Patient safety incident response policy

Effective date: 30/10/2024

Estimated refresh date: 31/10/2025

	NAME	TITLE	SIGNATURE	DATE
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Purpose

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

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

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

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

Scope

This policy is specific to patient safety incident responses conducted solely for the purpose of learning and improvement across TBC Healthcare.

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

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

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

Our patient safety culture

TBC Healthcare has fostered a just culture in the organisation. To continue to develop this, staff engage in regular service meetings, enabling them to discuss and raise any concerns to senior staff/managers. Staff have regular supervision, where they are encouraged to raise any issues that they are concerned about. Staff are also directed to the Whistleblowing Policy.

Feedback is sought from staff, patients and other stakeholders in order to promote and improve dialogue and transparent reporting. TBC Healthcare has adopted a Freedom to Speak Up (FTSU) policy.

All those that provide feedback/raise concerns receive feedback from their line manager or via the reporting system. The reporting system is the same system where safeguarding incidents are recorded. The Operations Manager maintains the CIFF spreadsheet which captures all incidents within the organisation including:

- complaints
- safeguarding referrals
- incident reports (patient safety)
- Patient feedback
- IG incidents
- Freedom to Speak Up reports

These matters are reported and discussed in the weekly management meetings in order to identify and review responses, and to manage risks.

Data from feedback 2023/2024 demonstrates that staff are happy with the way that their concerns and Freedom to Speak Up matters are managed. When patients raise concerns or complain, they are attended to by a senior member of the management team and issues dealt with efficiently and speedily.

The process in place to report incidents to regulators and other stakeholders as required, is that a senior manager undertakes the reporting actions, including contacting the Information Commissioners Office/CQC within 72 working hours. Issues that could undermine reporting, such as fear of reprisal, are addressed by ensuring that the service works transparently and from a learning culture perspective.

Patient safety partners

Patient safety partners have been engaged and will continue to be engaged by encouraging their attendance at oversight stakeholder meetings. Continued design and development of the incident response processes are undertaken in 6 monthly Clinical Governance meetings. This enables the maintenance of the plan and allows the implementation of future developments. Learning from events is crucial to the progress of proactive risk assessment and management.

We understand that patients and carers and families have a range of needs, and they require compassion and empathy when any incidents arise.

Addressing health inequalities

TBC Healthcare's Approach to Health Inequalities and Patient Safety:

1. Understanding Inequalities:
    - TBC Healthcare recognizes that various factors, including protected characteristics, can lead to health inequalities. These inequalities affect access to care, engagement, outcomes, and overall safety, potentially impacting life chances and risks.
2. Data Collection and Analysis:
    - The organization emphasizes the importance of using data to identify any disproportionate risks to patients based on specific characteristics. This will inform patient safety incident responses and drive improvements in care quality.
3. Health Inequalities in Reviews and Actions:
    - Reviews of patient safety incidents will consider whether health inequalities have contributed to any risks or harms. All protected characteristics will be considered, and findings will contribute to quality improvement efforts.
4. Ongoing Plan Development:
    - The organization will continue to analyze population and patient safety data to identify inequalities. This data will influence the development of future versions of the patient safety incident response plan.
5. Accessibility and Inclusion:
    - Reports and plans will incorporate accessible tools such as easy-read formats, translation, and interpretation services to ensure maximum participation from patients and stakeholders.
6. Inclusive Patient Safety Incident Response:
    - Patient safety responses will include:
        - Identifying unwarranted variations in outcomes based on specific characteristics.
        - Addressing support needs for patient engagement, focusing on what each person can contribute.
        - Ensuring diversity in recruitment, particularly where gaps are identified in staff with specific characteristics.
7. Consideration of Diverse Needs:

- When engaging patients, families, carers, or staff following safety incidents, their diverse needs will be considered, including those from:
  - Ethnic minorities
  - People with learning disabilities or autism
  - Individuals with dementia
  - People requiring accessible communication (e.g., Deaf, non-English speakers)
  - LGBTQ+ individuals

8. Staff Training and Skill Development:
   - TBC Healthcare will ensure that staff are trained and equipped to support this inclusive approach to patient safety and health equality.
9. Auditing and Trend Analysis:
   - All incidents are audited every six months to identify trends and possible gaps. This is reviewed in Clinical Governance meetings to develop strategies to address any health inequalities, using system-based responses and specific tools (e.g., interpreters, sign-language, easy-read, braille).

By integrating these practices, TBC Healthcare aims to reduce health inequalities and ensure that all patients, families, and carers are effectively engaged in the management and learning from patient safety incidents.

System based approach

"a system refers to a set of common objects or people and the relationships and interactions that make them part of a larger whole, working together towards a common purpose."

Transforming services: a systems based approach – UK Health Security Agency (blog.gov.uk)

Engaging patients, families and carers in the process of developing safety action plans is integral to the flexibility of TBC Healthcare. TBC uses telephone, email, videoconferencing, letters and face to face contact to promote involvement and feedback is sought in a similar way, with the addition of surveys. A system-based approach considers all parts of the incident and how they relate to each other, with the key aims of:

- 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.
- Supportive oversight focused on strengthening response system functioning and improvement.
  (Patient Safety Incident Response Framework (PSIRF) published - Patient Safety Learning)

The staff induction programme includes training on how we engage with those affected by patient safety incidents, how TBC Healthcare learns from incidents, how TBC Healthcare develop their proportionate responses to incidents (with examples) and how transparency, honesty and learning is key to strengthening and improving responses.

