Cleveland Clinic
London
Safety, Quality, Patient Experience & Governance

Stand Up for Safety-Our Patient Safety Incident Response Plan (PSIRP)

2024-2025

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Contents

Foreword from our Safety, Quality & Patient Experience Director

When questioned about the purpose behind investigating incidents, the common response often centres around the concept of learning. However, this understanding frequently remains confined to grasping the specific details of what transpired, whereas it should embrace a more comprehensive perspective. How often do we encounter the simplistic response of "we investigated it" when addressing an incident? To what degree have concrete changes or improvements been demonstrably achieved through these methodologies over the past two decades?

Since our establishment in 2021, Cleveland Clinic London has devoted the last two years to embedding operational processes that elevate our approach to patient safety incidents. Numerous instances underscore our dedication to learning and engagement. Particularly noteworthy is the substantial progress made in nurturing a restorative just culture that prioritizes psychological safety.

A crucial aspect of this transformative journey involves fostering a patient safety culture that encourages open communication. Initiating conversations and encouraging individuals to speak up within the context of a patient safety incident can be challenging. We are actively exploring ways to empower and support our colleagues in effectively understanding the perspectives of those involved.

It is paramount to acknowledge that investigations serve valuable purposes. Sharing findings, engaging with those directly involved, validating decisions in patient care, and facilitating psychological closure for affected parties are fundamental objectives of any investigation.

Our current challenge lies in developing an investigative approach that generates thematic insights to propel continuous improvement. Unlike previous frameworks, the Cleveland Clinic's "Stand up for Safety" - Patient Safety Incident Response Framework (PSIRF) signifies a comprehensive shift in how we conceptualize and respond to patient safety events to prevent recurrence. PSIRF, unlike its predecessors, is not a mere adjustment or adaptation but rather a systemic transformation focusing on learning and improvement.

In the pursuit of optimal safety outcomes for patients, an exceptional patient safety culture is imperative. Cleveland Clinic London remains steadfast in its commitment to evolving into a high-reliability organization, ready to embark on the next phase of our journey. PSIRF stands as a foundational element in this ongoing journey. Recognizing the intricacies of cultural transformation, we are dedicated to embodying an organization that authentically embraces a safety culture, providing an environment where individuals feel secure to voice their concerns.

Richard

Richard Lloyd-Booth
Director Safety, Quality & Patient Experience

Introduction

Cleveland Clinic London (CCL) is delighted to present the 'Stand Up for Safety' - Patient Safety Incident Response Plan (PSIRP). This comprehensive plan outlines our commitment to responding to and learning from patient safety events reported by both caregivers and patients, aligning with CCL's ongoing efforts to enhance the quality and safety of care. The plan is designed to be adaptable as needed, showcasing CCL's flexibility in addressing specific circumstances surrounding patient safety issues and incidents and catering to the needs of those affected.

Scope

It is essential to note that while CCL provides contracted services to the NHS, the Patient Safety Incident Response Framework (PSIRF) applies to any patient treated by CCL. Additionally, despite the NHS's exclusion of primary care from PSIRF, CCL has chosen to include its primary care services from the beginning. This decision aims to ensure a consistent approach to all Patient Safety Incidents (PSIs) and provides a broader pool of patient safety information for learning and improvement. This document should be read in conjunction with the introductory Patient Safety Incident Response Framework (PSIRF) (2019), which outlines the requirement for the development of this plan.

CCL has collaborated with major health insurers, the Care Quality Commission, and the North West London Integrated Care Board (ICB), with the approval of NHS England (NHSE). This collaboration reflects the spirit of cooperation at the core of PSIRF.

The plan is rooted in CCL's Quality Assurance Framework, policies on Serious Safety Event reporting, Radar - the Quality Management System, and a specific PSIR Policy. This policy provides caregivers with clear pathways for escalation, proportionate responses to PSIs, safety action development, safety and quality improvement plans, and ongoing monitoring for continuous improvement.

