Patient Safety Incident Response (PSIRF)
Policy BHT Pol 322

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Document History

Version	Issue	Reason for change	Authorising body	Date
1	0	New Policy	Quality & Clinical Governance Committee TPSG	Feb 2024 April 2024

Contents

ASSOCIATED POLICIES AND DOCUMENTS

BHT Ref	Title	Link
BHT Plan	Patient Safety Incident Response Plan (PSIRP)	
BHT Pol 007	Being Open and Duty of Candour Policy	BHT Pol 007
BHT Pol 032	Standards of Behaviours and Conduct Policy & Procedure	BHT Pol 032
BHT Pol 093	Safeguarding Adults Policy	BHT Pol 093
BHT Pol 149	Safeguarding Children Policy	BHT Pol 149
BHT Pol 092	Freedom To Speak Up Policy	BHT Pol 092
BHT Pol 130	Information Risk Policy	BHT Pol 130
BHT Pol 135	Monitoring Compliance with legislation (and other obligations)	BHT Policy 135
BHT Pol 021	Policy on Responding to Concerns Complaints and Compliments	BHT Pol 021
BHT Pol 125	Records Management Policy	BHT Pol 125
BHT Pol 128	Recruitment and Selection Policy and Procedures	BHT Pol 128
BHT S102	Risk Management Strategy	BHT S102
BHT Pol 215	Adult Mortality Review Process Policy	BHT Pol 215
BHT Pol 90	Psychological Wellbeing in the Workplace	BHT Pol 90
Guideline 773.4	Management of Child Deaths	Eolas Medical 773.4
Website	New levels of Harm definitions from NHS England LFPSE National Guidance (June 2023)	NHS England (2023) Policy Guidance or recording patient safety events and level of harm

Website	NHS England: Patient Safety Incident Response Framework	NHS England » Patient Safety Incident Response Framework
Website	NHS England (2023) Policy Guidance or recording patient safety events and level of harm	NHS England (2023) Policy Guidance or recording patient safety events and level of harm
Website	Healthcare Safety Investigation Branch (HSIB)	Healthcare Safety Investigation Branch (hsib.org.uk)

Term/Abbreviation	Definition
After Action Review (AAR)	A meeting with those involved in the incident and local area seeking to understand what happened, what had been expected to happen, why was there a difference and is there any local learning from the event, and whether there may be wider issues requiring further learning responses.
BOB ICB	The Buckinghamshire, Oxfordshire, and Berkshire West Integrated Care Board (BOB ICB)– plan and provide health and care services for nearly two million people who live and work in the local authority areas of Buckinghamshire, Oxfordshire, and Berkshire.
Debrief	A rapid meeting to review the event to answer the same questions as for the AAR review and to provide colleagues support
Engagement Lead	The identified member of colleagues who is leading on engagement with, and involvement of, the patient / family / carer. This member of colleagues could be the Family Liaison Officer and/or another member of colleagues who is involved in the learning process. Sometimes the two can co-exist
Initial Findings Report (IFR)	This is a written initial review of the incident/event, usually completed by one author. This will include a timeline of events, highlighting any immediate risks and whether there are any concerns that may require a subsequent learning response. They will usually be requested to determine whether a PSII response may be required (as per our PSIRP).
Learning Lead	The identified member of colleagues who is leading the learning response
Learning Response	A response to a patient safety incident focusing on learning. The response can be delivered through a toolbox of methodologies.
LFPSE	The Learn from Patient Safety Events (LFPSE) service is a new national NHS service for the recording and analysis of patient safety events that occur in healthcare.
MDT Review	A follow up-multidisciplinary meeting to understand the wider organisational issues, including subject matter experts and other relevant stakeholders.
Patient Safety Incident	NHS England national policy defines it as an unplanned, unexpected, or unintended event where something has happened, or failed to happen, as a result of the care or treatment provided that could have or did lead to patient harm
Patient Safety Incident Investigation (PSII)	An in-depth system-based investigation that seeks to identify and understand all the factors and issues that contribute to the incident.
Patient Safety Response (PSR)	A response to patient safety incidents for the purpose of learning and improving patient safety.
Patient Safety Incident Response Plan (PSIRP)	An organisation's plan represents a proposal for how they intend to respond to patient safety incidents over a period of 24 months. PSIRP is not a permanent rule that cannot be changed.

	Organisations must remain flexible and consider each patient safety incident in light of the specific circumstances in which it occurred and the needs of those affected, as well as the PSIRP.
Thematic Analysis	A thematic review can identify patterns in data to help answer questions, show links, or identify issues. Thematic reviews typically use qualitative rather than quantitative data to identify safety themes and issues to review multiple cases of a similar nature to derive themes.

1 INTRODUCTION

This policy supports the best practice guidance set out in the NHS England Patient Safety Incident Response Framework (PSIRF) and explains how Buckinghamshire Healthcare NHS Trust (the Trust) will approach the development and maintenance of effective systems and processes for responding to patient safety incidents and issues for the purpose of learning and improving patient safety.

2 PURPOSE OF POLICY

The PSIRF advocates a coordinated and data-driven response to patient safety incidents. It embeds patient safety incident responses 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 as per the PSIRF National policy which can be found here Key Aims of PSIRF

These aims align to our existing Trust values which are:

- Collaborate together as a team
- Aspire to be the best
- Respect everyone, valuing each person as an individual
- Enable people to take responsibility

This document should be read alongside the Trust's Patient Safety Incident Response Plan (PSIRP).

3 SCOPE OF POLICY

This policy relates to all colleagues working within the Trust and is specific to patient safety incident responses conducted solely for the purpose of learning and improvement across the Trust.

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 complex interactions among several components of the healthcare system and not from a single component. This approach is specific to patient safety incident responses conducted solely for the purpose of learning and improvement across all BHT services as identified in the Patient Safety Incident Response Plan and the clinical services listed on the Trust's website.

Learning 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. Where other processes exist with a remit of determining liability or to apportion blame, or cause of death, their principal aims differ from a patient safety learning response. Such processes as those listed below are therefore outside of the scope of this policy:

- Claims handling,
- Human resources investigations into employment concerns,
- Professional standards investigations,
- Information governance concerns
- Estates and facilities concern

- Financial investigations and audits
- Safeguarding concerns
- Coronial inquests and criminal investigations
- Complaints (except where a significant patient safety concern is highlighted)

For clarity, the Trust considers these processes as separate from any patient safety incident response. Information from a patient safety incident 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.

4 ROLES AND RESPONSIBILITIES

4.1 Principles of oversight

Working under PSIRF, organisations are advised to design oversight systems to allow an organisation to demonstrate improvement rather than compliance with centrally mandated measures.

The Trust will work collaboratively with BOB ICB to ensure we have effective oversight and improvement of patient safety across our systems and to support where appropriate cross-organisational learning. This will involve participation in identified relevant forums such as Regional Patient Safety & Improvement Forum, regular PSIRF reviews, peer reviews and educational events.