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

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

In planning, organising and implementing effective incident management procedures TBC Healthcare ensures that:

a) Systems for reporting accidents, incidents and risks, and patients/service users at risk are clearly defined.

b) Causes of accidents and incidents are thoroughly investigated and any measures which prevent a reoccurrence are actioned.

c) Lessons are learnt and, where appropriate, disseminated across the organisation.

d) There is a rapid follow up and feedback for all incidents.

e) Those affected by incidents are involved in identifying and addressing system-wide concerns.

f) The data collected creates meaningful information to support learning.

g) support is provided for staff involved in accordance with TBC Healthcare's Supporting Staff policy.

h) actions required to address all risk management issues are co-ordinated by the management team.

i) communication with the patient(s)/relative(s), where appropriate, is in line with TBC Healthcare Being Open/Duty of Candour Policy.

j) communication between the senior management and any clinical staff involved is facilitated.

k) clinical advice is available.

l) the clinical lead and those affected by an incident develop an action plan to improve systems and minimise the risk of reoccurrence.

Patient safety incident response planning

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

TBC Healthcare takes a proportionate response to patient safety incidents and builds a response that takes the wishes and feelings of those involved into account. Responses may include additional training, targeted actions and management intervention, where appropriate.

TBC Healthcare ensures that

- There are links and alignment between patient safety and quality improvement systems and processes, and related clinical governance systems and processes, including complaints.
- Insight is shared between patient safety and quality improvement teams, and teams benefit from collective expertise.
- The patient safety incident response policy and **all** other relevant policies promote a just culture (eg they do not include automatic suspension or removal of business-as-usual activities from staff involved in patient safety incidents).
- Information governance agreements allow information sharing within and between relevant bodies to support effective communication during both incident response and improvement endeavours.
- Governance/reporting structures are clear to staff, patients, and the public, and encourage openness and transparency.
- The organisation's patient safety incident response policy is published on its website.

TBC Healthcare's data department compile reports to the management board to enable the analysis and understanding of organisational data. This is discussed in Clinical Governance meetings and cascaded to staff to ensure everyone has the same understanding and knowledge.

Stakeholder meetings are promoted to enable involvement in TBC Healthcare's PSIRF and other relevant developments. The stakeholder engagement mapping has led to the development of surveys and jot forms to gain the views of patients/other professionals who do not wish to be part of the stakeholder group.

Each identified patient safety incident is managed individually and the rationale for each response is provided at that time.

TBC Healthcare's policy regarding patient safety incidents are updated as required and at least every year and in accordance with emerging intelligence and improvement efforts.

TBC Healthcare's PSIRF policy is published on our external facing website.

Resources and training to support patient safety incident response

Specific knowledge and experience are required for those leading learning responses and those in oversight roles. This includes knowledge of systems thinking and system-based approaches to learning from patient safety incidents.

Those involved in the quality assurance of patient safety incident response (ie provider boards/executive leads) must have the knowledge to constructively challenge the strength and feasibility of safety actions to improve underlying system issues. They must be able to recognise when the proposed safety actions following a patient safety incident response do not take a system-based approach; for example, where they inappropriately focus on revising policies without understanding 'work as done' or involve self-reflection for certain individuals rather than reviewing wider system influences.

Those in system oversight roles (ie provider board PSIRF lead(s), ICB PSIRF leads, the Care Quality Commission (CQC) relationship managers and inspectors) must have knowledge of effective oversight and supporting processes, including effective use of data for assurance and patient safety incident response system development.

Staff in oversight roles must be appropriately trained to support the practical application of PSIRF oversight principles and standards.

TBC Healthcare follows the below training requirements for the appropriate staff.

PSIRF training requirements

Topic	Minimum duration	Content	Learning response leads	Engagement leads	Those in PSIRF oversight roles
Systems approach to learning from patient safety Incidents	2 days/12 hours	• Introduction to complex systems, systems thinking and human factors • Learning response methods: including interviewing and asking questions, capturing work as done, data synthesis, report writing, debriefs and after-action reviews • Safety action development, measurement, and monitoring	✔		
Oversight of learning from patient safety incidents	1 day/6 hours	• NHS PSIRF and associated documents • Effective oversight and supporting processes • Maintaining an open, transparent and improvement focused culture • PSII commissioning and planning			✔
Involving those affected by patient safety incidents in the learning process	1 day/6 hours	• Duty of Candour • Just culture • Being open and apologising • Effective communication • Effective involvement • Sharing findings • Signposting and support		✔	
Patient safety syllabus level 1: Essentials for patient safety (for all staff)	eLearning	• Listening to patients and raising concerns • The systems approach to safety: improving	✔	✔	✔

