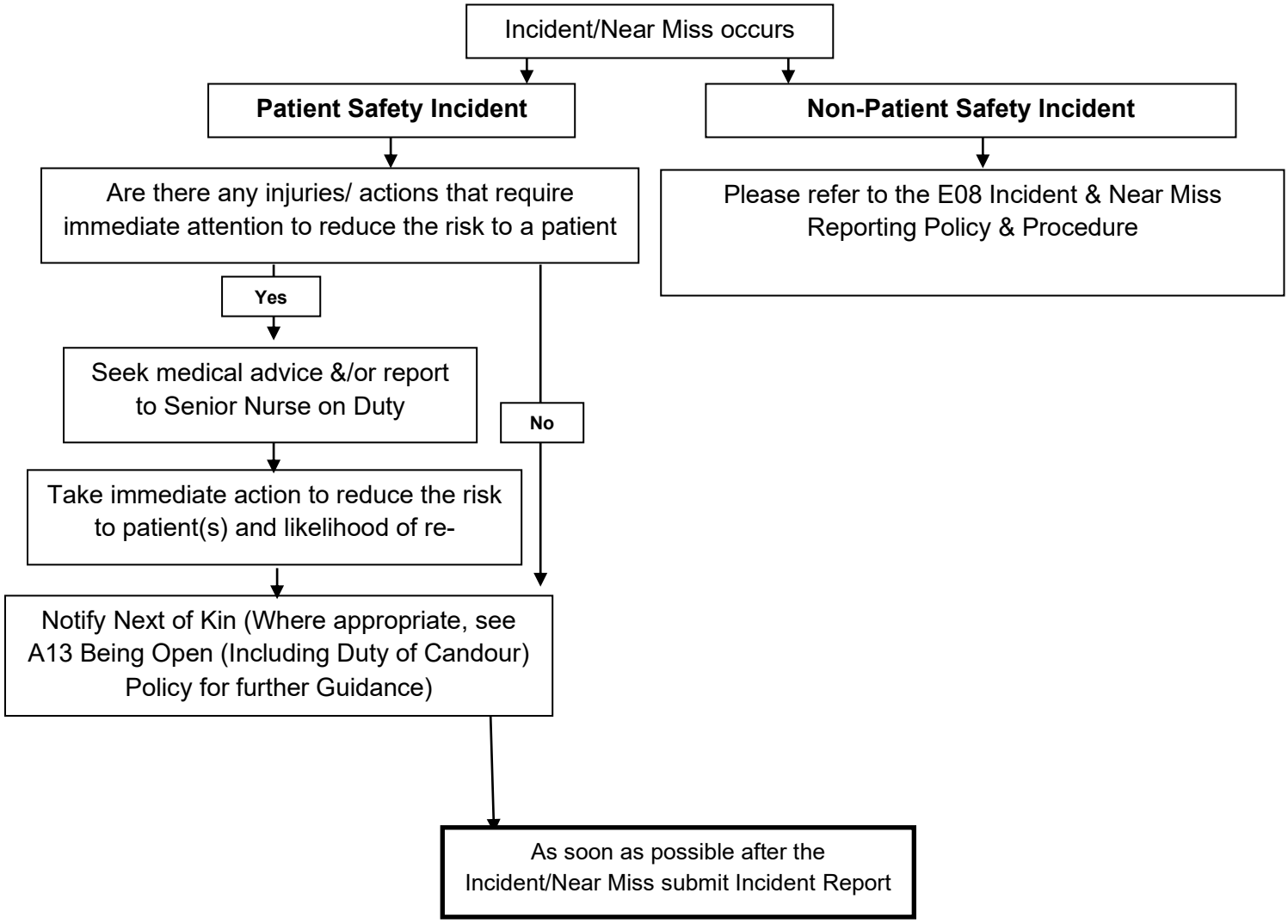
9. Strive for equity
Organisations may differ from patients, families, and healthcare staff in what they consider is the appropriate response to a patient safety incident. The opportunity for learning should be weighed against the needs of those affected by the incident. Engagement leads need to understand 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.

Please refer to the Engagement and involvement procedure for more guidance. (Summarised in figure 1 below).

