

Patient Safety Incident Response (PSIR) Policy

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Original Author (name and role)	Jenni Bell, Hospice Manager
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Main Headings:	<ol style="list-style-type: none"> 1. Purpose 2. Scope 3. Our Patient Safety Culture 4. Patient Safety Partners 5. Addressing Health Inequalities 6. Engaging & Involving Patients, Families & Staff Following a Patient Safety Incident 7. Patient Safety Incident Response Planning 8. Responding to Patient Safety Incidents 9. Oversight of Roles & Responsibilities 10. Complaints & Appeals 11. Related Policies 12. Governance, Monitoring & Review
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Signed:

Date:

Director of Clinical Services:

Signed:

Date:

Chief Executive Officer:

1. Purpose

This policy supports the requirements of the Patient Safety Incident Response Framework (PSIRF) and sets out Claire House Children's Hospice'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

2. Scope

This policy is specific to patient safety incident responses conducted solely for the purpose of learning and improvement across all care services provided by Claire House Children's Hospice.

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.

3. Our Patient Safety Culture

In all organisations, there are occasions when actions or events happen which are untoward and cause loss, harm or damage, or have the potential to do so. When this happens, it is essential to have an open and transparent process for reporting and managing such incidents in order to learn, develop and improve.

At Claire House, when incidents occur, there must be systems in place to respond to them. These systems include recognising harm and the potential for harm, and undertaking a swift, thoughtful and practical response, without inappropriately blaming individuals. These systems must protect patients and ensure a robust investigation is carried out.

Claire House encourages the reporting of incidents, both clinical and non-clinical, as part of Clinical Governance, and promotes an open, positive and fair approach to incident reporting. Incident forms have been re-named 'Care Improvement Forms' (CIFs) to help promote this positive approach.

Claire House aims to ensure that everyone working within the Hospice feels safe and confident to speak up. We encourage our Leadership Team and Trustees to take the opportunity to learn and improve from those who speak up. Claire House has Freedom to Speak Up Guardians who work in different departments, and all are available to support staff wherever needed. Staff also have access to the Employee Assistance programme, Occupational Health, and can be referred for face to face counselling.

Accurate and timely reporting of incidents and near misses enables lessons to be learned and change to be implemented. Analysis of trends and patterns provides information to inform education and training programmes, revise policies, procedures, and guidelines, build on strengths and improve areas for development.

Claire House will remain proactive in risk management and will balance learning through responding to incidents and exploring issues and improvement work.

For the purpose of this policy, the following definitions are applicable:

NEVER EVENT:

"Never Events are defined as serious incidents that are wholly preventable because guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and should have been implemented by Healthcare providers" (NHS Improvement, 2018)

WHAT ARE NEVER EVENTS?

The NHS have a defined list of Never Events. Some of these do not apply to the care provided at Claire House, for example, due to the fact we do not undertake surgery. For the purposes of reporting at Claire House, the following Never Events will apply:

- 1) Administration of medication by the wrong route (Oral/Enteral medicine or feed/flush by any parenteral route)
- 2) Overdose of insulin due to abbreviations or incorrect device
- 3) Falls from poorly restricted windows
- 4) Chest or neck entrapment in bed rails
- 5) Misplaced naso or oro-gastric tubes

6) Scalding of patients

Please refer to 'Never Events List 2018' NHS Improvement for further details

https://improvement.nhs.uk/documents/2266/Never_Events_list_2018_FINAL_v5.pdf

HARM:

What Is Harm?

Harm can be defined as any actual or potential ill effects, danger or material damage suffered by an individual. Harm can be deliberate but may also be accidental or caused by negligence. It may be physical, or it may be psychological or emotional. In healthcare, patients will often be more vulnerable to harm than others owing to their illness. There are many different forms that harm can take in healthcare, such as:

- General harm from healthcare provided
- Acquired infections, falls, and dehydration
- Treatment specific harm – harm that is associated with a specific treatment or the management of a particular disease, for example adverse drug events
- Harm due to overtreatment – patients may be harmed from being given too much treatment, either through error for example a drug overdose or from well-intended but excessive intervention, for example treatment at end of life that is painful and not necessary
- Harm due to failure to provide appropriate treatment - this is when the health care professionals fail to provide the appropriate treatment for the symptom, injury, etc
- Harm resulting from delayed or inadequate diagnosis – staff may not diagnose as acute situation or causes of symptom quick enough
- Psychological harm and feeling unsafe – for example, if a patient is made to feel anxious by the behaviour of a health care professional *Vincent et al (2013)*

Training: (Training will be required based upon the needs of the role).