4.2 Ensuring that PSIRF is central to overarching safety governance arrangements

The Trust Board will receive assurance regarding the implementation of PSIRF and associated standards via existing reporting mechanisms such as the Patient Safety Board, Patient Experience Board, Clinical Effectiveness Board, Care Group Performance Reviews and Trust sub-board Quality & Clinical Governance Committee.

The Trust will source necessary training such as the Patient Safety Syllabus (Health Education England) and other patient safety training options as appropriate to the roles and responsibilities of its colleagues in supporting an effective organisational learning response to incidents.

Updates will be made to this policy and associated PSIRP as part of regular oversight. A review of this policy and associated PSIRP should be undertaken at least every 3 years.

4.3 Quality assuring learning response outputs

The Trust will implement a Patient Safety Incident Panel (PSIP) to ensure that PSIIs and learning responses are conducted to the highest standards and to support the executive sign off process and ensure that learning is shared trust wide across all care groups, and safety improvement work is adequately directed.

The PSIP will also take oversight and provide executive sign off for all PSRs unrelated to deaths.

5 RESPONSIBILITIES

Chief Executive Officer
The CEO is responsible for ensuring that the appropriate governance arrangements are in place to support openness between healthcare professionals and patients and/or their carers, colleagues, and visitors.

Chief Operating Officer
The post holder is responsible to the Chief Executive Officer in ensuring that governance arrangements are in place and risks are managed within the Trust.

Chief Nurse Officer
Designated Executive Director for PSIRF. The Chief Nurse will oversee the development, review, and approval of the Trust's policy and PSIRP ensuring that they meet the expectations set out in the national patient safety incident response standards. The policy and PSIRP will promote the restorative just working culture that the Trust aspires to.

Chief Medical Officer
Has the lead responsibility for the Learning from Deaths process.

Deputy Chief Nurse
Has delegated responsibility from the Chief Nurse for enacting the development, review, and approval of the Trust's policy and PSIRP ensuring that they meet the expectations set out in the national patient safety incident response standards.

Care Group Directors, and other senior Managers (including senior Governance roles in Care Groups): Have responsibility for ensuring Care Group commitment to implement the policy as well as for putting effective governance, systems, and processes in place to enable successful implementation.

Patient Safety Specialists and Patient Safety Manager: Have responsibility for providing patient safety expertise and independence to support the implementation of the policy, as well as working alongside operational colleagues to develop effective governance, systems, and processes for successful implementation of the policy.

Managers and Service Leads: Are responsible for ensuring their services and teams are provided with the right conditions to support them to engage in and practically implement the policy

Patient Safety Investigators: Have responsibility for providing patient safety expertise and independence to support the investigation of Patient Safety Incidents as well as working alongside operational colleagues to complete robust Safety Improvement action plans and monitor and update these as required.

Family Liaison Officer: Have responsibility for leading on engaging with and involving those affected by a patient safety incident including supporting with the completion of Duty of Candour requirements.

All colleagues: Have a responsibility to behave in a way which supports an effective patient safety culture.

6 POLICY CONTENT

6.1 Our Patient Safety Culture

The importance of an open, just, and compassionate culture across the organisation is paramount to ensuring that we always put patient care first, and that we continually look at ways to learn. Colleagues and patients are encouraged to raise any concerns about the quality of care, patient safety and poor behaviors and we have developed a range of ways people can do this, including through our Freedom to Speak up guardian, our Datix system and Staff survey.

We continue to encourage a positive incident reporting culture in the Trust. When an incident is reported this is used as an opportunity to learn through our established safety forums and quality governance arrangements as well as regular data analysis to identify trends and emerging themes.

6.2 Patient Safety Partners

The Patient Safety Partners (PSP) can be patients, carers, family members or other lay people (including NHS colleagues from another organisation). Our patient safety partners will work alongside clinical colleagues and patients/families to co-design and implement patient safety initiatives, training, resources, support activities around governance and other opportunities to improve the safety of care.

This role across the NHS will evolve over time and in our Trust the main purpose of the role is to be a voice for the patients and community who utilise our services and ensure that patient safety is at the forefront of all that we do.

PSPs will communicate rational and objective feedback focused on ensuring that patient safety is maintained and improved, this may include attendance at governance meetings, reviewing patient safety, risk and quality and being involved with contributing to documentation including policies, learning responses and reports. This information may be complex, and the PSPs will provide feedback to ensure that patient safety is our priority. PSPs should participate in the review of patient safety incidents, assist in the implementation of patient safety improvement initiatives, and develop patient safety resources which will be underpinned by training and support specific to this new role in collaboration with the patient safety team to ensure PSPs have the essential tools and advice they need.

6.3 Addressing health inequalities

As outlined in our Patient Safety Incident Response Plan (PSIRP) the Trust has an important role to play in reducing inequalities in health by improving access to services and tailoring services around the needs of the local population to be inclusive. We are committed to reducing this variation through developing colleagues' knowledge and awareness and continuing to collect and use data to assess existing or potential future patient safety risks from across the range of protected characteristics.

6.4 Engaging and involving patients, families and colleagues following a patient safety incident.

The Patient Safety Incident Response Framework 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 colleagues). 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.

We are committed to continuously improving the care and services we provide. We want to learn from any incident where care does not go as planned or expected by our patients, their families, carers, or colleagues to prevent recurrence.

We recognise and acknowledge the significant impact patient safety incidents can have on patients, their families, and carers. We also acknowledge the impact incidents have on colleagues and the Trust is committed to continue working on our safety culture to foster an environment of psychological safety and well-being where our colleagues feel safe to openly review and learn from incidents.

Getting involvement right with colleagues, patients, and families in how we respond to incidents is crucial, particularly to support improving the services we provide.

Part of this involves our key principle of being open and honest whenever there is a concern about care not being as planned or expected or when a mistake has been made.

To meet our regulatory and professional requirements for Duty of Candour (see BHT Pol 007: Being Open and Duty of Candour), we will 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.

A Family Liaison Officer will be allocated to each Patient Safety Incident investigation (PSII) and any other specific learning response which has been identified as requiring an engagement lead by the Patient Safety Team or Investigator. This may be the individual who is leading or supporting the actual learning response and / or this may be a dedicated Family Liaison Officer (depending on the nature of the incident). The Trust has commissioned dedicated Patient Safety Investigators who will support the Care Groups with the appropriate learning and ensure that patient safety is prioritised, and clinical resources are protected.

The Trust has Patient Advice and Liaison Service (PALS) and a Complaints Service. People with a concern, comment, complaint or compliment about care or any aspect of the Trust services are also encouraged to speak with a member of the care team. For more information see BHT Pol 021: Policy on Responding to Concerns Complaints and Compliments.

6.5 Patient safety incident response planning and our PSIRP

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.

The Trust will take a proportionate approach to its response to patient safety incidents to ensure that the focus is on maximising improvement. Our PSIRP details how this has

been achieved in addition to describing how the Trust will meet both national and local focus for patient safety incident responses. PSIRP will remain flexible and will be reviewed regularly to ensure we consider the specific circumstances in which each patient safety incident occurred and the needs of those affected. We will review it every 12-18 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 months.