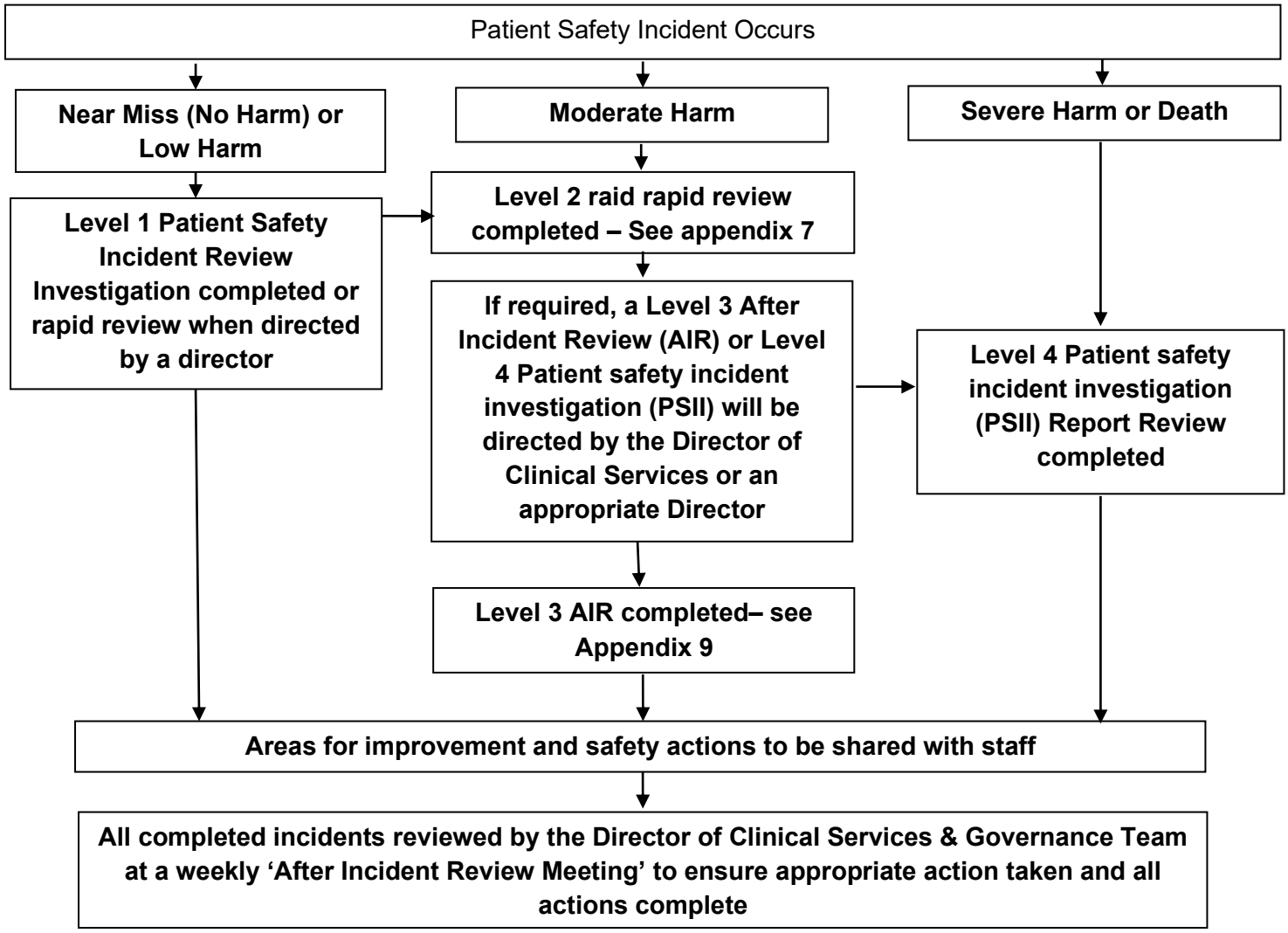
Figure 1 – Four steps of engagement



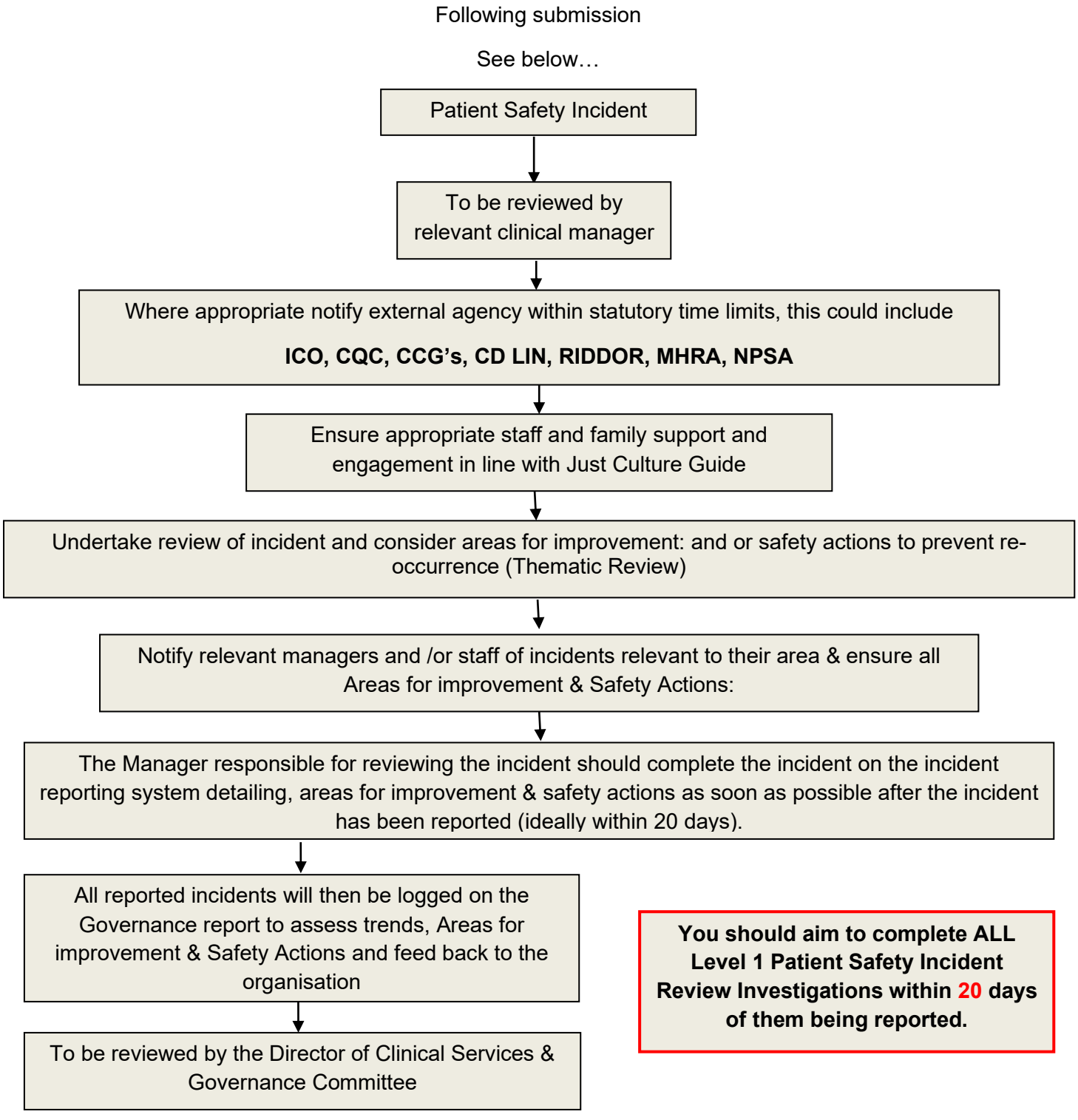
Appendix 3 - Incident Reporting Flowchart



Appendix 4 Level of Investigation Flowchart



Appendix 5 - Following up on a reported patient safety incident – areas for improvement and safety actions