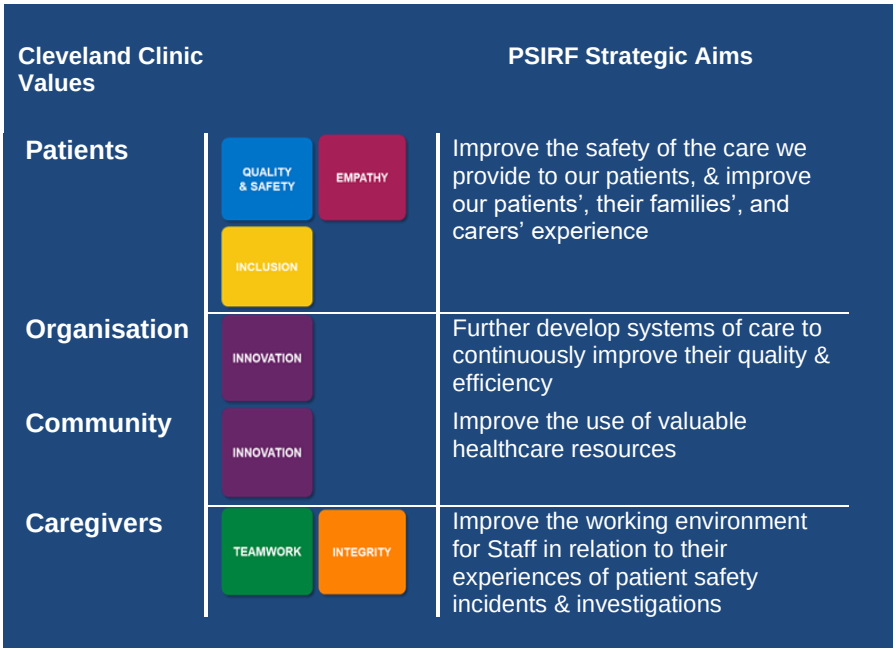
This plan spans a 12-month period in alignment with the national Patient Safety Strategy for England Patient Safety Incident Response Framework (2019). The PSIP will continually evolve as CCL learns from its experience within PSIRF. CCL will maintain flexibility, considering the specific circumstances in which patient safety issues and events occurred, as well as the needs of those affected. The objective of this approach is continuous improvement, and consequently, this document will be subject to bi-annual reviews initially.

Strategic aims

Safety is deeply ingrained in Cleveland Clinic's core values of Quality & Safety, permeating every facet of our operations. The overarching enterprise goal is to provide harm-free, high-quality care to all patients we serve. The "Stand Up for Safety" initiative fosters psychologically safe environments for Caregivers, encouraging them to voice concerns without fear of reprisal. The Patient Safety Incident Response Plan (PSIRP) ensures that the working environment and the outcomes of any learning responses or safety event investigations contribute to our organisation's commitment to high reliability.

The PSIRF is built on four strategic aims aligned with Cleveland Clinic London's values, as defined by the global Cleveland Clinic Foundation. These aims are illustrated in Figure 1, and the implementation of PSIRF integrates them into our daily work.

Figure 1.



We aim to cultivate a climate supporting a just culture and an effective learning response to patient safety incidents. The shift in emphasis from the quantity to the quality of investigations aims to make them more rigorous, identifying causal factors and systemic improvements. Our overarching objective is to optimise current resources, enhance the quality of investigations, and ensure a proportionate response to patient safety incidents, ultimately leading to a safer and more reliable healthcare environment. This approach promotes ownership, rigor, expertise, and efficacy.

Engaging patients, families, carers, and caregivers in investigations and other responses fosters a deeper understanding of issues and causal factors. This approach ultimately facilitates the development and implementation of improvements in a more effective manner. The "Communicate with H.E.A.R.T" service model, an enterprise-wide framework, outlines communication and service excellence behaviours for all caregivers. This empowers caregivers to address patient and colleague concerns and questions with care and responsiveness.