Topic	Minimum duration	Content	Learning response leads	Engagement leads	Those in PSIRF oversight roles
		the way we work, rather than the performance of individual members of staff • Avoiding inappropriate blame when things don't go well • Creating a just culture that prioritises safety and is open to learning about risk and safety			
Patient safety syllabus level 1: Essentials for patient safety (for boards and leadership teams)	eLearning	• The human, organisational and financial costs of patient safety • The benefits of a framework for governance in patient safety • Understanding the need for proactive safety management and a focus on risk in addition to past harm • Key factors in leadership for patient safety • The harmful effects of safety incidents on staff at all levels			✔
Patient safety syllabus level 2: Access to practice	eLearning	• Introduction to systems thinking and risk expertise • Human factors • Safety culture	✔	✔	✔
Continuing professional development (CPD)	At least annually	• To stay up to date with best practice (eg through conferences, webinars, etc) • Contribute to a minimum of two learning responses	✔	✔	

Topic	Minimum duration	Content	Learning response leads	Engagement leads	Those in PSIRF oversight roles
					✔

NHS England » Patient safety incident response standards

Our patient safety incident response plan

A key part of developing the PSIRF Plan is understanding the key issues that lead to risks for patient safety, known as the Patient Safety Profile. To understand the patient safety incident profile, a wide source of information about risks to patients have been reviewed and evaluated. The process of developing the patient safety incident profile was to have held stakeholder engagement events and request completion of surveys to determine views.

Our plan sets out how TBC Healthcare intends to respond to patient safety incidents over a period of 12 to 18 months. The plan is not a permanent set of rules that cannot be changed. We will remain flexible and consider the specific circumstances in which each patient safety incident occurred and the needs of those affected, as well as the plan.

Reviewing our patient safety incident response policy and plan

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

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

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

Responding to patient safety incidents

Patient safety incident reporting arrangements

TBC Healthcare staff are encouraged to report all patient safety incidents to the Operations Manager, and to document it on our electronic recording system. Every reported incident is triaged by the Patient Safety Officer/Safeguarding Lead. The Patient Safety Officer/Safeguarding Lead has responsibility for liaising with external bodies and partner providers to ensure effective communication via a single point of contact.

This includes internal and external notification requirements for the reporting of patient safety related incidents. All staff are required to:
• Report all incidents, patient safety events and near misses via the electronic incident reporting system.
• Ensure the details of any incidents or patient safety events are contemporaneously and objectively reported in the patient's clinical record.
• Raise any concerns about situations that led to, or could lead to, an incident, patient safety event, or a near miss, with their line manager or the Patient Safety Officer/Safeguarding Lead.
• Actively participate in any subsequent reviews or learning responses, providing a written account, attending multidisciplinary fact-finding and feedback meetings etc as needed.
• Attend a Coroner's inquest if called to do so.
• Undertake mandatory training in the reporting of incidents/patient safety events.
• Undertake additional training, as required, to ensure competence.

We will make available appropriate support to those staff involved in an incident or patient safety event, where this is required (Further detail can be found in our Supporting Staff Policy).

Patient safety incident response decision-making

1. PSIRF Compliance:
    - TBC Healthcare has systems in place to meet the requirements for reviewing patient safety incidents under the Patient Safety Incident Response Framework (PSIRF). Some incidents will require mandatory Patient Safety Incident Investigations (PSII), while others may need review or referral to another team or body.
2. Proactive and Reactive Response:
    - The Patient Safety Incident Response Plan (PSIRP) supports the proactive allocation of resources for patient safety incidents. However, there will always be a reactive element when responding to incidents.
3. Decision-Making for Unexpected Incidents:
    - For incidents that indicate unexpected risks or potential for learning and improvement, but fall outside the scope of the PSIRP, the Clinical Directors will lead the decision-making process. This will be done in consultation with the Clinical Governance Board and managers**.**

This ensures that the trust is both proactive and flexible in responding to incidents, with clear decision-making structures in place when incidents fall outside of standard protocols.

Initial Steps:

1. Incident Recording:
    - A patient safety incident is recorded.
2. Incident Meeting:
    - The incident is reviewed in a meeting to identify immediate actions and determine if further review is required.
3. Staff Support:
    - Support is provided to staff, and the Duty of Candour is actioned when necessary.

Decision-Making:

1. Initial Review:
    - The Clinical Governance Board reviews the incident against the Patient Safety Incident Response Plan (PSIRP) to determine if a Patient Safety Incident Investigation (PSII) is necessary.
2. Path 1 - Automatic PSII:
    - If a PSII is indicated, it moves to Action Taken, Path 1.
3. Path 2 - PSIRP Inclusion:
    - If the incident isn't automatically flagged for a PSII, it's assessed whether the incident is included in the PSIRP.
    - If yes, it moves to Action Taken, Path 2.
4. Emerging Risks or New Trends:
    - If the incident is not part of the PSIRP, the Patient Safety Officer will assess whether the incident, when considered with others, indicates a new or emerging risk that requires further exploration.
    - If yes, the Clinical Governance Board decides the most proportionate response and proceeds with Action Taken, Path 2.
    - If no further action is necessary, the process moves to No Further Action.

Action Taken:

- Path 1 – PSII Investigation:
    - The Patient Safety Team conducts a PSII investigation.
    - The response uses a system-based approach to:
        - Gather information.
        - Involve those affected (staff, families, carers, or patients).
        - Identify areas for learning and improvement.
        - Align learning with ongoing improvement initiatives.
        - For certain reviews, oversight will be provided through specific panels
        - Develop safety actions collectively, considering ongoing improvement work.
- Path 2 – Learning Response:
    - A learning response is undertaken according to the PSIRP (e.g., after-action review, MDT review).
    - If the learning response indicates the need for escalation to a PSII, the Patient Safety Team conducts a PSII investigation, using the same system-based approach outlined in Path 1.