Appendix 6 - GUIDANCE NOTES FOR ALL PATIENT SAFETY INCIDENT REVIEWS

Incident Investigation

- Use the System Engineering Initiative for Patient Safety (SEIPS) framework to investigate all patient safety incidents. (See Appendix 7 for more details)
- Purpose is to identify the potential causes for an incident and identify recommendations to prevent / minimise a similar incident from happening again.
- Be open and transparent.
- Compose a chronological timeline, with no gaps - be factual
- Ensure compassionate engagement with staff / patient / NOK / family as soon as possible after the incident – ideally within 72 hours.
- Organise a Review Meeting at the earliest opportunity; invite at least one independent panel member.
- Conclude the investigation, describe suggest recommendations and Safety Actions.
- Create a Safety Action Plan; requires SMART (Specific, Measurable, Attainable, Relevant and Time-bound) actions – it is *not* about number of actions, **it is about quality of actions**
- Pass for Director oversight and sign-off.
- Keep everyone involved in the investigation updated and share the outcome of the investigation.
- Implement Safety actions and audit compliance with any new processes / guidance introduced.
- Share learning with colleagues within the Department and across the organisation (where directed).

****The Level 1 Patient Safety Incident Review Investigations should ideally to be completed within 20 days of the incident occurring.**

Please note: Trinity may share the incident report as a conclusive investigation report with the patient / NOK / family and external agencies, so please ensure a high-quality, presentable report, written for the lay-person to understand**

Appendix 7 - An introduction to System Engineering Initiative for Patient Safety SEIPS

Healthcare is a complex socio-technical system. Healthcare is complex because it is highly variable, uncertain, and dynamic. Healthcare is a socio-technical system because it is characterised by multiple interactions between various components, both human and technological.:

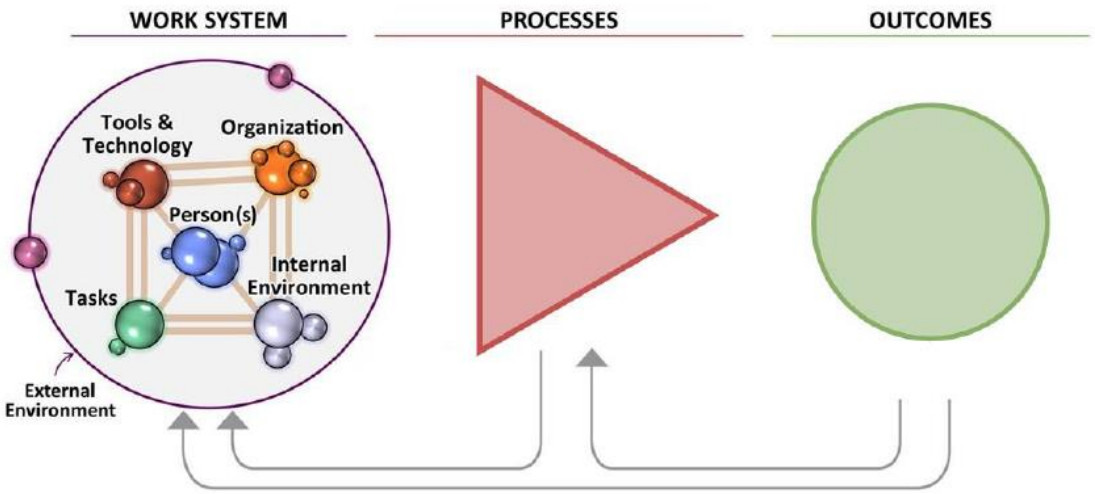
What is SEIPS?

SEIPS is a framework for understanding outcomes within complex socio-technical systems.

Figure 1 provides an overview of the System Engineering Initiative for Patient Safety (SEIPS) framework, combining SEIPS 2.01 and SEIPS 1012. The figure It describes how a **work system** (or socio-technical system, left) can influence **processes** (work done, middle), which in turn shapes **outcomes** (right).

The SEIPS framework acknowledges that work systems and processes constantly adapt (see arrows in Figure 1).

Figure 1. Overview of the SEIPS framework



What are the different parts of the work system?

A ‘work system’ consists of six broad elements: external environment, organisation, internal environment, tools and technology, tasks and person(s). Figure 2 provides a brief overview of the different elements and potential contributory factors to consider during a learning response.

People cannot be separated from the work system; their deliberate placement at the centre emphasises that design should support – not replace or compensate for – people.

Using SEIPS to learn from patient safety incidents

SEIPS can be used as a general problem-solving tool (eg to guide how we learn and improve following a patient safety incident, to conduct a horizon scan, and to inform system design).

Figure 3 (the work system explorer) provides questions to help explore different work system elements. Figure 4 provides a blank template; this is also available as a MS PowerPoint.

Patient safety incidents result from multiple interactions between work system factors. SEIPS prompts us to look for interactions rather than simple linear cause and effect relationships. When a learning response thoroughly examines the different work system components and their interactions safety actions can focus on wider system issues, not individuals.