A rigorous planning exercise will be undertaken every two years and more frequently if appropriate 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, PSII reports, improvement plans, complaints, claims, colleagues survey results, inequalities data, and reporting data) and wider stakeholder engagement.

A copy of our current PSIRP can be found via CAKE or through contacting the Patient Safety Team

7 Training requirements

The Trust has committed to ensuring that we fully embed PSIRF and meet its requirements. We have therefore used the NHS England patient safety response standards (2022) to frame the resources and training required to allow for this to happen. A summary of training requirements can be found in Appendix 6.

8 Review methodologies

8.1.1 PSII's:

The Patient Safety Investigator, who is a senior member of the Patient Safety Team will lead the completion of PSIIs and work with services and the care group/s to encourage a shift towards PSIRP principles of the whole system approach, psychological safety and compassionate engagement of colleagues, patient, and families.

The completion of the PSII will be supported by the care group senior leads which will include the Care Group Clinical Governance Lead or subject matter expert. Any care group colleagues supporting the completion of the final PSII report should be Band 8A or above in line with PSIRF best practice guidance. However, where appropriate, there may be representation from a Band 7 - with appropriate oversight from senior colleagues. This would however depend on the nature and complexity of the incident and response required and take into consideration the professional development and career progression needs of colleagues.

Any care group members supporting an investigation will not have been involved in the patient safety incident itself or be an individual who directly manages those colleagues.

Once completed the final PSII report will be presented and discussed by the Patient Safety Incident Panel (PSIP) which will be chaired by the Chief Nurse (or designate) or the Chief Medical Officer (or designate). The terms of reference of the PSIP can be obtained from the Patient Safety Team.

8.1.2 Other PSR methodologies (or learning responses):

A senior member of the relevant Care Group/s (i.e., Consultant, Care Group Director, Clinical Governance lead or Care Group Director of Nursing) will be responsible to identify a designated individual to lead on the learning response. The individual should have an appropriate level of seniority, expertise, and influence within the Trust; should be a Band 8A or above in line with PSIRF best practice guidance. However, where appropriate there may be some representation from a Band 7 - with appropriate oversight from senior colleagues' members. This would however depend on the nature and complexity of the incident and response required and take into consideration the professional development and career progression needs of colleagues.

A senior member of the Patient Safety Team should attend learning responses to support the implementation of PSIRF values and ensure ongoing support and learning of the new review methodologies being implemented. They will also ensure a degree of objectivity is brought to the group especially where the review methodology may involve colleagues that provided direct care to the patient.

Those colleagues affected by patient safety incidents will be afforded the necessary support and be given time to participate in learning responses. All Trust managers will be able to utilise other teams such as Health and Wellbeing to ensure that there is a dedicated colleague's resource to support such engagement and involvement.

The Trust will utilise both internal and, if required, external subject matter experts with relevant knowledge and skills, where necessary, throughout the learning response process to provide expertise (e.g., clinical, or human factors review), respond to Terms of Reference, give advice, and assist with proof reading.

The Trust will have in place governance arrangements to ensure that a level of objectivity is brought to all learning responses. This will mean that some learning responses (i.e., PSII) will not be led by colleagues who were involved in the patient safety incident itself or by those who directly manage those colleagues.

9 Responding to Patient Safety Incidents

9.1.1 Reporting arrangements

All colleagues are responsible for reporting any patient safety event on our Trust incident reporting system (Datix) in accordance with Datix operational procedures. Definitions of harm will apply in accordance with the new NHS England (2023) National Policy.

9.1.2 Response and decision making

A triage system will be implemented to ensure a prompt review of incident reporting – this will happen at multiple levels including service/Care Groups/corporate patient safety. This is to ensure a timely review of reported incidents and also to determine which incidents need to be further escalated. Furthermore, there will be a new focus, moving away from solely responding to the level of harm to also seeking to identify those incidents where there are the significant opportunities for learning.

The process behind this is detailed in Appendix 2 and will be subject to change as it is tested in the initial implementation phase of PSIRF.

Identified incidents (as outlined in PSIRP) will be reviewed and discussed at the regular PSIP for a collaborative decision between the Patient Safety Team and Care Group representatives.

Pressure ulcer, falls, VTE, medication and infection prevention and control incidents (as outlined in PSIRP) will be initially reviewed by the subject matter experts and then collated into thematic analysis to inform the wider Trust learning and improvement plan and discussed at the Harm Free Care Group and Care Group Governance meetings before reporting into the Patient Safety Board.

9.1.3 Role of Patient Safety Incident Panel (PSIP)

The Trust will maintain an Executive-led PSIP (replacing LRDP and SIEDM panel) to oversee the operation and review, including supporting the final sign off process for all learning responses and PSIIs.

The panel will further provide guidance to Care Groups regarding selection of appropriate learning response tool and also support to ensure that all learning is shared widely to enable best practice and rapid learning across all teams and departments. It is anticipated that the guidance provided by the PSIP will be a short to medium term assurance mechanism which can be phased out in time as the Care Groups become more familiar with the learning responses and mechanism for improvement and sharing of learning. The core long term function of the PSIP will be to review all PSIIs and provide final executive and ICB sign-off of these investigations.

Through this mechanism the Board will be assured that it meets expected oversight standards but also understands the ongoing and dynamic patient safety and improvement profile within the organisation.

Flexibility will be considered if an incident is escalated prior to biweekly PSIP, and appropriate immediate actions will be taken as required to mitigate any risk.

The Patient Safety Team 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. Whilst this will include some incidents escalated as PSII, the Patient Safety team will work with the Care Groups to have effective processes in place to ensure that any incidents meeting external reporting needs are appropriately escalated.

A 6 monthly summary report will be provided to Patient Safety Board to ensure oversight and assurance.

9.1.4 Role of Harm Free Care Group

The Harm Free Care Group will have delegated responsibility for the consideration of all pressure ulcer, falls, VTE, medication and infection prevention and control incidents (as outlined in PSIRP) after initial review by the subject matter experts and clinical governance leads supported by a Patient Safety Investigator. Themes will be collated and presented at a monthly meeting to inform the wider Trust learning and improvement plan before reporting into the Patient Safety Board.

Harm Free Care Group will also have oversight of the outcomes of Patient Safety Responses related to the above category of incidents 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. Learning will also be shared directly by the Care Group governance facilitator at the Care Group Governance meeting to ensure rapid and actionable improvement work is undertaken.

The process behind this decision-making phase is detailed in Appendix 2 and will be subject to change as it is tested in the initial implementation phase of PSIRF. There will be clear records maintained regarding this decision-making process and this will be shared with relevant senior management and Patient Safety Board on a quarterly basis.