Final Outcome:

- Review and Monitoring:
    - The learning response is reviewed by the Clinical Governance Board (Patient Safety Oversight Panel).
    - Safety actions and learning are monitored, aiming for improvement in patient safety and the experience of patients and families.

No Further Action:

- Log Event for Future Planning:
    - The event is logged for future incident response planning and continues with ongoing improvement work or risk mitigation strategies.
    - Information from the incident is used for future risk management or service improvement activities.

This process ensures that incidents are systematically reviewed, actions are taken based on the level of risk, and improvements are driven by ongoing learning and response.

Responding to cross-system incidents/issues

The Patient Safety Officer ensures incidents identified as presenting potential for significant learning and improvement for another provider are communicated to ensure the other organisation's patient safety team (or equivalent) are aware. Where required, summary reporting can be used to share insights with another provider about their patient safety profile.

TBC Healthcare works with other providers and the relevant ICBs to establish and maintain robust procedures to facilitate the free flow of information and minimise delays to joint working on cross-system incidents. The Patient Safety Oversight Panel will act as the liaison point for such working.

When appropriate, TBC Healthcare will defer to the ICB for coordination where a cross-system incident is felt to be too complex to be managed as a single provider. Internal cross-system learning issues will be identified by using a systems-approach to PSII, trends and learnings. If cross-function issues are identified the appropriate Clinical Director will be informed to ensure action coordination by the learning response lead. Patient feedback and complaint trends related to patient safety will be fed back to the Clinical Governance Board for comment, review and action alignment.

Timeframes for learning responses

All reported incidents must be assessed by a Learning Response Lead within 1 week (5 working days). It is important that learning responses, including PSIIs, should begin promptly and be completed within 6 months of the incident report. The timeframe for completing a PSII should be agreed with those affected, balancing thoroughness with the potential impact of delays on individuals and safety.

In exceptional cases which may be time-consuming, an extended timeframe must be approved by the Patient Safety Oversight Panel and those affected. If external bodies or individuals cannot provide information within the timeframe, the response should proceed with available data, with the option to revisit if new information emerges. Oversight remains with the Patient Safety Oversight Panel/Clinical Governance Board**.**

Safety action development and monitoring improvement

TBC Healthcare will follow the NHS England Safety Action Development Guide (2022) for developing safety actions. This includes:

1. Agree Areas for Improvement (Identify improvement needs without predefining solutions).
2. Define the Context (Establish the approach to developing safety actions).
3. Define Safety Actions (Focus on system-level solutions, collaborating with all involved stakeholders, including patients and staff).
4. Prioritise Actions (Determine which actions to test for implementation).
5. Define Safety Measures (Set metrics to assess effectiveness and assign responsibility for tracking results).
6. Follow SMART Principles (Ensure safety actions are specific, measurable, achievable, relevant, and time-bound).

Improvement actions will prioritize system-level changes rather than reliance on staff education or training.

Safety action development and improvement will be monitored at every Clinical Governance Board meeting.

Safety improvement plans

Safety Improvement Plans (SIPs) aim to integrate findings from patient safety incident responses and trend analyses. SIPs are coordinated by the Patient Safety Officer and overseen by the Patient Safety Oversight Panel to align with TBC Healthcare's organizational priorities.

Incidents causing or potentially causing moderate to severe harm related to care will trigger a learning response and quality improvement process:

- Programme-Specific Actions: Triaged to relevant staff teams by the Patient Safety Officer.
- Cross-Programme Actions: Coordinated with appropriate functions, monitored on the risk management framework.

Patient safety incident trends and improvement recommendations are reviewed quarterly:

- Improvement actions require clear safety measures to track progress.
- Data must include comparisons of incident frequency relative to patient enrolment in each programme.
- The Clinical Governance Board reviews and prioritizes patient safety recommendations.
- Final decisions are made by the Operations Manager.
- Actions are collated by the Clinical Governance Board minute taker and updated by the designated action owner or Patient Safety Officer.

Oversight roles and responsibilities

TBC Healthcare is committed to focus on demonstrating improvement rather than just compliance with mandated measures, guided by the framework's "mindset" principles.

The Clinical Governance Board is accountable for effective patient safety incident management, including supporting cross-system or multi-agency work and independent investigations (PSIIs) as required.

The Clinical Directors are the executive lead for PSIRF. Responsibilities include:

- Ensuring compliance with national patient safety standards.
- Embedding PSIRF into safety governance.
- Quality-assuring outputs from learning responses.

The Clinical Directors also provide leadership, advice, and support in complex cases and liaises with external bodies in collaboration with the Medical Lead and Operations Manager.

- The Clinical Directors oversee the quality of patient safety learning responses and PSIIs.

- The Operations Manager leads on safety learning and improvement initiatives and holds overall accountability for patient safety within the organisation.

All Senior Managers receive training and professional development per national patient safety incident response standards.

Complaints and appeals

TBC Healthcare understands that patients, service users, and carers may occasionally be dissatisfied with aspects of care or services.

Concerns may be raised with the professional involved in the patients care, or with the patient coordinator (patient care team). This does not automatically begin the formal TBC Healthcare complaints process.