Figure 2. Overview of the SEIPS work system

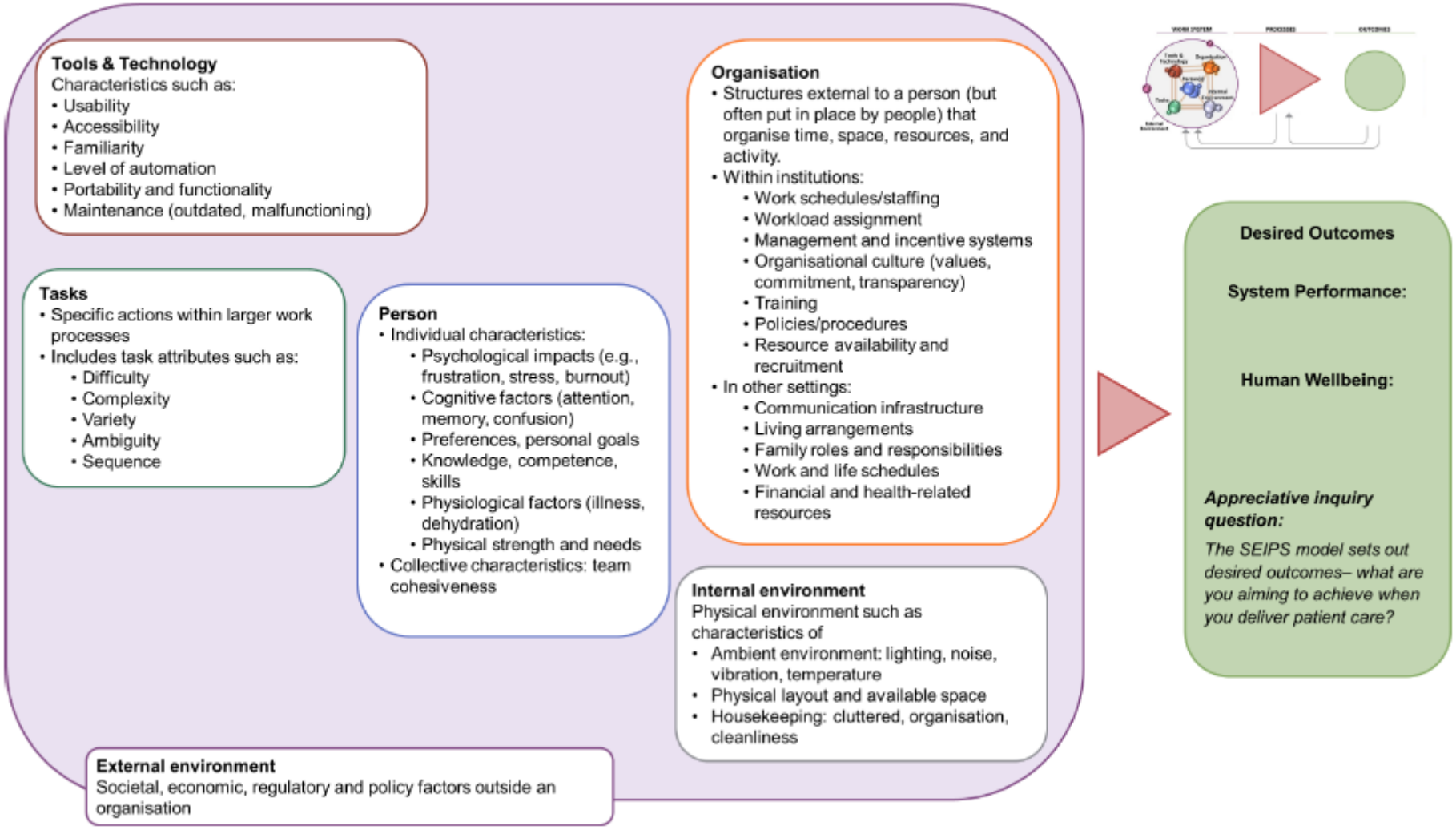


Figure 3. SEIPS work system explorer questions

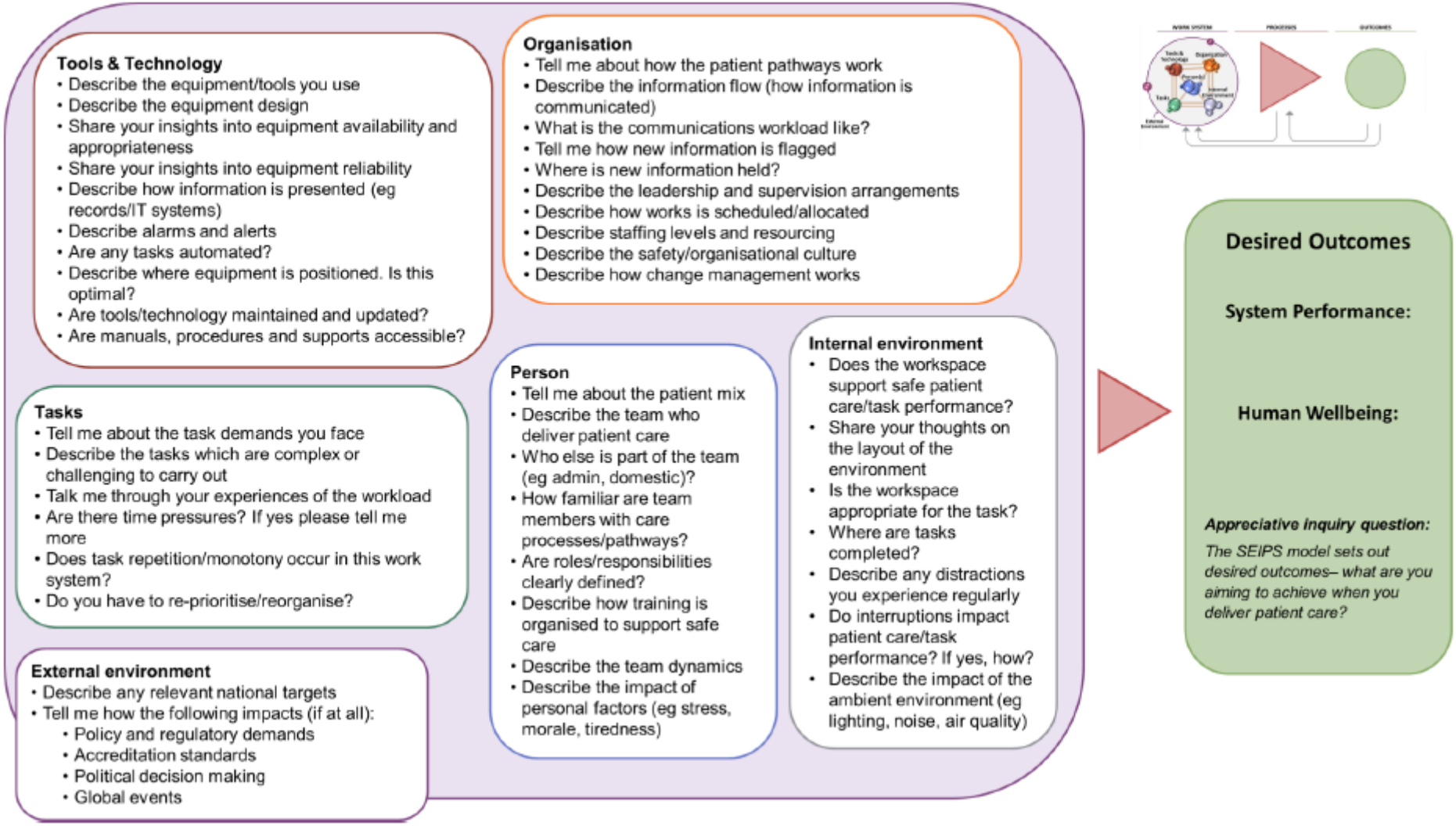
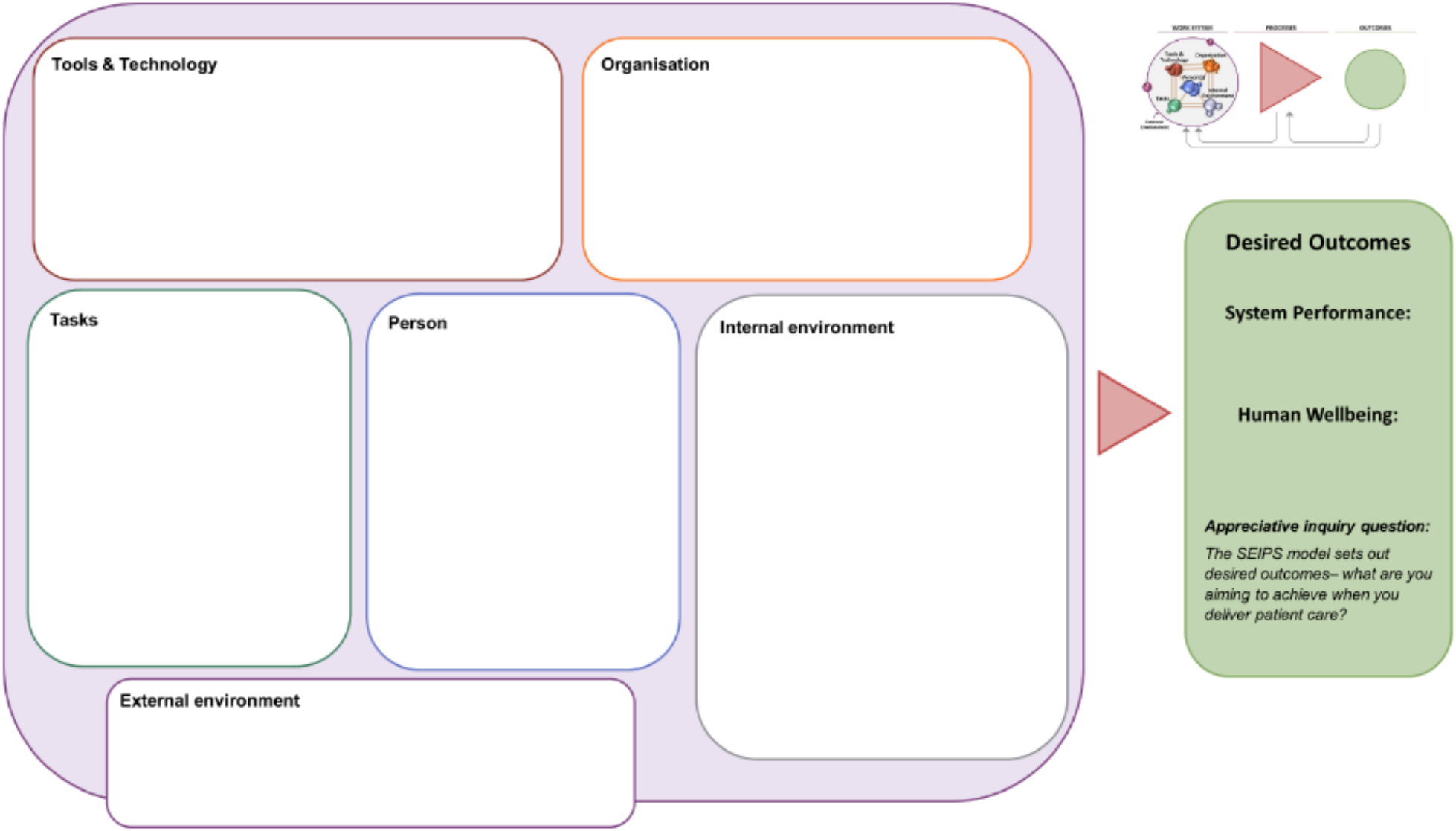


Figure 4. SEIPS work system template



Appendix 7 - GROUND RULES AND GUIDANCE NOTES FOR INVESTIGATING INCIDENTS (INCORPORATING RAPID REVIEW & AIR)

General ground rules and guidance notes:

- Ensure all relevant Senior Managers / Directors have been notified. When out of hours, escalate to the Senior Manager / Director on call.
- Seek advice and help – communicate with the Quality & Governance Team, who can provide help and support.
- Keep all relevant Senior Managers / Directors up to date.
- Before communicating with external agencies (e.g. CQC, ICS, Coroner, NHSE&I etc.), liaise with the relevant Senior Manager / Director (when out of hours, discuss with the Senior Manager / Director call / Out of Hour Manager On Call).
- Take it very seriously – more often than not, there is a fellow human being at the centre of this, who may have been harmed.
- If required, collect statements from staff / patient / NoK / family / injured party as soon as possible – ideally within 72 hours.
- Investigate promptly and thoroughly.
- Be open and transparent.
- Focus on learning – preventing or minimising an incident of a similar kind from occurring.
- Support patient / family / colleagues affected by the incident / keep them informed.
- Be timely with your investigation; stick to timescales.
- Conclude the investigation, describe cause/s and suggest recommendations.
- Ensure the report is of a high-quality, presentable standard, free from spelling and grammatical mistakes.
- Create a Plan of Action; requires SMART (Specific, Measurable, Attainable, Relevant and Time-bound) actions – is not about number of actions, it is about quality of actions.
- Upload all relevant information / report onto the incident reporting system & complete 'areas for improvement and safety actions' section.

Ground rules and guidance notes for Plans of Actions:

- Plan of Action requires SMART (Specific, Measurable, Attainable, Relevant and Time-bound) actions.
- It is *not* about number of actions, **it is about quality of actions.**
- Implement actions + audit compliance with any new processes / guidance introduced.
- Share learning with colleagues.