9.1.5 Responding to inherited incidents (those not attributable to our Trust)

The Patient Safety Team will forward those incidents identified as presenting potential for significant learning and improvement for another provider directly to that organisation's Patient Safety Team or equivalent. Where required, summary reporting can be used to share insight with another provider about their patient safety profile. This is likely to be operationalised through LFPSE introduction, but this will take time to implement and establish processes.

9.1.6 Responding to cross-system incidents

The Trust will work with partner 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 Team will act as the liaison point for such working and will have supportive operating procedures to ensure that this is effectively managed.

The Trust will defer to the ICB for co-ordination where a cross-system incident is felt to be too complex to be managed as a single provider. We anticipate that the ICB will give support with identifying a suitable reviewer in such circumstances and will agree how the learning response will be led and managed, how safety actions will be developed, and how the implemented actions will be monitored for sustainable change and improvement.

9.1.7 Mortality review Group (MrG)

The Trust will maintain an Executive-led MrG to oversee the operation and decision-making of the SJRs.

MrG will also support the thematic analysis of SJRs which will be collated and presented biannually.

Through this mechanism the Clinical Effectiveness Board will be assured that it meets expected oversight standards and is able to identify ongoing and dynamic patient safety and improvement profile related to mortality within the organisation.

9.2 Timescales for learning responses

9.2.1 For PSIIs

Where a PSII for learning is indicated, the investigation must be started as soon as possible after the patient safety incident is reported and should ideally be completed within

six weeks to 3 months of their start date. No local PSII should take longer than 6 months.

Most importantly, the time frame 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 (e.g., when a partner organisation requests an investigation is paused, or the processes of an external body delays access to information) the Trust can consider whether to progress the PSII and determine whether new information indicates the need for further investigative activity once this is received. This would require a decision by the Executive-led PSIP.

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 Trust and those affected. The Patient Safety Team will manage all requests for extensions to time frames and ensure that PSIIs are completed in as timely a manner as possible.

9.2.2 For Patient Safety Responses

Patient Safety Responses must be started as soon as possible after the patient safety incident is reported and should ideally be completed within six weeks of their start date. In some exceptional circumstances this may take longer particularly when ensuring family questions are comprehensively responded to.

9.2.3 Safety action development and monitoring improvement

The Trust will have systems and processes in place to 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 areas for improvement of the Trust's working systems where change could reduce risk and potential for harm. The Trust will generate safety actions in relation to each of these defined areas for improvement.

Learning responses should not describe recommendations as this can lead to premature attempts to devise a solution - safety actions in response to a defined area for improvement depend on factors and constraints outside of the scope of a learning response. To achieve successful improvement safety action development will be completed in a collaborative way with a flexible approach from Care Groups and the support of the Quality Improvement Team with their improvement expertise.

9.2.4 Safety action development

The Trust will use the process for development of safety actions as outlined by NHS England in the Safety Action Development Guide (2022) as follows:

- Agree areas for improvement – specify where improvement is needed, without defining solutions
- Define the context – this will allow agreement on the approach to be taken to safety action development

- Define safety actions to address areas of improvement – focused on the system and in collaboration with teams involved
- Prioritise safety actions to decide on testing for implementation
- Define safety measures to demonstrate whether the safety action is influencing what is intended as well as setting out responsibility for any resultant metrics
- Safety actions will be clearly written and follow SMART principles and have a designated owner

9.2.5 Safety action monitoring

Safety Actions must continue to be monitored by the Clinical Governance Teams, with oversight from the Patient Safety Team, through the Datix Safety Action module and/ Datix Risk module.

Care Group reporting on the progress with safety actions including the outcomes of any measurements will be made to the Patient Safety Board.

For some safety actions with wider significance this may require reporting to the Trust Executive Management Committee (i.e., actions which are part of a Never Event or Safeguarding incident).

9.2.6 Safety Improvement plans

Safety improvement plans bring together findings from various responses to patient safety incidents and issues. The Trust has several overarching safety improvements plans in place which are adapted to respond to the outcomes of improvement efforts and other external influences such as national safety improvement programmes. These are reported through the Patient Safety Board and Trust Quality & Clinical Governance Committee.

Our PSIRP has outlined the local priorities for focus of investigation under PSIRF. These were developed due to the opportunity they offer for learning and improvement across areas where there is no existing plan or where improvement efforts have not been accompanied by reduction in apparent risk or harm.

The Trust will combine the outcomes from existing patient safety incident reviews (formerly SI reports) where present with future learning responses conducted under PSIRF, to create related safety improvement plans.

The Care Groups will work collaboratively with the Patient Safety Team and Quality Improvement Team and others to ensure there is an aligned approach to development of plans and resultant improvement efforts.

Where overarching systems issues are identified by learning responses outside of the Trust local priorities, a new safety improvement plan will be developed. These will be identified through Care Group governance processes and reporting to the PSIP who may commission a safety improvement plan. Again, the Care Groups will work collaboratively with the Patient Safety Team and Quality Improvement Team and others to ensure there is an aligned approach to development of the plan and resultant improvement efforts.

10 COMPLAINTS AND APPEALS

The Trust recognises that there will be occasions when patients, families or carers are dissatisfied with aspects of the care and services provided by the Trust. Details on how these are managed can be found in BHT Pol 021: Policy on Responding to Concerns Complaints and Compliments

On occasion concerns or complaints can be raised by individuals that bring to light the occurrence of a patient safety incident. Such concerns or complaints will be brought to the weekly Care Group Governance Reviews to consider the best approach to responding to these. In some instances, these may meet the criteria for a PSII or Patient Safety Response in which case they will be discussed at the PSIP to agree the best approach to responding to their concerns.

In addition, patients, families, and their carers who have been affected by a patient safety incident and involved in the subsequent learning response may have cause to raise concerns about how this was carried out. If the colleague's member(s) leading the learning response are not able to support resolution of their concerns, then they will be directed to the complaints process in support of answering their concerns.

11 MORTALITY

This policy should be read in conjunction with BHT Pol 215 Adult Mortality Review Process Policy.

The Trust PSIRP sets out the Trust's approach to aligning patient safety activities with those required from the Adult Mortality Review Process Policy and guideline 773.4 Management of Child Deaths. The Trust believes that by aligning both routes for learning, greater opportunities for triangulation of information can be promoted supporting the identification of themes and trends and minimising duplication of information requests for our colleagues.