Figure 2

A High Reliability Organisation (HRO) is our aspiration, where all processes, policies, and procedures are consistently adhered to, and potential errors are identified and rectified before causing serious harm to patients or caregivers. To achieve HRO status, we have developed two sets of behaviours: CORE Behaviours for all caregivers and LEAD Behaviours for leaders. If each caregiver incorporates and models these behaviours daily, our goal of achieving Zero Harm is attainable. (Figure 3) All caregivers undergo customized Level 1 & Level 2 face-to-face Patient Safety, high-reliability universal skills & Governance Training during their induction, closely linked to the national PSIRF NHS training and competency program.

To become an HRO, we have developed two sets of behaviours that can help us stop harm before they occur: CORE Behaviours for all caregivers and LEAD Behaviours for leaders. If every caregiver incorporates and models these behaviours into their work every day, we will achieve our goal of Zero Harm.

Figure 3

Cleveland Clinic London Overview

Cleveland Clinic mission — caring for life, researching for health, educating those who serve — has driven us to seek continual innovation and improvement over our 100-year history.

Cleveland Clinic London has rapidly expanded its presence in the healthcare landscape, offering state-of-the-art services to a diverse international clientele.

Cleveland Clinic London is registered with the Care Quality Commission to provide its services

Cleveland Clinic London Ltd, as a service provider is registered with the Care Quality Commission to carry out the following Regulated Activities:

- *Family Planning*
- *Treatment of disease, disorder or injury*
- *Surgical procedures*
- *Diagnostic and screening procedures*

Here's an overview of its key milestones and current capabilities:

CCL Journey:

- The journey began in 2021 with the opening of the first outpatient centre Portland Place Outpatient Centre Opened in London.
- In March 2022, the Cleveland Clinic Hospital London officially opened its doors.
- Our second outpatient Moorgate Outpatient Centre opened December 2023.

Patient Reach:

- Cleveland Clinic London has successfully served over 20,000 patients, attracting individuals from more than 100 countries. This reflects its status as a global healthcare destination.

Caregiver Strength:

- Boasting a dedicated team, Cleveland Clinic London comprises over 1,440 caregivers, including over 300 medical doctors and 500 nurses. This diverse and skilled workforce is committed to delivering high-quality care.

Figure 4

Situational Analysis

At CCL, we have a Patient Safety Team that oversees the patient safety investigations and incidents in accordance with the current Serious Incident Framework 2015. From 31st March 2024 we will transition to the new patient safety incidence response framework.

Core patient safety activities undertaken at CCL include:

- Delivering patient experience training via Induction
- Liaising with Cleveland Clinic Enterprise on the global patient safety strategy
- 'Stand Up for Safety'
- High reliability training
- Developing patient safety culture
- Identifying risks and reviewing risks regularly on the Risk Register
- Implementing actions in response to patient safety alerts

Other activities within the CCL that provide insights to patient safety include:

- Learning from Deaths Mortality Reviews (Structured Judgement Reviews)
- Mortality & Morbidity Meetings
- MDT Meetings
- Routine quality surveillance
- Freedom to Speak Up
- Safeguarding concerns,
- Complaints
- Compliments and patient feedback
- Payor Quality reporting
- Benchmarking against national clinical registries e.g., NJR, NICOR, PHIN

Table 1: CCL reviewed data from organisational opening Sept 2021 to Dec 2023

	2021	*2022*	*2023*
Never Events	0	0	0
Serious Incidents (Regulatory reportable)	0	3	3
Coroner-Initiated patient safety investigations	0	0	3
Incident referred for independent investigation	0	0	0
Total	0	3	6

Defining our Patient Safety Incident Profile

Cleveland Clinic London (CCL) is committed to a robust patient safety culture, and the patient safety incident profile is meticulously defined through a comprehensive analysis of organisational data since the opening of its sites. The profiling process encompasses various data sources, offering a holistic view of patient safety incidents. Key resources mined for this purpose include:

1. Patient Engagement Surveys:
   - Insights from patient engagement surveys provide valuable perspectives on the patient experience and potential safety concerns.
2. Risks:
   - Continuous monitoring of risks through monthly Quality and Safety reports ensures proactive identification and mitigation of potential hazards.
3. RADAR Events (Quality Management System):
   - Leveraging RADAR events within the Quality Management System facilitates the tracking and analysis of safety-related incidents, enabling a swift response.
4. Audits:
   - Regular audits contribute to the evaluation of adherence to safety protocols and standards, identifying areas for improvement.
5. Data Security and Protection:
   - Ensuring the security and protection of patient data is a critical component, and any incidents related to data security are thoroughly assessed.
6. Morbidity & Mortality Reviews:
   - In-depth structured judgement reviews of morbidity and mortality cases provide insights into clinical outcomes, helping identify areas for improvement in patient care.
7. CQC Reports:
   - The examination of Care Quality Commission (CQC) reports offers external evaluations, aligning CCL's practices with established quality and safety standards.

The patient safety incident profile is further enriched by considering diverse sources such as complaints, investigations, whistleblowing incidents, Freedom to Speak Up (FTSU) reports, and risk assessments. This multifaceted approach ensures a comprehensive understanding of patient safety events and potential areas for improvement.

Continuous Improvement in Patient Safety and Quality at CCL

Cleveland Clinic London (CCL) upholds an unwavering commitment to continuous improvement in patient safety and experience.

Within CCL's Quality Assurance Framework, the Safety & Quality Improvement Plan (SQIP) currently plays a pivotal role. The SQIP is a dynamic tool employed to identify safety and quality improvement initiatives deemed crucial for ensuring patient safety. CCL strategically categorises these initiatives into two key areas: strategic initiatives and key safety quality initiatives.

Strategic Initiatives:

- Mitigate Significant Threats: Interventions designed to address substantial threats to clinical safety and quality, safeguarding patients and caregivers.
- Pursue High-Impact Opportunities: Initiatives focusing on strategic patient safety and continuous improvement with the potential for significant positive impact.

Key Quality Initiatives:

- Enhance Clinical Quality- Transforming Care: Initiatives identified to seize significant opportunities for elevating clinical quality standards and patient outcomes.
- Mitigate Threats to Safety and Effectiveness: Interventions aimed at proactively managing and mitigating threats to patient safety, clinical effectiveness, and patient centeredness.

The Quality & Safety Board at CCL plays a crucial role in overseeing the SQIP. They not only approve the plan but also monitor progress on each initiative. This governance ensures accountability and alignment with the organisation's commitment to continuous enhancement.

The SQIP serves as a dynamic and responsive tool, aligning with CCL's commitment to adapt and improve in the face of changing circumstances. By categorising initiatives into strategic and key quality areas, CCL ensures a targeted and prioritised approach to patient safety and continuous improvement, fostering a culture of excellence and vigilance in healthcare delivery.

Enhance Clinical Quality- Transforming Care	**Continuous Improvement- Mitigate Threats to Safety and Effectiveness**	**Elevate Care Experience & Care Team Engagement**
What we plan to do:	What we plan to do:	What we plan to do:
To consistently deliver the fundamentals of patient care to ensure our patients are kept safe and free of avoidable harm by developing our culture of quality and safety. Continue to seek out opportunities to benchmark the effectiveness of our care so we can demonstrate our excellent health outcomes.	Providing ongoing training and simulation. Leverage technology solutions. Putting patients at the centre of what we do by involve patients in their care plans and encourage them to actively participate in their healthcare decisions.	Be recognised for providing legendary and innovative patient centric care and services which enhance and exceed our patient's expectations

Our patient safety incident response plan: National Requirements

Cleveland Clinic London (CCL) is committed to responding proportionately to patient safety events associated with the key risks identified in our situational analysis. This framework provides flexibility in selecting response methods based on the nature, severity, frequency, and learning objectives associated with each patient safety incident (PSI). Regardless of the chosen response method, the overarching aims remain consistent:

1. Respond to Concerns: Address concerns raised by any patient, their family, or a staff member promptly and comprehensively.
2. Understand Incident Contributors: Conduct thorough investigations to understand the contributing factors that led to the occurrence of the incident in the first place.
3. Identify Areas for Improvement: Identify and analyse areas for improvement, acknowledging the systemic aspects that may have contributed to the incident.
4. Enhance Safety for Future Patients: Implement measures to improve safety, ensuring that lessons learned are applied to prevent similar incidents and enhance overall patient safety for future patients.