Ground rules and guidance notes for post-investigation actions:

- Provide ongoing proportionate support to patient / family / NOK / colleagues affected by the incident.
- Inform the patient / NOK / family to inform them that the investigation has concluded. Arrange for the report to be shared with the patient / NOK / family, in line with their preference + offer a meeting – relevant staff to ensure they prioritise availability for such meeting.

Appendix 8 - Level 2 – RAPID REVIEW FORM

****THIS FORM SHOULD BE SUBMITTED TO THE DIRECTOR WHO REQUESTED IT ASAP AFTER THE INCIDENT HAS BEEN REPORTED (IDEALLY WITHIN 72 HOURS)****

Patient Safety Incident Details		
Incident date:		
Incident number:		
Area/Department where the Incident Occurred:		
Date rapid review finalised:		
Duty of Candour (Where Applicable)		
DoC Lead:		
Initial Verbal Undertaken	No ☐ Yes ☐ Date undertaken: Method: Face 2F/Phone Call etc.	
Initial DoC Letter Sent	No ☐ Yes ☐ Date Undertaken:	
Reason for DoC non compliance:		
Rapid Review Lead		
Name/s and designation of staff undertaking the review:	**Name**	**Designation**

BRIEF DESCRIPTION OF THE INCIDENT:

What Happened in the incident?
Situation:
Background:
What is the current condition of the person harmed?

What immediate actions have been taken to maintain safety
Action Taken:
Further Action Required at this stage:

What are the areas of initial Areas for improvement?
initial Areas for improvement:

What further lines of enquiry are required	
Is further investigation required?	No ☐ Yes ☐
If so: what level of investigation	SI ☐ Concise ☐ N/A ☐
Specific areas for review within the investigation:	

DESCRIBE THE IMPACT ON THE PERSON INJURED AND THE LEVEL OF HARM:

Confirmed level of attributable harm

DIRECTOR SIGN OFF:

Name	Designation	Department	Date

Safety Action(s)	Date

Confirmed level of harm:

Further investigation required? No ☐ Yes ☐

GUIDANCE NOTES FOR A LEVEL 2 - RAPID REVIEW

Rapid Review:

- Establish what happened, in context.
- Establish the current condition of the person/people the incident affected.
- Identify the immediate actions which have been taken to maintain safety.
- Identify the initial areas of learning.
- Confirm the level of harm caused.
- Establish what further lines of enquiry are required, i.e., After Incident Review (AIR)
- Quality Check & Sign-off by relevant Director.
- Once approved, Quality & Governance Team to upload the final version of the Rapid review to the incident reporting system.

****The rapid review is required to be completed (i.e. report with the relevant Director), ideally within 72 hours (3 days) of the incident occurring.**

Please note: Trinity may share the rapid review report as a conclusive investigation report with the patient / NoK / family and external agencies, so please ensure a high-quality, presentable report, written for the lay-person to understand**

Appendix 9 AFTER INCIDENT REVIEW (AIR) REPORT

Incident Number:	**Patient NHS Number:**	**Investigation Author:**
Date of Incident: **Date Incident reported:**	**Patient Date of Birth:**	**Date of report:**
Incident Category:	**Department/area:**	**Version:**
Duty of Candour Lead:		
Details of duty of candour notifications with persons affected by the incident:	Include brief details and dates of the initial duty of candour communication and any follow up communication. Also include here how the outcome of the investigation and report will be shared with the patient/NOK/family.	
Patient/Service User/Family Engagement:	Describe how the patient/service user/family has been engaged in the process. Describe any concerns which the patient/service/family user has requested to be explored.	
Staff Involvement	In brief outline what support and debrief has been provided to staff involved in the incident and what has occurred. Refer to staff involvement with the investigation and how the report findings will be shared with the staff.	
	Discussion points	
Overview of the incident:	Brief overview of incident:	
Investigation analysis and key findings:	What happened? Any issues identified, and what impact they had on the incident and outcome? Any areas of good practice identified?	

Conclusion:	

Areas for improvement and safety actions

Areas for improvement:	
Safety action:	
To be actioned by:	
Due date:	
Areas for improvement:	
Safety action:	
To be actioned by:	
Due date:	

Timeline of events

Point No.	Date	Time	Event / what happened	Gaps/omissions in care or treatment identified	Information Source

Sign Off

Confirmed Severity: No Harm/Minimal Harm/Moderate Harm/Severe Harm/Unexpected Death

Director of Clinical Services Approval	Designation:	Name:	Signature:	Date:.

GUIDANCE NOTES FOR A LEVEL 3 – AFTER INCIDENT REVIEW

After Incident Review (AIR)

(Moderate Harm incidents, incident trends / cluster reviews, or some near miss incidents as directed)**:**

- The After Incident Review (AIR) process is a structured approach to undertaking a de-brief and a constructive way of identifying areas for improvement and safety actions. The After Incident Review (AIR) follows the same principles of the '*After Action Review*', which was first used by the US army on combat missions to reflect on the work of a group and identifying strengths, weaknesses and areas for improvement.
- An AIR is constructed of four questions:
  1. *What was expected to happen*?
  2. *What actually occurred*?
  3. *Why was there a difference*?
  4. *What can be learned*?
- Once the AIR report has been produced, Quality Checking and final sign-off will be completed by the relevant Director.

****The AIR investigation is required to be completed (i.e. report with the relevant Director) as soon as possible after the incident has occurred but timescales may depend on family and staff engagement. It is important to clearly communicate expected timescales and agree them with all parties involved in the investigation.**

Please note: Trinity may share the AIR report as a conclusive investigation report with the patient / NOK / family and external agencies, so please ensure a high-quality, presentable report, written for the lay-person to understand**

Appendix 10 - Patient safety incident investigation (PSII) report

Incident ID number:	
Date incident occurred:	
Report approved date:	
Approved by:	

Distribution List			
Name:		**Job Role:**	

About Patient Safety Incident Investigations

Patient safety incident investigations (PSIIs) are undertaken to identify new opportunities for learning and improvement. PSIIs focus on improving healthcare systems; they do not look to blame individuals. Other organisations and investigation types consider issues such as criminality, culpability or cause of death. Including blame or trying to determine whether an incident was preventable within an investigation designed for learning can lead to a culture of fear, resulting in missed opportunities for improvement.