12 Supporting documents

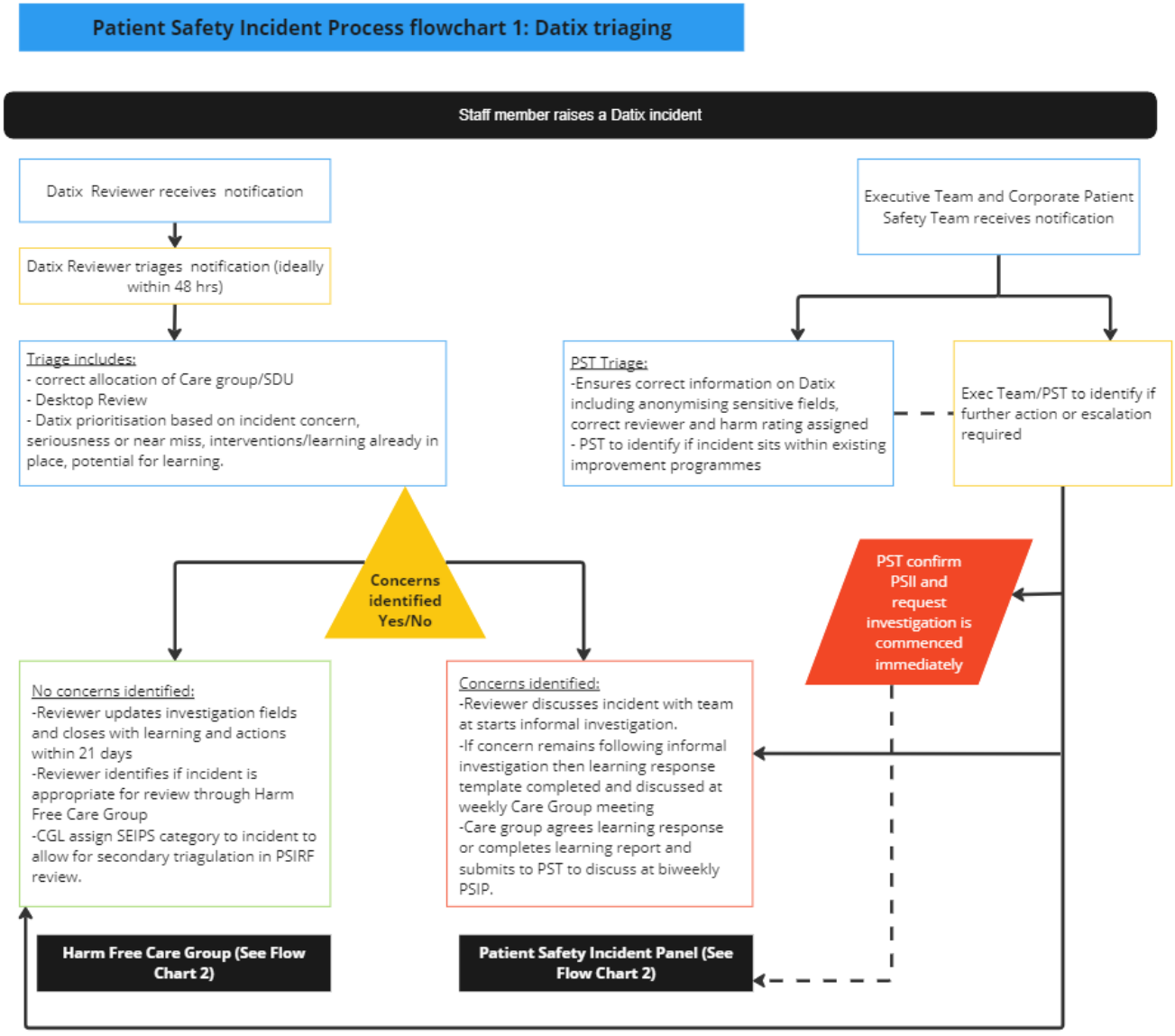
The PSIRF is supported by further detail provided in four supporting documents:

- Engaging and involving patients, families and staff following a patient safety incident
- Guide to responding proportionately to patient safety incidents
- Oversight roles and responsibilities specification
- Patient safety incident response standards

13 APPENDICES

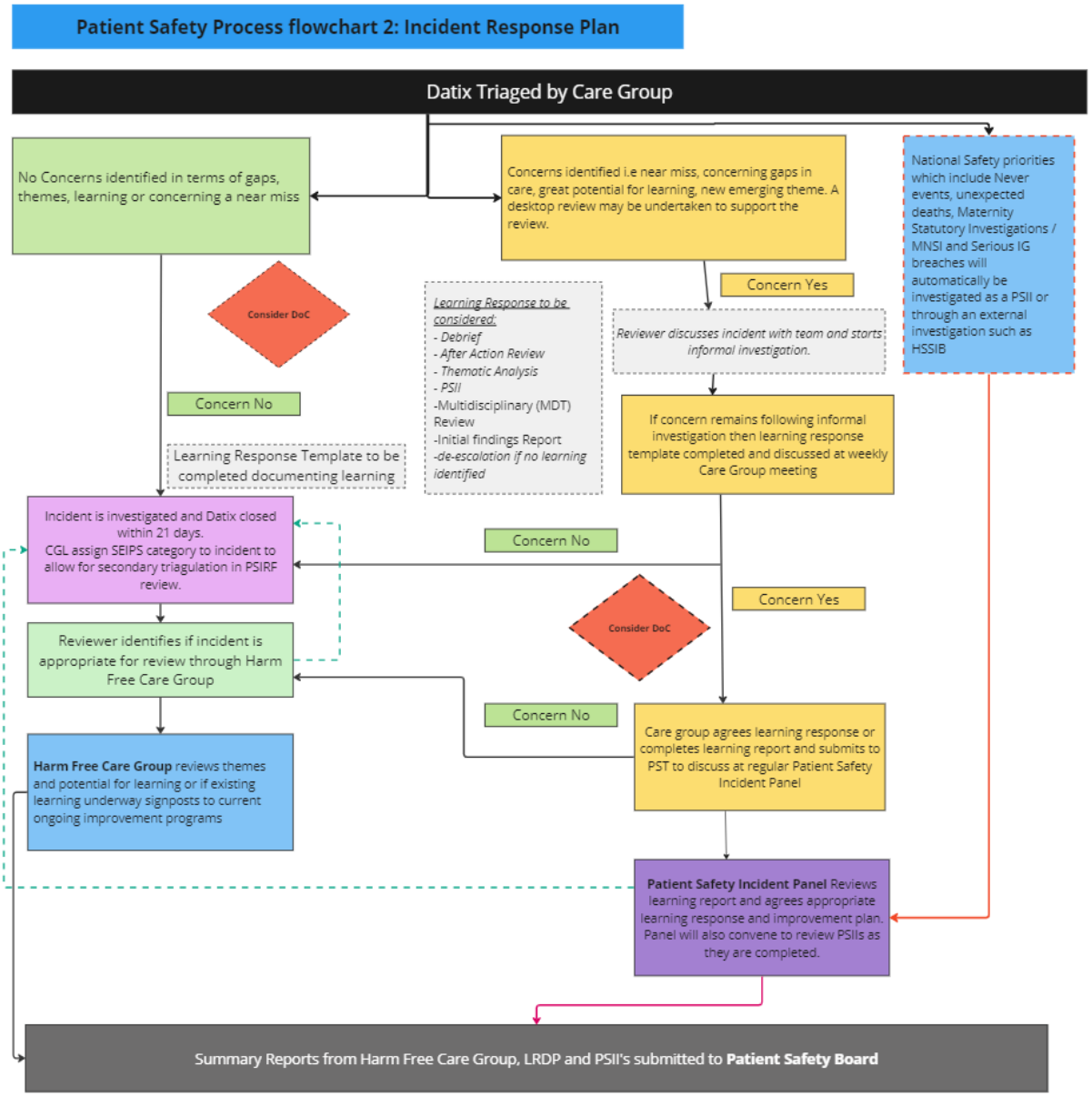
Appendix 1: Patient Safety Incidents Triage process