Complaints are a more formal communication and require a formal response through TBC Healthcare's Complaint procedure. Complaints will be managed respectfully, openly and honestly, involving those affected and ensuring that outcomes are shared.

TBC Healthcare values all feedback as an opportunity to further develop and improve standards across the service.

Patients, relatives or carers who have concerns about how a patient safety incident and learning response is being managed should speak with the Operations Manager at Head Office. The Operations Manager will do their best to assist with any concerns.

Appendix 1

PATIENT SAFETY INCIDENT
POLICY AND PROCESS

Policy No	
Responsible Person	Registered Manager
Date Issued	November 2024
Next Review Date	Every two years
Authorised by	Janet Biglari
Version No	04

Title	**Patient Safety Incident Policy and Process**
Author	Martha Walker amended C Konzon
Responsible Person	Registered Manager
Authorised	
Issue Date	November 2024
Review Date	Every years unless review required earlier
Policy No and Version	Version 04
References	Heart of England NHS Foundation

Scope	All individuals in the employ of this establishment *('employ' means any person who is employed, self-employed, volunteer, working under practising privileges or contract of service with this establishment)*

AIM

TBC Healthcare, in its approach to incident investigation, aims to develop a non-punitive culture so long as there has been no flagrant disregard of TBC Healthcare's policies, fraud or gross misconduct.

The aim of an investigation into an Incident or a Near Miss is to identify any deficiencies in care and to learn lessons from these findings to develop safer practices and environment for the benefit of patients, staff and visitors to its premises.

POLICY

This policy describes TBC Healthcare's policy for the management of incidents classified as 'Patient Safety Incidents' that members of staff must follow if the event occurs as a result of any work activity conducted by or on behalf of TBC Healthcare. It encompasses the management of both clinical and non-clinical Incidents and Near Misses. This policy also covers incidents relating to employees, visitors, and sub-contractors.

Key Points

- What is a Patient Safety Incident or Near Miss?
- Guidance for managers and staff in the investigation process for Patient Safety Incidents and Near Misses
- Reporting requirements and timeframes

Patient Safety Incident is defined by TBC Healthcare as:

- An accident or incident when a patient, member of staff or member of the public suffers serious injury, major unexpected harm or unexpected death (or the risk of death or serious injury) on premises where health care is provided, or whilst in receipt of healthcare
- Any event where the actions of staff are likely to cause significant public concern
- Any event that might seriously impact upon the delivery of services and / or which is likely to produce significant legal, media or other interest and which, if not properly managed, may result in the loss of TBC Healthcare's reputation or assets.

A Near Miss is defined by TBC Healthcare as:

- An event that almost happened but was averted.
- The event may be either clinical or nonclinical

Reporting a PSI or Near Miss

All staff must complete a report form (appendix 1) and email to the Operations Manager at Head Office.

Standards

This policy outlines the issues to be addressed by TBC Healthcare. In planning, organising and implementing effective accident and incident investigation procedures and ensure that:

a) Systems for reporting accidents, incidents and risks, service users at risk are clearly defined.
b) Causes of accidents and incidents are thoroughly investigated and any measures which prevent a reoccurrence is actioned.
c) Lessons are learnt and where appropriately disseminated across the organisation.
d) There is a rapid follow up for all accidents and incidents.

The data collection creates meaningful management information to support learning.

General

- The Operations Manager will co-ordinate the management of the incident;
- The initial scope of the investigation will determine the extent of the problem and define the resources required to support the investigation;
- The PSI process will incorporate the appropriate communication standards described in the Being Open Policy;
- The PSI process will incorporate the appropriate standards described in the Supporting Staff Policy
- TBC Healthcare will communicate with all relevant external organisations during the investigation, as appropriate (including CQC).
- Where appropriate TBC Healthcare will communicate the incident to the NHS Patient Safety Team (PSIRF).

Definitions & Scope
TBC Healthcare defines:

a) Incident - as a sequence of events that may or may not result in an injury, loss or damage.

b) An accident - as an unplanned or unexpected event that may or may not cause death, injury, damage, loss.

c) Near miss - as an incident without an adverse outcome.

d) Hazard - something that has the potential to cause harm.

e) Risk - as a combination of the severity of the harm in the likelihood that the harm will occur.

f) Personal accident - is any accident, no matter how small, which did or could have adversely affected any person. This does not include any incident caused deliberately, for example by an act of violence or by fire.

g) Work or environmental ill health is a case of known or suspected work or environmental related ill health, for example infection, dermatitis etc.

h) Violence, abuse or harassment is any incident involving verbal abuse, unsocial behaviour, intimidation, sexual or racial harassment or physical assault whether or not injury results.

i) Dangerous occurrence - as unspecified events which may not result in a reportable incident but has the potential to do significant harm.

j) Serious events - is an unexpected occurrence involving suicidal ideation, serious physical or psychological injury to service users or others.

Monitoring & Review
All incidents from the above sections must be reported in weekly management meetings. All clinical staff must take responsibility for reporting such incidents in an appropriate detailed manner. Failure to comply with the requirements of any TBC Healthcare health and safety policies and procedures may result in disciplinary action.

Internal Reporting & Investigation
Employees:

a) Employees should complete all relevant documentation related to any incident and submit this to their clinical lead within 24 hours.

b) Employees should assist where possible and appropriate during any investigation undertaken by their manager.

c) If a service user discloses suicidal ideation or self-harm, this must be immediately reported following the procedures described “in office or out of office hours concerns” document.

d) For discussion in regard to practice issues out of office hours please contact Catherine Konzon.