The key aim of a PSII is to provide a clear explanation of how an organisation's systems and processes contributed to a patient safety incident. Recognising that mistakes are human, PSIIs examine 'system factors' such as the tools, technologies, environments, tasks and work processes involved. Findings from a PSII are then used to identify actions that will lead to improvements in the safety of the care patients receive.

PSIIs begin as soon as possible after the incident and are normally completed within three months. This timeframe may be extended with the agreement of those affected, including patients, families, carers and staff.

If a PSII finds significant risks that require immediate action to improve patient safety, this action will be taken as soon as possible. Some safety actions for system improvement may not follow until later, according to a safety improvement plan that is based on the findings from several investigations or other learning responses.

The investigation team follow the Duty of Candour and the Engaging and involving patients, families and staff after a patient safety guidance in their collaboration with those affected, to help them identify what happened and how this resulted in a patient safety incident. Investigators encourage human resources teams to follow the Just Culture guide in the minority of cases when staff may be referred to them.

PSIIs are led by a senior lead investigator who is trained to conduct investigations for learning. The investigators follow the guidance set out in the Patient Safety Incident Response Framework and in the national patient safety incident response standards.

A Note of Acknowledgment

In writing this report it is important to acknowledge and thank all those who participated in the investigation and gave their time to share their thoughts including 'the patient', 'the patient's family and/or Next of Kin', and 'staff' (Please delete as appropriate) Thank you for engaging with this investigation and for your openness and willingness to support improvements.

Executive Summary

Incident Overview

Summary of key findings

Summary of areas for improvement and safety actions

Background and Context

Description of the patient safety incident

Investigation approach

Investigation team

Role:	Job Title:	Department:
Investigation commissioner/convenor:		
Investigation lead:		

Summary of investigation process

Terms or reference

Information gathering

Findings

Summary of findings

Areas for improvement

Safety actions

Safety Actions Summary Table								
Area for improvement:								
No.	**Safety action description** ***(SMART)***	**Safety action owner**	**Target date for implementation**	**Date Implemented**	**Tool/measure**	**Measurement frequency** ***(e.g. daily, monthly)***	**Responsibility for monitoring/ oversight** ***(e.g. specific group/ individual, etc)***	**Planned review date**

Safety Actions Summary Table								
Area for improvement:								
No.	**Safety action description** ***(SMART)***	**Safety action owner**	**Target date for implementation**	**Date Implemented**	**Tool/measure**	**Measurement frequency** ***(e.g. daily, monthly)***	**Responsibility for monitoring/ oversight** ***(e.g. specific group/ individual, etc)***	**Planned review date**

Appendices (Delete if not required)

References (Delete if not required)

GUIDANCE NOTES FOR COMPLETING A PATIENT SAFETY INCIDENT INVESTIGATION (PSII) REPORT

General writing tips

A PSII report must be accessible to a wide audience and make sense when read on its own. The report should:

- use clear and simple everyday English whenever possible
- explain or avoid technical language
- use lists where appropriate

keep sentences short.

Notes on writing a note of acknowledgement

In this brief section you should thank the patient whose experience is documented in the report along with contributions from their family and others (including carers, etc) who gave time and shared their thoughts.

You could consider referring to the patient by name or as 'the patient' according to their wishes.
Also thank the healthcare staff who engaged with the investigation for their openness and willingness to support improvements.

Notes on writing the executive summary
To be completed **after the main report has been written.**

Notes on writing the summary of key findings for the executive summary
Add a brief overview of the main findings here (potentially in bullet point form).

Notes on writing about areas for improvement and safety actions for the executive summary
Add a bullet point list of the areas for improvement highlighted by the investigation and list any safety actions.
Note whether the area for improvement will be addressed by development of a safety improvement plan.
Some actions to address identified areas for improvement may already have been designed in existing an organisational safety improvement plan. Note that here.
Areas for improvement and safety actions must be written to stand alone, in plain English and without abbreviations.
Refer to the Safety action development guide for further details on how to write safety actions.
NB: The term 'lesson learned' is no longer recommended for use in PSIIs.

Notes on writing about background and context
The purpose of this section, where appropriate, is to provide a short, plain English explanation of the subject under investigation – in essence, essential pre-reading to assist understanding of the incident. It might be a description of a pulmonary embolism, aortic dissection, cognitive behavioural therapy, NEWS, etc.
It may also be worth using this section to summarise any key national standards or local policies/guidelines that are central to the investigation.

Notes on writing a description of the event
The purpose of this section is to describe the patient safety incident. It should not include any analysis of the incident or findings – these come later.
Think about how best to structure the information – eg by day or by contact with different services on the care pathway.
It should be written in neutral language, eg 'XX asked YY' not 'YY did not listen to XX'. Avoid language such as 'failure', 'delay' and 'lapse' that can prompt blame.
If the patient or family/carer has agreed, you could personalise the title of this section to '[NAME]'s story/experience'.

Notes on writing about the investigation process

If useful, you should include a short paragraph outlining the investigation process:

- how the incident was reported (eg via trust reporting system)
- how agreement was reached to investigate (eg review of patient safety incident response plan, panel review, including titles of panel members)
- what happened when the investigation was complete (eg final report approved by whom)?
- how actions will be monitored.

Notes on writing about scope

In this section you should describe any agreed boundaries (that is, what is in and out of scope) for the investigation. For example, you might want to note:

- the aspects of care to be covered by the investigation
- questions raised by the those affected that will be addressed by the investigation

If those affected by the patient safety incident (patients, families, carers and staff) agree, they should be involved in setting the terms of reference as described in the Engaging and involving patients, families and staff after a patient safety incident guidance.