** Please note that statutory National Safety priorities which include Never events, unexpected deaths, Maternity Statutory Investigations / MNSI and Serious IG breaches will automatically be investigated as a PSII or through an external investigation such as HSSIB.*

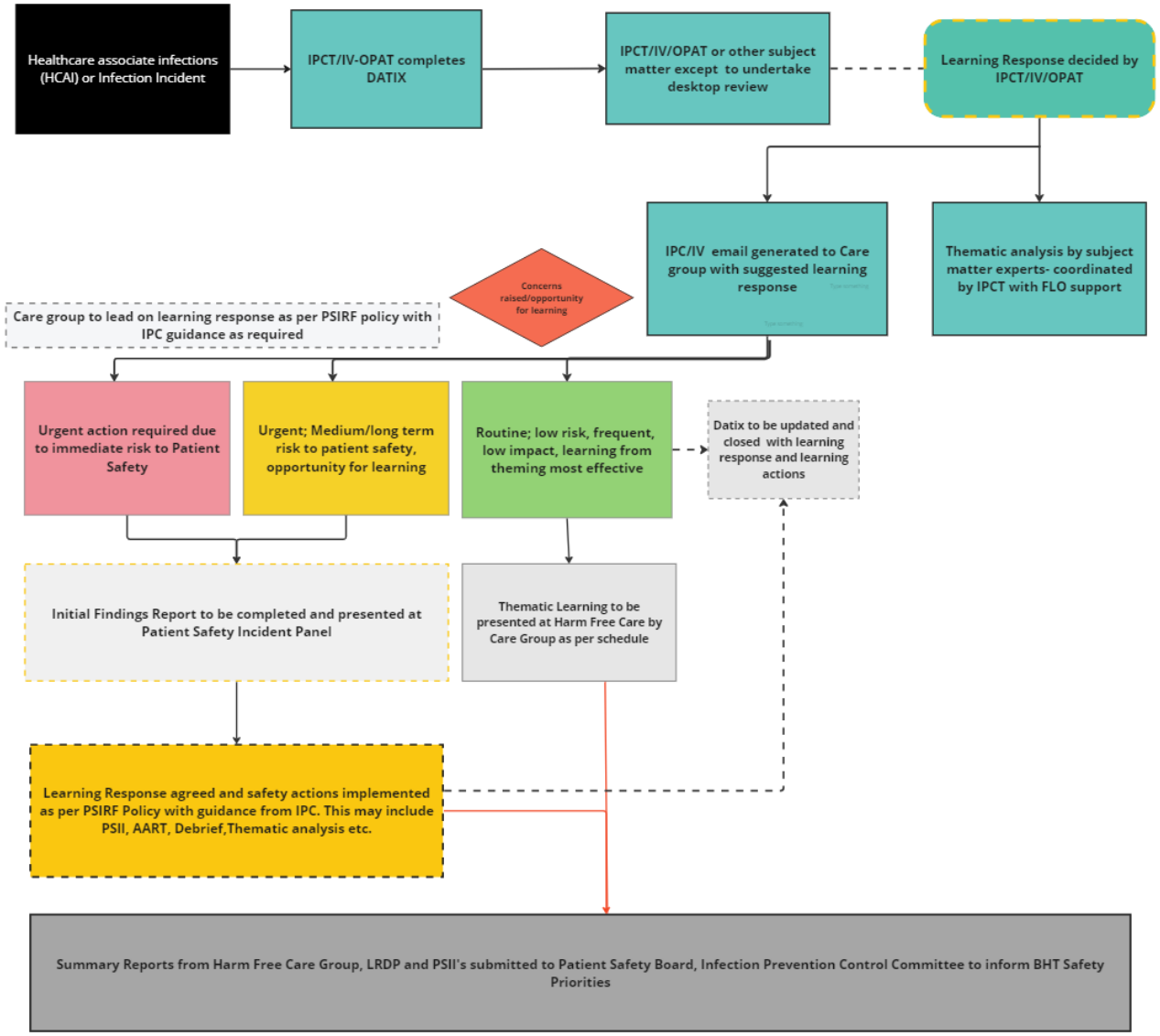


Appendix 2: Incident response plan

** Please note that statutory National Safety priorities which include Never events, unexpected deaths, Maternity Statutory Investigations / MNSI and Serious IG breaches will automatically be investigated as a PSII or through an external investigation such as HSSIB.*



Appendix 3: PSIRF Incident Response Plan- Infection Prevention and Control



Appendix 4: External Reporting Requirements

Safeguarding concerns

Colleagues should always record all adult safeguarding concerns on the Datix system, completing an incident form and sending a copy to the Local Authority. Any conversations with the Local Authority or updates received must be subsequently recorded on the Datix system. For children refer to the safeguarding children's policy and procedures. See BHT Safeguarding Adults Policy Pol and Safeguarding Children Policy BHT Pol 149 for further information.

The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR)

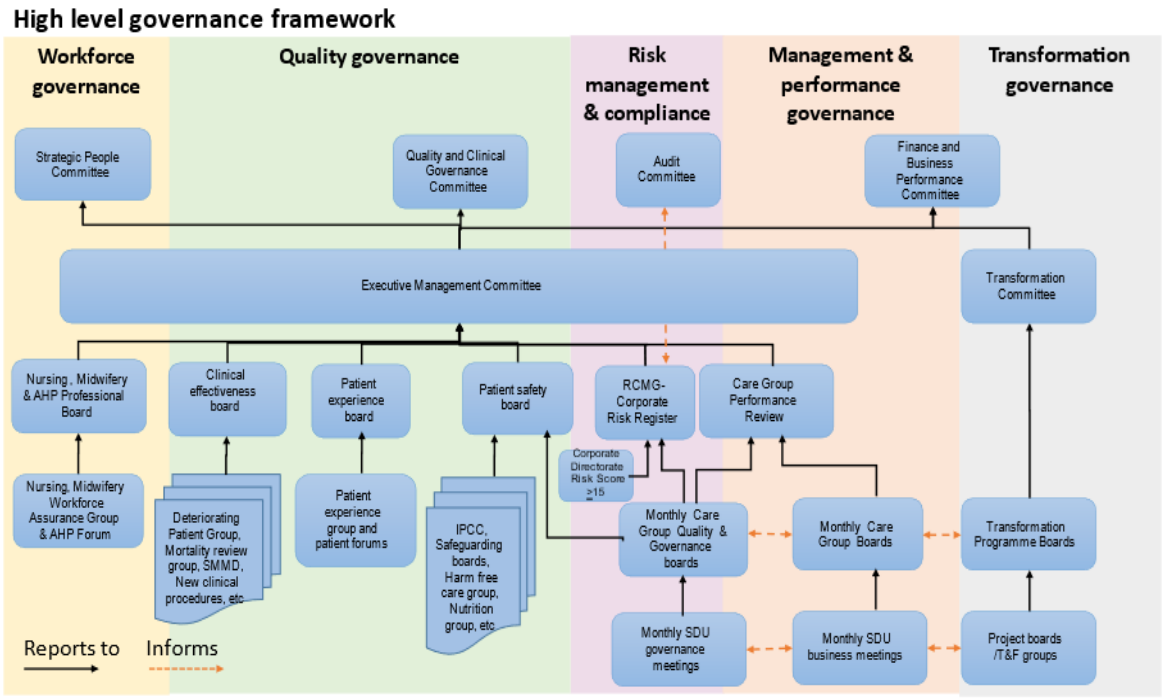
The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) 2013 require employers, people in control of premises and in some cases the self-employed to report certain types of injury, occupational ill-health and dangerous occurrences to their enforcing authority which occur arising out of, or in connection with work. The enforcing authorities for Healthcare Trusts are the Health & Safety Executive (hereafter referred to as the HSE) and for patient-related incidents. All injuries that fall into the reportable injuries group above and result from a work-related accident are reportable under RIDDOR and the incident reporting process (Datix).