Managers:

1) Managers and Clinical Supervisors shall ensure that all the correct documentation has been completed by the employee.

2) Managers and Clinical Supervisors should conduct an investigation into the Incident and provide a detailed report on their findings.

3) Managers should ensure that all records relating to any incidents are retained on file for a period of ten years.

Executive Lead

A senior manager will be nominated as the executive lead. A more appropriate executive lead may be appointed as required. They will:

- Take executive lead for the investigation of the PSI.
- Oversee a thorough and timely investigation process

Clinical Governance Committee

- To ensure that all PSIs and Near Misses have been appropriately reported to the Clinical Governance Committee for discussion as PSIRF
- To ensure that support is provided for staff involved in a PSI in line with TBC Healthcare's Supporting Staff policy.
- To co-ordinate the actions required for the directorate to address all risk management issues in relation to the incident.
- To co-ordinate communication with the patient(s)/relative(s), where appropriate, and in line with TBC Healthcare Being Open Policy
- To facilitate communication between the senior management and any clinical staff involved in the incident.
- To provide advice on clinical issues relating to the incident.
- To work with the clinical lead and investigation lead to develop an action plan to improve systems and minimise the risk of reoccurrence, as identified by the investigation report

Training

The Operations Manager will ensure provision of training for relevant staff, to enable them to carry out their duties and responsibilities relating to incident management. This may include the risk management training and other support and advice, as appropriate to the needs of the individual.

All employees and sub-contractors must be fully informed and aware of TBC Healthcare's accident, incident and hazard reporting systems and its consequences in order to be able to own the system and ensure its success.

TBC Healthcare will provide relevant training to all staff at induction and as part of the appraisal system.

TBC Healthcare will provide training for those managers responsible for health and safety and will undertake training in the grading of incidents, accidents, statutory and organisational requirements, investigation techniques and risk assessments.

TBC Healthcare will provide relevant further training as a result of learning from experience.

Clinical Risk

All employees shall ensure that if they are involved in or discover an incident that they attend to the immediate needs of service users affected by the incident, making sure any injured person or ill person safe thus minimising further risk.

They should immediately inform the Practice Manager where they are working of the incident and also make immediate contact with the Operations Manager to log the incident into TBC Healthcare's incident spreadsheet.

Any equipment involved in the incident should be taken out of use, labelled do not use and put to one side awaiting investigation.

Once immediate actions have been taken to re-establish the safe environment and initial service users' safety, the incident must be formally documented in the appropriate reporting forms as soon as practical. All staff's Line Manager must be informed of the incident within 24 hours.

TBC Healthcare holds in-house a full manual regarding the management of health, safety and welfare and all employees should refer to this, which is available from TBC Healthcare offices.

Improvement

TBC Healthcare is committed to ensuring local and organisational learning from aggregated data, including PSI's, in line with TBC Healthcare's Incident Reporting and Management Policy and Procedure.

TBC Healthcare shares lessons learnt across the whole company.

As a minimum, TBC Healthcare will seek to use lessons learnt to make changes in organisational culture or practice from PSI's and Near Misses

The Operations Manager, supported by the Clinical Governance Committee is responsible for monitoring improvement actions and addressing barriers to implementation.

END

Appendix 2

PSI / Near Miss Report

Incident details: Date	Time of incident:	Location:

Incident reported by: Date and time reported:	Incident reported to:

Names of those involved if Staff	
PPS no and initials if patient	

Details of those involved	If patient PPS number and initials only
Patient / Visitor / Staff *(circle)*	
Full name	
Address *	
email	
Telephone	
* for member of staff please give position	

Details of those involved	If patient PPS number and initials only
Patient / Visitor / Staff *(circle)*	
Full name	
Address *	
email	
Telephone	
* for member of staff please give position	
Please add additional details of others involved on separate sheet of paper	
Details of incident: *Keep factual, including a description of any medical devices, medicines or equipment involved*	

Any other information that contributed to the incident:	
Describe any immediate action taken to protect and/or improve patient/visitor/staff safety:	
Next steps *(e.g. reported to practice manager/medical director for investigation, planned correspondence with patient)*	
Result of internal investigation to be included with this report.	
This incident report was completed by:	
Signature	
Name (PRINT)	
Position	
Date	
Time	

Appendix 3

1. Patient safety incident response policy standards

Providers are required to create a patient safety incident response policy that describes the systems and processes they have in place to learn and improve following a patient safety incident. Creating the right foundations for effective incident response is critical.

Where patient safety incident response standards are not met at the time the policy is approved, an achievable roadmap for meeting these must be set out.

As part of the design and development of their patient safety incident response policy organisations should uphold the following standards:

- There are links and alignment between patient safety and quality improvement systems and processes, and related clinical governance systems and processes, including complaints.
- Insight is shared between patient safety and quality improvement teams, and teams benefit from collective expertise.
- The patient safety incident response policy and **all** other relevant policies promote a just culture (eg they do not include automatic suspension or removal of business-as-usual activities from staff involved in patient safety incidents).
- Information governance agreements allow information sharing within and between relevant bodies to support effective communication during both incident response and improvement endeavours.
- Governance/reporting structures are clear to staff, patients, and the public, and encourage openness and transparency.
- The organisation's patient safety incident response policy is published on its website.