Patient safety incident type	Required response	Lead body response
Incidents meeting the Never Events criteria	PSII	CCL
Incident leading to death thought more likely than not due to problems in care	PSII	CCL
Deaths of persons with learning disabilities	PSII	CCL refer to Learning Disability Mortality Review (LeDer)
Safeguarding incidents	These must be reported to CCL Safeguarding Lead and Director Safety Quality & Patient Experience for review and multi-professional investigation. CCL will contribute towards domestic independent inquiries, joint targeted area inspections, domestic homicide reviews and any other safeguarding reviews (and inquiries) as required to do so by the local safeguarding adults boards	Local designated professionals for child and adult safeguarding

Our Patient Safety Incident Response Plan: Local Focus

Our Stand Up for Safety framework acknowledges that the response method chosen should align with the specific characteristics of each incident. This approach allows for a nuanced response strategy that considers the incident's severity, frequency, and the type of learning needed. The goal is to foster a culture of continuous improvement, where every patient safety event serves as an opportunity to enhance the quality and safety of care provided by CCL.

Patient Safety Event	Description	CCL Proportionate Response Type
Surgical Site Infection/ Blood Stream Infection	Infection post-surgery	Post Infection Review and Thematic Analysis
Return to Theatre	All return to theatre within 30 days	Case Note Review and Audit
Cardiac Tamponade	All Cardiac Tamponades	Observation & Thematic Review
Falls with Fracture or Haemorrhage	Inpatient falls leading to injury or haemorrhage	Post Fall protocol and PSII
Hospital Acquired Pressure Ulcers	HAPU Grade PU2 and above	After Action Review
Good Catch	Retained foreign body	After Action Review
Patient Safety & Quality Improvement Projects* **CCL Safety & Quality Improvement plan 2024-2026*	Analysis of recurring patient safety incidents within Radar such as medication events, Falls. Allows for pattern analysis and continues to analyse newly occurring events	Thematic Review
Hospital Acquired Thrombosis (HAT)	Avoidable HAT, mortality associated with HAT, based on the level of harm from the thematic review	Full PSII investigation
Deterioration of a patient	Failure to recognise and treat early deterioration	Full PSII investigation
Mortality Review	Expected and Unexpected Deaths	Structured Judgement Review Tool PSII if following completion of Structured Judgement Tool, cases where the overall care score is 3 or less, or the overall avoidability score is 4 or less, escalation is required and PSII investigation is triggered
All other patient safety Incidents	All other patient safety Incidents that do not meet the requirement of a PSII	Managers review - STAR SWARM huddle, local action and shared learning

Patient Safety Incident reporting arrangements

Local reporting of patient safety incident Investigations (PSIIs)

The full details of the reporting arrangements are detailed within the CCL's Incident Management Policy. The policy provides the reporting structure for reporting incidents at CCL including regulatory reporting to External Agencies. Our new Patient Safety Incident Response Policy will describe how the insight from our learning responses feeds into driving future safety improvement plans.

Tiered huddles occur daily providing a channel of escalation to Patient Safety Events. All events reported as causing moderate, physical harm or above will be discussed at the daily Tier 1- Safety, Quality and Patient Experience (SQPE) Safety event meeting to determine if further information is required and decide on the type of investigation required. The patient safety events are then discussed with senior managers and leaders at the Tier 3 huddle.