Other External Agencies

Other organisations may need to be informed dependent upon the type of incident. The Patient Safety Team will be responsible for this. Organisations or parties to be reported to could include:

- Police.
- Coroner.
- NHS England.
- Commissioners.
- Health and Safety Executive.
- Medical Devices Agency.
- Care Quality Commission (CQC)
- Buckinghamshire Healthcare Legal Advisors.
- Local Safeguarding Children Boards/Safeguarding Adult Boards.
- Other Health Providers.
- University/Education Providers.

Appendix 5: High level governance framework



Appendix 6: Training Requirements
Incident reporting and management training (Datix)

Incident Reporter Training- For all colleagues and it will include sharing principles of incident reporting and how to report using the Trust incident reporting system.

Incident Handler Training- For all colleagues responsible for taking on the role of handler of an incident.

Patient Safety Syllabus Training - Expected standards

Level 1 Patient Safety Syllabus – For All: This module is non-mandatory for all colleagues, clinical and non-clinical working in the Trust. However, all colleagues are encouraged to complete this module annually.

Level 2 Access to Practice: For all clinical colleagues at Band 7 or above, with potential to support or lead patient safety learning responses. (i.e., AAR's, SWARM huddle, Hot debriefs etc.).

Level 1 training is available via iAspire training hub.

Level 2 training is available through Education, Learning, Development & Inclusion Team, via iAspire and HSIB.

The Patient Safety Specialist will take oversight of compliance with the support of the wider patient safety and governance teams.

Training for those leading a PSII 'team approach' or working in dedicated patient safety and clinical governance roles.

Colleagues working in patient safety and clinical governance roles that are expected, as part of their role, to participate in patient safety learning responses will have to meet the PSIRF training competency requirements summarised as following:

- Completion of Patient Safety Syllabus Level 1 and 2 (as above)
- Completion of a minimum of two-days 'Whole System Approach' training. Participate in 'Engagement and Involvement of those affected by a patient safety incident' (HSIB 6-hour training).
- Completion of Thematic Analysis training via Education, Learning, Development &
- Inclusion Team, iAspire or directly delivered by Patient Safety Team. Modules are also available via HSIB.
- Maintain their competencies by contributing to at least two PSIIs per year
- Participate in locally arranged training on all Patient Safety Response methodologies

The Clinical Governance Teams will maintain a record of PSIRF training compliance requirements for patient safety and governance teams on iAspire to allowing monitoring of adherence to training guidance.

Training for those participating in a PSII 'team approach'

Individual dedicated 'learning response leads' (LRL) will be assigned to complete PSIIs. The LRLs would have to meet the competency requirements outlined above in section 8.2.3. LRL's will receive an appropriate level of support through formal or informal training sessions to ensure they contribute to the investigation by applying PSIRF principles of whole system, safety culture and compassionate engagement of patient and their family. This training which will include but is not limited to investigative interviewing skills, appreciative enquiry techniques and SEIPS modelling.

The Education, Learning, Development & Inclusion Team will hold records for all those that have attended formal Learning response leads training and that currently provide support with investigations.

The Patient Safety Team will continue supporting all Care Groups to ensure all incidents reviews (whether PSII or other methodology) meet PSIRF standards and to promote a cultural progression towards whole system approach and compassionate engagement of colleagues, patients, and families.

Competency requirements for colleagues leading any type of learning response:

As a Trust we expect that colleagues leading learning responses are able to:

a. Apply principles of safety culture and psychological safety to all learning responses they lead
b. Apply human factors and systems thinking principles to gather qualitative and quantitative information from a wide range of sources.
c. Summarise and present complex information in a clear and logical manner and in report form.
d. Manage conflicting information from different internal and external sources.
e. Communicate highly complex matters and in difficult situations.

Support for those new to this role will be offered from the Patient Safety Team, Clinical Directors, senior Governance Lead roles and other senior Managers within Care Groups. Further training and guidance will be available through iAspire.

Training for those involved in engagement with patients, families, or carers

Colleagues working in patient/family engagement lead roles (i.e., Family Liaison Officer) and colleagues regularly engaged in supporting patients/families during a patient safety incident (i.e., to complete statutory duty of candour conversations) need to complete the 'Engagement and involvement with those affected by a patient safety incident' training as recommended in the PSIRF.

As an alternative to the specific training, colleagues can access a suitable quantity of Making Families Count webinars.

Records of such training will be maintained by the Education, Learning, Development & Inclusion Team as part of their general education governance processes. The Family Liaison Officer will take Trust oversight of compliance with the support of the wider Patient Safety Team. Clinical Care Groups will take responsibility for ensuring colleagues

required to fulfil this role have accessed the required training and support.

Competency requirements for engagement leads:

As a Trust we expect that engagement leads are able to:

a. Communicate and engage with patients, families, colleagues, and external agencies in a positive and compassionate way.
b. Listen and hear the distress of others in a measured and supportive way.
c. Maintain clear records of information gathered and contact those affected.
d. Identify key risks and issues that may affect the involvement of patients, colleagues, and families, including any measures needed to reduce inequalities of access to participation.
e. Recognise when those affected by patient safety incidents require onward signposting or referral to support services.
f. Ensure that the voice of patient and/or family is heard, and their concerns and views reflected as part of the investigation review process.

Oversight roles training and competencies

Those in oversight roles (i.e., senior management) and responsible for Trust sign-off of PSIIs need to complete:

- Completion of Patient Safety Syllabus Level 1 and 2
- Completion of a minimum of two-days 'Systems approach to learning from patient safety Incidents' training with appropriate approved provider.
- Completion of 1 day/6 hours 'Oversight of learning from patient safety incidents' training.
- Participate in 'Engagement and Involvement of those affected by a patient safety incident' 1 day/6 hours. Alternatively, colleagues can access a suitable quantity of Making Families Count webinars.
- All those with an oversight role in relation to PSIRF will undertake continuous professional development in incident response skills and knowledge, and network with peers at least annually to build and maintain their expertise.