	Level 1 e-learning: Essentials of Patient Safety for all Staff (Provided by e-lfh module)	Level 2 e-learning Access to Practice 1 & Access to Practice 2 (Provided by e-lfh module)	e-learning Essentials of Patient Safety for Boards and Senior Leadership Teams (Provided by e-lfh module)	Systems Approach to Learning (2 days / 12 hours) (Provided by HSIB)	Involving those affected by Patient Safety Incidents in the Learning Process (Provided by HSIB)
All Hospice Staff	✓				
All Staff who will undertake any Incident Investigation (Band 6 and above)	✓	✓		✓	
Patient Safety Specialist & Engagement Leads (CLT)	✓	✓		✓	✓

Patient Safety Executive Lead (Director of Clinical Services)	✓	✓	✓		
ELT	✓		✓		
Trustees	✓		✓		

4. Notification and Involvement of External Agencies

Depending on the Incident it may be necessary to notify and involve external agencies, including:

- Care Quality Commission (CQC)
- Integrated Care Board (ICB) of child if relevant
- LADO (Local Authority Designated Officer)
- Controlled Drugs Accountable Officer (CDAO)
- Controlled Drugs Local Intelligence Network (LIN)
- Coroner
- Health & Safety Executive (HSE)
- Health Education England
- Information Commissioner (for serious data breaches)
- Local Authorities
- Medicines and Healthcare Regulatory Agency (MHRA)
- Police
- Professional Regulators including Nursing & Midwifery Council (NMC), The Health and Care Professionals Council (HCPC) and General Medical Council (GMC)
- UK Health Security Agency (formerly Public Health England)
- All incidents are logged through the Vantage Incident Reporting System, with any incidents classified as patient safety events being submitted to LFPSE via the same platform.

Failure to report a Never Event is unacceptable and can signal cultural and safety failings in an organisation. Deliberate failure is likely to constitute a breach of Care Quality Commission (CQC) requirements.

5. Addressing Health Inequalities

Claire House recognise that we have a core role to play in reducing inequalities by improving access to palliative care services and tailoring those services around the needs of the local population in an inclusive way.

We will use data intelligently to assess for any disproportionate patient safety risk to patients from across the range of protected characteristics. As part of our new incident response framework,

protected characteristics will be considered as part of the patient safety review to give insight into any apparent inequalities. Although some of the nine protected characteristics of age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex and sexual orientation may not be applicable to Claire House Children's Hospice, they all need to be considered and appropriate adjustments made if required (e.g., involvement of an interpreter). Wider health inequality variables (e.g., mental health conditions) that can affect care that people receive should also be considered.

Engagement of patient, families and staff following a patient safety incident is critical to the review of patient safety incidents and their response. We will ensure that we use available tools such as easy read, translation and interpretation services and other methods as appropriate to meet the needs of those concerned and maximise their potential to be involved in our patient safety incident response.

Equity, Diversity and Inclusion (EDI) remain a clear priority for Claire House and through this we endorse a zero acceptance of racism, discrimination, and unacceptable behaviours from and toward our workforce and our patients/service users, carers and families. With explicit role modelling led by our Leadership Teams, we will use these principles to underpin patient safety training and implement the system-based approach to patient safety responses which is at the heart of PSIRF best practice.

6. 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.

As well as meeting our regulatory and professional requirements for Duty of Candour, we want to be open and transparent with our patients, families, and carers because it is the right thing to do. This is regardless of the level of harm caused by an incident. We will do this by creating the right foundations, process and nine guiding principles, as set out below.