Quality and Safety Board

The Quality and Safety (Q&S) Board is chaired by The President. The Q&S Board meet quarterly and has oversight of the quality and safety agenda for CCL and approval for risks, PSII and other patient safety reviews. QSB reports to the Executive Team and provides assurance on reports received.

Patient Safety & Experience Sub-Committee

Patient Safety & Experience Sub-Committee is chaired by the Director of Safety, Quality, and patient experience, meets monthly and reports into the Integrated Governance Committee. The sub-committee will seek reassurance from our Clinical Institutes regarding patient safety and experience events.

Procedures to support patients, families and carers affected by PSIIs

Cleveland Clinic London is committed to the principles of a Just Culture for ensuring fair, open and transparent treatment of caregivers who are involved in patient safety incidents. CCL have embedded these principles into our current procedures in the review of incidents. At CCL we recognise the significant impact of patient safety incidents.

The Patient Experience Team are available to all patients who wish to share their experience, we welcome feedback on all aspects of care and all concerns and complaints are investigated thoroughly and confidentially.

Duty of candour requires Caregivers to be open and transparent with the people who use the service. When a specified safety incident has occurred in respect of care provided, the regulation sets out a clear set of legal duties on providers about how and when to notify people using their service (or their relevant representatives) about those safety incidents. Regulation 20 also describes when a notification about a safety incident needs to be made to the Care Quality Commission (CQC) (CQC, 2014).

Patient Safety Team will advise and signpost Caregivers to the following support resources.

- Mental Health First Aid (MHFA) – England
  - Provides: workplace guidance for employers and employees, information on mental health first aid training
- Occupational Health Service
- Freedom to Speak Up Guardian: A confidential service for Caregivers if they have concerns about the organisational response to a patient safety incident.
- Second Victim Support -A website resource for healthcare staff and managers involved in patient safety incidents.

There will be identified Caregivers who will have training in Engaging patients and families after a patient safety incident and involving patients and families in any subsequent investigations and/or incident reviews

Appendix 1

Method	Description
Patient safety incident investigation (PSII)	A PSII offers an in-depth review of a single patient safety incident or cluster of incidents to understand what happened and how.
MDT review	An MDT review supports health and social care teams to learn from patient safety incidents that occurred in the significant past and/or where it is more difficult to collect staff recollections of events either because of the passage of time or staff availability. The aim is, through open discussion (and other approaches such as observations and walk throughs undertaken in advance of the review meeting(s)), to agree the key contributory factors and system gaps that impact on safe patient care
STAR Swarm Huddle	The STAR Swarm huddle is designed to be initiated as soon as possible after an event and involves an MDT discussion. Stop, Think Act review is HRO skill that all Caregivers are taught. Staff 'swarm' to the site to gather information about what happened and why it happened as quickly as possible and (together with insight gathered from other sources wherever possible) decide what needs to be done to reduce the risk of the same thing happening in future.
After Action review	AAR is a structured facilitated discussion of an event, the outcome of which gives individuals involved in the event understanding of why the outcome differed from that expected and the learning to assist improvement. AAR generates insight from the various perspectives of the MDT and can be used to discuss both positive outcomes as well as incidents. It is based around four questions: • What was the expected outcome/expected to happen? • What was the actual outcome/what actually happened? • What was the difference between the expected outcome and the event? • What is the learning?
Thematic Review	A thematic review can identify patterns in data to help answer questions, show links or identify issues. Thematic reviews typically use qualitative (e.g. open text survey responses, field sketches, incident reports and information sourced through conversations and interviews) rather than quantitative data to identify safety themes and issues. Thematic reviews can sometimes use a combination of qualitative data with quantitative data. Quantitative data may come from closed survey responses or audit, for example.
Case Note Review	A case note review in healthcare refers to the process of examining and evaluating patient records to assess the quality of care provided. The process involves several key steps: Selection of case notes, Examination of records, Assessment of care quality, Identification of issues or trends, Recommendations for improvement, Follow up and monitoring.

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