Notes on writing about information gathering

The purpose of this section is to provide a short overview of your investigation approach. You should include a brief overview of your methods including:

- investigation framework and any analysis methods used. Remember to keep jargon to a minimum (eg the investigation considered how factors such as the environment, equipment, tasks and policies influenced the decisions and actions of staff)
- interviews with key participants (including the patient/family/carer)
- observations of work as done
- documentation reviews, eg medical records, staff rosters, guidelines, SOPs
- any other methods.

Recorded reflections, eg those used for learning portfolios, revalidation or continuing professional development purposes, are not suitable sources of evidence for a systems-focused PSII.
Statements are not recommended. Interviews and other information gathering approaches are preferred.

Notes on writing your findings
The purpose of this section is to summarise your analysis of the information you have gathered and to state the findings you have drawn from that analysis.
You may choose to include diagrams and/or tables to communicate your analytical reasoning and findings.
Do not re-tell the story in the description of the patient safety incident. This section is about the ‘how’ the incident happened, not the ‘what’ and ‘when’.
Start with an introductory paragraph that describes the purpose of the section and structure you are going to use.
For your findings to have impact you will need to communicate them in a clear and logical way. Before you start, think about how best to structure the section, then make a plan.
You may find sub-headings useful. The structure you choose will depend on your investigation, but you could organise the information as follows:

- by the themes you have identified during the investigation – in which case put your strongest theme first
- following the framework or the analytical method you used
- in chronological order corresponding to the care pathway described in the reference event, eg community care, ambulance service, acute care (taking care not to repeat the story of the reference event)
- in order of the main decision points during the incident.

Use clear, direct language, eg ‘The investigation found…’
If the section is long and contains multiple sub-sections, consider adding a summary of key points at the end of each sub-section.
text (glossaries should be avoided).

Technical terms should be kept to an absolute minimum. If they are required, you should explain them in the text (glossaries should be avoided).
Include your defined areas for improvement and safety actions (where appropriate) in the relevant places in this section.
Areas for improvement that describe broader systems issues related to the wider organisation context are best addressed in a safety improvement plan. You should describe what the next stages are with regards to developing a safety improvement plan that will include meaningful actions for system improvement.

Notes on writing the final summary

The purpose of this section is to bring together the main findings of the investigation.
Areas for improvement and associated safety actions (if applicable) should be listed using the table provided (also available in Appendix B of the safety action development guide).
If no actions are identified the safety action summary table is not required. Instead you should describe how the areas for improvement will be addressed (eg refer to other ongoing improvement work, development of a safety improvement plan).

Notes on appendices

Include any necessary additional details such as explanatory text, tables, diagrams, etc (Delete this section if there are none).

Notes on references

Include references to national and local policy/procedure/guidance, and other data sources as required.

EQUALITY AND DIVERSITY IMPACT ASSESSMENT

POLICY STATEMENT:

Trinity Hospice is committed to creating a culture in which diversity and equality of opportunity are promoted actively and in which unlawful discrimination is not tolerated.

Trinity Hospice believes in the principles of social justice, acknowledges that discrimination affects people in complex ways and is committed to challenge all forms of inequality. To this end, The Hospice will aim to ensure that:

- individuals are treated fairly, with dignity and respect regardless of their age, marital status, disability, race, faith, gender, language, social/ economical background, sexual orientation or any other inappropriate distinction;
- it affords all individuals, volunteers and employees the opportunity to fulfil their potential;
- it promotes an inclusive and supportive environment for staff, volunteers and visitors;
- it recognises the varied contributions to the achievement of the Hospice's, mission made by individuals from diverse backgrounds and with a wide range of experiences.

Title of policy/ proposal/ activity:	E08PSIRF Patient Safety Incident Response Framework & Near Misses Reporting Policy & Procedure
Equality Impact Assessment Group (names):	Jo Nicholls
Date:	In line with policy review date

1. Briefly describe the aims, objectives and purpose of the proposal	Policy & Procedure sets out best practice for reporting incidents and near misses.
2. Are there any associated objectives of the proposal, please explain	No
3. Who is intended to benefit from the proposal and in what way?	All staff, volunteers, patients and visitors to Trinity Hospice & Palliative Care Services.
4. What outcomes are wanted from this proposal?	Clear concise guidelines
5. What factors/forces could contribute/detract from the outcomes?	Failure to follow policy
6. Who are the main stakeholders in relation to the proposal?	All Staff and Volunteers
7. Who implements the proposal and who is responsible?	TMT
8. Is it likely that that the proposal **could** have a positive or negative impact on minority **ethnic** groups. What existing evidence (either presumed or otherwise) do you have for this?	No
9. Is it likely that that the proposal **could** have a positive or negative impact due to **gender.** If so, please outline what the impact might be. What existing evidence (either presumed or otherwise) do you have for this?	No
10. Is it likely that that the proposal **could** have a positive or negative impact due to **disability.** If so, please outline what the impact might be. What existing evidence (either presumed or otherwise) do you have for this?	No

11. Is it likely that that the proposal **could** have a positive or negative impact on people due to **sexual orientation.** If so, please outline what the impact might be. What existing evidence (either presumed or otherwise) do you have for this?	No
12. Is it likely that that the proposal **could** have a positive or negative impact on people due to their **age.** If so, please outline what the impact might be. What existing evidence (either presumed or otherwise) do you have for this?	No
13. Is it likely that that the proposal **could** have a positive or negative impact on people due to their **religious belief.** If so, please outline what the impact might be. What existing evidence (either presumed or otherwise) do you have for this?	No
14. Is it likely that that the proposal **could** have a positive or negative impact on people with **dependants/caring responsibilities?** If so, please outline what the impact might be. What existing evidence (either presumed or otherwise) do you have for this?	No
15. Is it likely that that the proposal **could** have a positive or negative impact on people due to them being **transgender or transsexual.** If so, please outline what the impact might be. What existing evidence (either presumed or otherwise) do you have for this?	No
16. Can any adverse impact be justified on the grounds of promoting equality of opportunity for a particular group? (For example, the proposal may be deliberately designed to promote equality for disabled people but may run the risk of this being at the expense of non-disabled people).	No
17. Is a full Equality Impact Assessment necessary?	No
18. If Yes date on which full impact assessment is to be completed by	
Signed on behalf of the organisation.	Jo Nicholls
Agreed review date	In line with policy review date