Guiding principles for openness and transparency

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

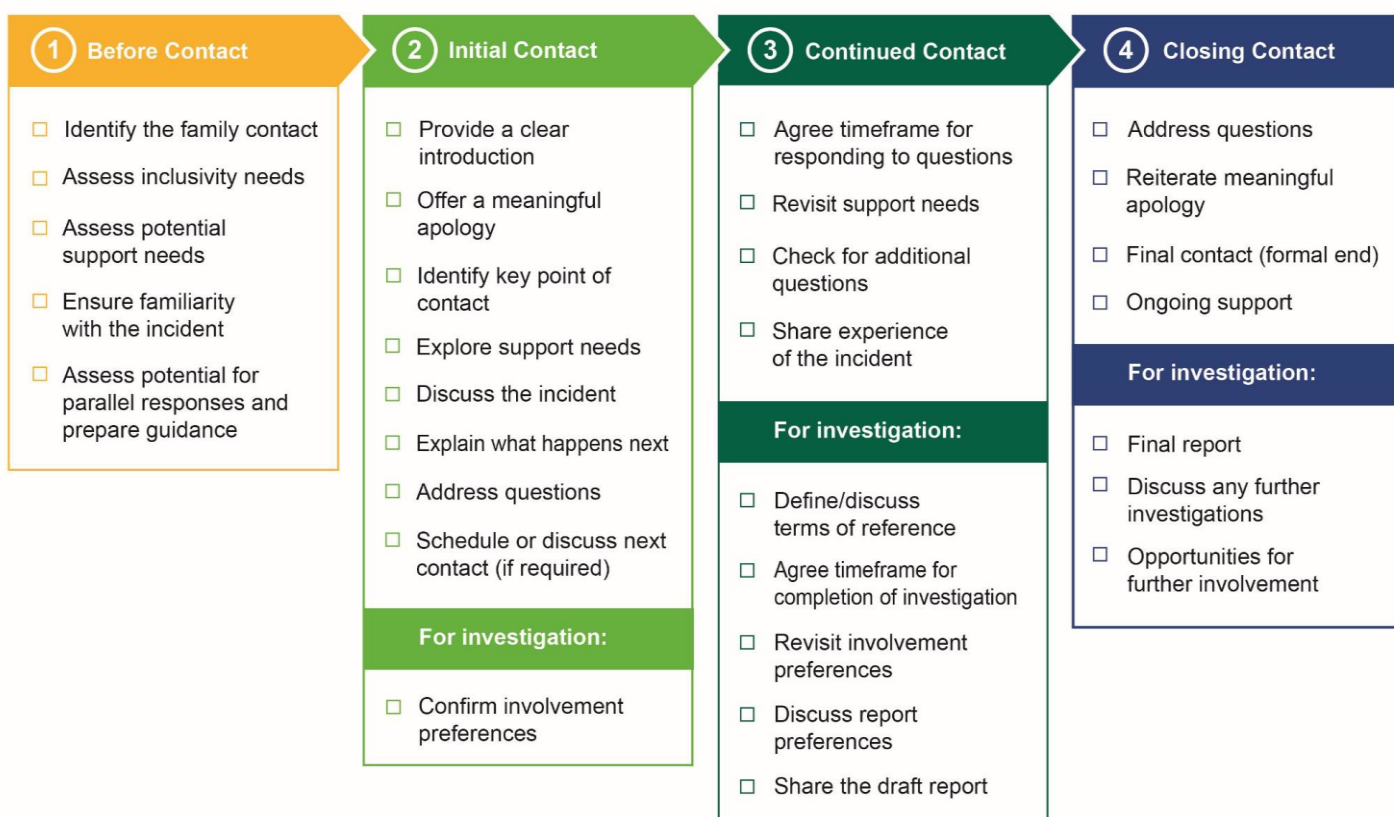
Everyone will experience the same incident in different ways. No one truth should be prioritised over others. Engagement leads should ensure that patients, families, and healthcare staff are all viewed as credible sources of information in response to a patient

9. Strive for equity

The opportunity for learning should be weighed against the needs of those affected by the incident. Engagement leads need to understand and seek information on the impact of how they choose response types on those affected by incidents and be aware of the risk of introducing inequity into the process of safety responses.

Steps of engagement:

For those incidents which meet the criteria for a PSII investigation, we will enable the four steps of engagement:



If a patient or family do not wish to be contacted directly to discuss a patient safety incident, Claire House will respond in accordance with local policies and procedures.

Other forms of support for those affected by incidents:

We recognise that there might also be other forms of support that can help those affected by a Patient Safety incident and will work with patients, families, and carers to signpost to their preferred source for this:

Healthwatch

<https://www.healthwatch.co.uk/> Healthwatch are an independent statutory body who can provide information to help make a complaint, including sample letters. You can find your local Healthwatch from the listing (arranged by council area) on the Healthwatch site <https://www.healthwatch.co.uk/your-local-healthwatch/list>

Citizens Advice Bureau

<https://www.citizensadvice.org.uk/> provides UK citizens with information about healthcare rights, including how to make a complaint about care received.

7. Patient Safety Incident Response Planning

PSIRF supports response 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.

Resources and Training to Support Patient Safety Incident Response

Our Patient Safety Incident Response Plan

Our plan sets out how Claire House Children's Hospice 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. The plan will highlight any themes, trends, or concerns and these areas will be investigated deeper.

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 12-18 months to ensure our focus remains up to date. This will also provide an opportunity to re-engage with stakeholders to discuss and agree any changes made.

Quarterly reporting will be provided to Wirral ICB via our quarterly report.

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.