2. Patient safety incident response plan standards

Providers are required to create a patient safety incident response plan that describes how they intend to respond to patient safety incidents, including the methods to be applied and rationale. Organisations must ensure their plan:

2.1. Demonstrates a thorough analysis of relevant organisational data.

2.2. Demonstrates a collaborative stakeholder engagement process (informed by thorough service and stakeholder mapping activities to ensure all areas are involved and represented appropriately).

2.3 Provides a clear rationale for the response to each identified patient safety incident type.

2.4. Is updated as required and in accordance with emerging intelligence and improvement efforts.

2.5. Is published on their external facing website.

3. Oversight

Oversight under PSIRF focuses on engagement and empowerment rather than more traditional command and control. When working under PSIRF, NHS providers, integrated care boards (ICBs) and regulators should design their systems for oversight "in a way that allows organisations to demonstrate [improvement], rather than compliance with prescriptive, centrally mandated measures" (Health Foundation, 2018).
Organisations should uphold the following standards:

3.1. Roles and responsibilities in relation to patient safety incident response are clearly described and understood by staff.

3.2. Oversight processes are underpinned by the 'oversight mindset' principles described in the Oversight roles and responsibilities specification (eg focus on improvement, are collaborative).

3.3. Oversight approaches consider the recommendations in the Oversight roles and responsibilities specification (eg a variety of data is used, is not 'one size fits all').

Competence and capacity

Learning response leads, those leading engagement and involvement and those in PSIRF oversight roles require specific knowledge and experience.

Organisations may differ in how they approach engagement and involvement – this activity may be led by the person leading a learning response, or by a family/staff liaison officer or similar. The patient safety incident response standards distinguish between the training requirements and competencies for these two roles but recognise they might be fulfilled by the same individual.

A tabular overview of training requirements is detailed in the Appendix.

4. Patient safety incident response resources

4.1. Learning responses are **not** led by staff who were involved in the patient safety incident itself or by those who directly manage those staff.
4.2. Learning response leads should have an appropriate level of seniority and influence within an organisation – this may depend on the nature and complexity of the incident and response required, but it is recommended that learning responses are led by staff at Band 8a and above.

4.3. Learning responses are **not** undertaken by staff working in isolation. A learning response team should be established to support learning responses wherever possible.
4.4. Staff affected by patient safety incidents are given time and are supported to participate in learning responses.

4.5. Learning response leads have dedicated paid time to conduct learning responses. If necessary, their normal roles are backfilled.

4.6. Subject matter experts with relevant knowledge and skills are involved, where necessary, throughout the learning response process to provide expertise (eg clinical or human factors review), advice and proofreading.

4.7. There is dedicated staff resource to support engagement and involvement of those affected.

5. Training provider requirements

5.1. Training is conducted by those who have attended courses in learning from safety incidents amounting to more than 30 days, are up to date in learning response best practice and have both conducted and reviewed learning responses. Accreditation with a recognised organisation is preferred.

6. Learning response training

6.1. Learning responses are led by those with at least two days' formal training and skills development in learning from patient safety incidents and experience of patient safety incident response.

6.2. Learning response leads have completed level 1 (essentials of patient safety **for all staff**) and level 2 (access to practice) of the patient safety syllabus.
6.3. Learning response leads undertake continuous professional development in incident response skills and knowledge, and network with other leads at least annually to build and maintain their expertise.

6.4. Learning response leads contribute to a minimum of two learning responses per year.

7. Competencies for learning response leads

All staff leading learning responses should be able to:

7.1. Apply human factors and systems thinking principles to gather qualitative and quantitative information from a wide range of sources.

7.2. Summarise and present complex information in a clear and logical manner and in report form.

7.3. Manage conflicting information from different internal and external sources.

7.4. Communicate highly complex matters and in difficult situations.

8. Engagement and involvement training

8.1. Engagement and involvement with those affected is led by those with at least six hours of training in involving those affected by patient safety incidents in the learning process.

8.2. Engagement leads have completed level 1 (essentials of patient safety **for all staff**) and level 2 (access to practice) of the patient safety syllabus.
8.3. Engagement leads undertake continuous professional development in engagement and communication skills and knowledge, and network with other leads at least annually to build and maintain their expertise.

8.4. Engagement leads contribute to a minimum of two learning responses per year.

9. Competencies and behaviours for engagement leads

9.1. Communicate and engage with patients, families, staff, and external agencies in a positive and compassionate way.

9.2. Listen and hear the distress of others in a measured and supportive way.

9.3. Maintain clear records of information gathered and contact with those affected.

9.4. Identify key risks and issues that may affect the involvement of patients, families, and staff.

9.5. Recognise when those affected by patient safety incidents require onward signposting or referral to support services.

10. Patient safety incident oversight

All individuals who have a role in patient safety incident response oversight (eg relevant executives, non-executives, and ICB leads) must undertake:

- At least one day (6 hours) training in oversight of learning from patient safety incidents.
- Level 1 (essentials of patient safety **for boards and senior leadership teams**) and level 2 (access to practice) of the patient safety syllabus. These modules cover systems thinking, human factors, risk expertise and safety culture, which form the basis required to undertake the additional PSIRF specific oversight training
- Continuous professional development in incident response skills and knowledge, and network with peers at least annually to build and maintain their expertise.