8. Responding to Patient Safety Incidents

Patient Safety Incident Response Decision-Making

- PSIRF itself sets no further national rules or thresholds to determine what method of response should be used to support learning and improvement. Claire House has developed its own response mechanisms to balance the effort between learning through responding to incidents or exploring issues and improvement work. In the work to create our plan we have considered what our incident insight has shown us about our patient safety profile. We have used this intelligence to build our local priorities for PSII.
- We have established a process for our response to incidents which allows for a clear set of mechanisms allowing for oversight of incident management and our PSIRF response.
- Staff will have escalation arrangements in place for the monitoring of patient safety incidents and this includes escalation of incidents which appear to meet the need for further exploration as a rapid review due to possibly meeting the criteria as PSII or due to the potential for learning and improvement or an unexpected level of risk.
- The Clinical Leadership Team (CLT) will have delegated responsibility for the consideration of incidents for PSII and for oversight of the outcomes of such reviews to ensure that recommendations are founded on a systems-based approach and safety actions are valid and contribute to existing safety improvement plans or the establishment of such plans where they are required.
- Local level incidents – line managers of all clinical areas have arrangements in place to ensure that incidents can be reported and responded to. Incident responses should include immediate actions taken to ensure safety of patients, public and staff, as well as indication of any measures needed to mitigate a problem until further review is possible. This may include for example, withdrawing equipment or monitoring response. Any response to an incident should be fed back to those involved or affected and appropriate support offered. Where Duty of Candour applies this must be carried out according to hospice guidance.
- Incidents with positive or unclear potential for PSII – all staff (directly or through their line manager) must ensure notification of incidents that may require a higher level of response as soon as practicable after the event through internal escalation processes (including out of hours) and this must include their immediate line manager. Duty of Candour disclosure should take place according to hospice guidance. Where it is clear that a PSII is required (for example, for a Never Event) the clinical line manager should notify the CLT as soon as practicable so that the incident can be shared to the Director of Clinical Services and then escalated to the Executive Leadership Team (ELT). A rapid review will be undertaken by the clinical line manager to inform decision making by CLT.
- Other incidents with unclear potential for PSII, must also be reported to CLT. A rapid review will be undertaken by the clinical line manager to inform this decision making. Significant incidents which may require consideration for ad-hoc PSII due to an unexpected level of risk and/or potential for learning should be included in this category.
- CLT will meet at the earliest opportunity to discuss the nature of any escalated incident, immediate learning (which should be shared via an appropriate platform), any mitigation identified by the rapid review or that is still required to prevent recurrence and whether the Duty of Candour requirement has been met. The group will define terms of reference for a PSII to be undertaken by the response lead. The group will also designate subject

matter expert input required for any investigation or highlight any cross system working that may be necessary, as well as indicating how immediate learning is to be shared.

- Where an incident does not meet the requirement for PSII, investigations will be undertaken in accordance with patient safety response plan. CLT may request a further investigative review or closure of the incident at a local level, with due consideration of any Duty of Candour requirement being met. CLT will also indicate how immediate learning is to be shared.
- CLT will have processes in place to communicate and escalate necessary incidents within NHS commissioning and regional organisations and the CQC according to accepted reporting requirements.

Timeframes for Learning Responses

Timescales for patient safety PSII

- Where a PSII for learning is indicated, the investigation must be started as soon as possible after the patient safety incident is identified and should ordinarily be completed within one to three months of their start date. No local PSII should take longer than six months.
- The timeframe for completion of a PSII will be agreed with those affected by the incident, as part of the setting of terms of reference, provided they are willing and able to be involved in that decision. A balance must be drawn between conducting a thorough PSII, the impact that extended timescales can have on those involved in the incident, and the risk that delayed findings may adversely affect safety or require further checks to ensure they remain relevant.
- In exceptional circumstances, a longer timeframe may be required for completion of the PSII. In this case, any extended timeframe should be agreed between the hospice and those affected.

Timescales for other forms of learning response

- A learning response must be started as soon as possible after the patient safety incident is identified and should ordinarily be completed within one month of their start date. No learning response should take longer than six months to complete.

Safety Action Development and Monitoring Improvement

Claire House acknowledge that any form of patient safety learning response (PSII or review) will allow the circumstances of an incident or set of incidents to be understood, but that this is only the beginning. To reliably reduce risk, better safety actions are needed.

Claire House will design, implement and monitor safety actions using an integrated approach to reduce risk and limit the potential for future harm. This process follows on from the initial findings of

any form of learning response which might result in identification of aspects of the hospice's working systems where change could reduce risk and potential for harm – areas for improvement. The hospice will generate safety actions in relation to each of these defined areas for improvement. Following this, the hospice will have measures to monitor any safety action and set out review steps.

9. Oversight Roles and Responsibilities

The Board of Trustees

Has a responsibility to ensure that it receives assurance that this plan is being implemented, that lessons are being learnt, and areas of vulnerability are improving. This will be achieved through reporting processes as well as receiving assurance via Clinical Governance Meeting. A quarterly report is presented at Clinical Governance which will include any patient safety incident investigations within the Hospice and monitors lessons learnt from these. Where concerns are identified relating to the robustness of lessons learned or actions planned the Board will seek assurances that these concerns are being acted upon.

Chief Executive Officer (CEO):

The CEO of Claire House is ultimately responsible and accountable for making sure that the organisation has the correct policies in place and that they are understandable, legal, up-to-date and implemented.

Director of Clinical Services (DCS) (Patient Safety Executive Lead) :

As the Registered Manager of the Clinical Services provided by Claire House, the DCS is legally responsible for the standard of care of the organisation. As such the DCS is responsible for the identification, formulation, implementation and communication of all clinical policies. The Director of Clinical Services should ensure all relevant internal and external agencies are notified accordingly.

Clinical Leadership Team (Patient Safety Specialist & Engagement Leads):

Are responsible for identifying if PSII is required, initiating the investigation and notifying the DCS. **They will act as Patient Safety Specialist & Engagement Leads** as directed by the Director of Clinical Services.

Head of Communications

The Head of Communications has responsibility to liaise closely with the CEO and Director of Clinical Services to assess the impact of the incident in relation to reputational risk for Claire House. Head of Communications is to ensure accurate and relevant communication relating to the incident both internally and externally with press and other agencies. They will monitor reputational impact on social media, and in the regular media and coordinate any actions required.

Head of Care Workforce, Education and Quality:

Will be responsible for, along with the Hospice Manager, identifying trends in incidents and then acting accordingly by introducing change management or additional training to reduce the potential of a further incident. **The Head of Care Workforce, Education and Quality may be identified by the DCS as a Patient Safety Specialist & Engagement Lead.**

Team Leaders/Hospice Lead Nurses (HLN):

Will be responsible for encouraging the reporting of all patient safety incidents and ensure all staff in their departments are competent in using the Vantage reporting system. Responsible for undertaking the necessary investigation relating to general incidents within their service area and ensuring this is documented fully. The Team Leader/HLN will support the development and delivery of actions in response to patient safety reviews/PSII investigations that relate to their area of responsibility.

Hospice Manager/Medicine Management Lead:

The Medicine Management Lead, along with the Practice Education Team will be responsible for identifying trends in incidents and then acting accordingly by developing and delivering actions identified.

The Medicine Management Lead will compile a report and an up to date quarterly log of incidents for Clinical Governance. At Clinical Governance the meeting will be informed of the incidents, the RAG rating of these incidents will be assigned, and any necessary actions taken, together with any lessons learned.

The Hospice Manager may be identified by the DCS as a Patient Safety Specialist & Engagement Lead.

Health & Safety Lead:

The Health & Safety Lead will attend quarterly Health & Safety Meetings where incidents will be discussed and outcomes actioned. They will then compile a report and up to date log of incidents for Clinical Governance. At Clinical Governance the meeting will be informed of the incidents, the trends, the RAG rating of these incidents and actions taken, together with any lessons learned.

All Staff Members & Volunteers:

All staff members and volunteers are responsible for following all internal policies and procedures regarding all aspects of incident management. They are encouraged to report any concerns or issues that could lead to an incident in a positive, open manner at the earliest opportunity. All staff and volunteers also have access to the Freedom to Speak Up Guardians for support and guidance in relation to reporting clinical incidents.

10. Complaints and Appeals

Claire House Children's Hospice has a complaints procedure which is available to all service users.

11. Related Policies

Health & Safety Policy
Complaints Policy
Whistleblowing Policy
Incident Policy
Managing Allegations against Staff Policy
Duty of Candour Policy

Engagement and Investigation Leads SOP
Complaints Hospice SOP
Investigating Complaints SOP
Investigating Complaints with Allegations against Staff SOP
Incident Reporting Including Care Improvement Form SOP
Care Improvement Form SOP

12. Governance, Monitoring and Review

This policy will be reviewed every 1 year until the PSIRF is fully implemented.

Every 4 years a rigorous planning exercise will be undertaken (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. The proposed date would be March 2028.

In compliance with statutory requirements:

- NHS England – Patient Safety Incident Response Framework August 2022
- NHS Improvement – Never Events List 2018, January 2018
- NHS Improvement – The Future of NHS Patient Safety Investigation March 2018
- The Health Foundation (2011) Report: Levels of Harm: Research Scan, London
- Care Quality Commission (Registration) Regulations