11. Competencies for individuals in oversight roles

All staff with oversight roles can:

11.1. Be inquisitive with sensitivity (that is, know how and when to ask the right questions to gain insight about patient safety improvement).

11.2. Apply human factors and systems thinking principles.

11.3. Obtain (eg through conversations) and assess both qualitative and quantitative information from a wide range of sources.

11.4. Constructively challenge the strength and feasibility of safety actions to improve underlying system issues.

11.5. Recognise when safety actions following a patient safety incident response do not take a system-based approach (eg inappropriate focus on revising policies without understanding 'work as done' or self-reflection instead of reviewing wider system influences).

11.6. Summarise and present complex information in a clear and logical manner and in report form.

Engagement and involvement of those affected by patient safety incidents

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

12. Compassionate engagement with those affected

All organisations are required to ensure:

12.1. Obligations relevant to the Duty of Candour are upheld.

Those affected by patient safety incidents should be:

12.2. Fully informed about what happened

12.3. Given the opportunity to provide their perspective on what happened.

12.4. Communicated with in a way that takes account of their needs.

12.5. Given an opportunity to raise questions about what happened and to have these answered openly and honestly.

12.6. Helped to access counselling or therapy where needed.

12.7. Given the opportunity to receive information from the outset on whether there will be a specific learning response and what to expect from the process.

12.8. Signposted to where they can obtain specialist advice and/or advocacy and/or support from independent organisations regarding learning response processes.

13. Meaningful involvement of those affected in a learning response

When a learning response takes place, those affected should be involved in a meaningful way. The following standards are endorsed for all learning responses but must be upheld where a patient safety incident investigation is undertaken.

Those affected should be:

13.1. Provided with a named main contact within the organisation with whom to liaise about any learning response and support.

13.2. Allowed to bring a friend, family member or advocate of their choice with them to any meeting that is part of the learning response process they are involved in.

13.3. Informed who will conduct any learning response and of any changes to that arrangement.

13.4. Given the opportunity to input to the terms of reference for the learning response, including being given the opportunity to request the addition of any questions especially important to them (note this does not mean that their requests must be met, but they must have any decision not to meet their request explained to them).

13.5. Given the opportunity to agree a realistic timeframe for any learning response.

13.6. Informed in a timely fashion of any delays with the learning response and the reasons for them.

13.7. Updated at specific milestones in the learning response should they wish to be.

13.8. Given the opportunity to review the learning response report with a member of the learning response team while it is still in draft and there is a realistic possibility that their suggestions may lead to amendments. Note this does not mean that their suggestions must be incorporated but any decision not to incorporate their suggestions must be explained to them.

13.9. Invited to contribute to the development of safety actions resulting from the learning response.

13.10. Given the opportunity to feedback on their experience of the learning response and report (eg timeliness, fairness, and transparency).

Proportionate responses

14. Timeframes

14.1. Patient safety learning responses start as soon as possible after the incident is identified.

14.2. Patient safety learning response timeframes are agreed in discussion with those affected, particularly the patient(s) and/or their carer(s), where they wish to be involved in such discussions.

14.3. Depending on discussions with those involved, learning responses are completed within one to three months and/or no longer than six months.

15. Patient safety incident response methodology

15.1. Responses are conducted for the sole purpose of learning and identifying improvements that reduce risk and/or prevent or significantly reduce recurrence.

15.2. Responses are insulated from remits that seek to determine avoidability/preventability/predictability; legal liability; blame; professional conduct/competence/fitness to practise; criminality; or cause of death.

15.3. With reference to the just culture guide, referral for individual management/performance review or disciplinary action only occurs for acts of wilful harm or wilful neglect.
15.4. Patient safety incident investigation reports are produced using the standardised national template.

15.5. Patient safety incident investigation reports are written in a clear and accessible way.

15.6. National tools (or similar system-based tools) are used and guides followed for learning response methods.

15.7. Learning and improvement work are adequately balanced – the organisation does not continue to conduct individual learning responses when sufficient learning exists to inform improvement.

16. Cross-system responses

16.1. ICSs provide necessary support to facilitate cross-system learning responses.

16.2. Where multiple organisations need to be involved in a single learning response, the response is led by the organisation best placed to investigate the concerns. This may depend on capability, capacity, or remit.

16.3. Organisations consider whether a learning response needs to examine the care provided throughout a specific care pathway as opposed to focussing solely on the part of the pathway most proximal to the incident.

16.4. Organisations actively engage partner organisations that provided care to the patient(s) involved where that care may have played a role in the incident being examined.

16.5. Organisations work together and co-operate with any learning response that crosses organisational boundaries.

17. Safety action and improvement

Organisations are required to develop safety actions to address areas for improvement identified in learning responses. Safety actions can relate to the local context or broader system issues. It is expected that:

17.1. Once systemic, interconnected contributory factors are robustly identified, the board/leadership team directs, champions and appropriately resources improvements, including by refocusing activity from individual responses to implementation and monitoring of required actions where appropriate.

17.2. All safety actions are developed with relevant stakeholders including those responsible for implementation.

17.3. The implementation and efficacy of all safety actions are **monitored,** and a named individual identified with responsibility for this.