Records of such training will be maintained by the Education, Learning, Development & Inclusion Team as part of their general education processes. The Patient Safety Specialist(s) will take oversight of compliance.

Competency requirements for colleagues with oversight roles:

As a Trust we expect that colleagues with an oversight role are able to:

a. Be inquisitive with sensitivity (that is, know how and when to ask the right questions to gain insight about patient safety improvement).
b. Apply human factors and systems thinking principles.

c. Obtain through conversations and assess both qualitative and quantitative information from a wide variety of sources.
d. Constructively challenge the strength and feasibility of safety actions to improve underlying systems issues.
e. Recognise when safety actions following a patient safety incident response do not take a system-based approach (e.g., inappropriate focus on revising policies without understanding 'work as done' or self-reflection instead of reviewing wider system influences).
f. Summarise and present complex information in a clear and logical manner and in report form.

Appendix 7: Reporting Incidents

Since 1 April 2010 all NHS organisations have been required to notify the Care Quality Commission (CQC) about events that indicate or may indicate risks to the on-going compliance with registration requirements, or that lead or may lead to changes in the details about the organisation in the CQC's register. For English Trusts these requirements are met by the reporting of all incidents to NHS England (via the Learn From Patient Safety Events system, LFPSE) which the CQC can then access.

To achieve a good standard of reporting the Trust must ensure there is a just culture and ethos of learning in order to prevent future incidents where possible but it also requires a robust process for the reporting and management of incidents. This process should facilitate openness, service improvement and sharing of learning within the organisation and within the wider health community. Incidents are rarely caused wilfully and are often caused by a number of factors, including system failures, human factors and lack of knowledge or skills. Staff are encouraged to feel able to raise concerns without fear of reprisals or victimisation, or punitive measures.

Staff should be assured that no disciplinary action will result from reported incidents or mistakes, except in circumstances where malicious, criminal, gross or professional misconduct is involved. In doing so, the primary aim is to promote a positive and non-punitive approach towards incident reporting, so long as there has been no flagrant disregard of the Trust's policies, fraud or gross misconduct.

Staff who need to raise concerns about a wrongdoing at work in a way which protects their interests and which ensures at the same time that instances of wrongdoing or alleged/apparent wrongdoing are properly investigated and any necessary actions taken should raise concerns in line with the Trust's Raising Concerns at Work (Whistleblowing) Policy BHT 092 (2021) which offers a framework of protection against victimisation, disciplinary action or dismissal for staff who raise genuine concerns.

The purpose of this guideline is to ensure staff at all levels of the organisation are aware of their roles and responsibilities in the reporting and management of incidents.

Definition of Incidents

Any event or circumstance arising during the Trust's business that could have, or did lead to, unintended or unexpected harm, loss or damage.

Role of affected/involved staff member

It is the responsibility of the affected / involved staff member:

- To familiarise themselves with this guideline and its content.
- If involved or witness to any incident and/or near miss, to ensure the situation has been made safe. If it is not possible for the staff member to make the situation safe (e.g., if they are injured) another member of staff, in most cases the Line Manager, must undertake this duty.
- To report any incident, defect or other concern (including near miss) directly to their line manager and complete an electronic incident report promptly. If the facility for electronic reporting is not readily available, a template form can be completed and submitted to the manager for further investigation and sign off – template provided by the Patient Safety Team.
- To familiarise themselves with the incident reporting help guides that are available on the Trusts intranet.

- To comply with and implement any remedial control measures arising from an incident report
- For needlestick, sharps, splash or exposure incidents, to follow current Occupational Health Guidance found in the Infection Control Manual.
- To share learning from incidents reported, by communicating with members of their own team, and more widely across the organisation through their Line Manager, or as appropriate.
- Ensure that injured staff attend an Accident and Emergency Department to be assessed and treated as appropriate.

Role of Senior Manager and Handler/Investigator – supported by the Care Groups governance team

It is the responsibility of the Senior Manager to ensure that:

- All staff within their Care Group are aware of the existence of this guideline.
- All staff likely to take charge of units within Care Groups have familiarised themselves with the incident reporting and investigation help guides that are available on the Trusts intranet.
- All staff receive basic training on the electronic incident reporting procedure, sufficient for their level of responsibility.
- Incidents are investigated and appropriate remedial action taken in accordance with Trust Policies, and finalised and closed within 3 weeks unless part of a Patient Safety Incident Investigation (PSII) (which would be noted on Datix).
- A mechanism exists to inform staff of actions taken, and any further actions required from staff.
- Any records or documentation suitable for potential use in court is entered onto the Datix system or kept in an appropriate manner in readiness for requests from the Litigation Team for legal disclosures, or for producing statements.
- It is the responsibility of Service Delivery Unit Leads to ensure that all incidents are discussed at their Clinical Governance Meetings and that learning is disseminated to their own staff and the rest of the organisation. It is the responsibility of Care Group Boards to monitor the effectiveness of their incident reporting processes within their Care Group, and to share learning more widely through the monthly Risk and Compliance Monitoring Group.

Examples of reportable incidents

This list is not exhaustive, and staff should report anything they feel or consider to have caused harm or be the potential for harm.

- ✓ Accessing internet sites with inappropriate content
- ✓ Acute illness caused by ingestion, inhalation or absorption through the skin
- ✓ Breaches of confidentiality e.g., failure to keep patient identifiable material secure, unauthorised disclosure of patient, staff or Trust information.
- ✓ Diathermy burns/ reaction to preparation agent
- ✓ Disclosure of passwords or other methods of system access
- ✓ Episode of VTE within 100 days of hospital admission
- ✓ Equipment malfunction
- ✓ Failings in patient identification
- ✓ Failure to act on results
- ✓ Failure to detect risk factor (e.g., allergy)
- ✓ Failure to protect computer system access
- ✓ Failures in communication
- ✓ Failures or delays of any kind
- ✓ Falls
- ✓ Hospital Acquired Infection
- ✓ Improper delegation to unsupervised junior

- ✓ Infusion problems, pump errors, over- and under-infusion
- ✓ Injury to an individual
- ✓ Intra-operative problems, major blood loss, cardiac arrest
- ✓ Lack of adequate facilities/ equipment
- ✓ Lack of monitoring
- ✓ Lack of pre-operative assessment, preparation, consent or marking
- ✓ Medications errors of any kind including omissions
- ✓ Misplaced naso or orogastric tube not detected prior to use
- ✓ Patient positioning problems
- ✓ Performance of operation that is not indicated
- ✓ Pressure ulcers – category 2, 3 and 4
- ✓ Problem with blood, body fluids, waste
- ✓ Problems associated with intubation
- ✓ Problems with medical records - illegible, inaccurate, omissions, misfiled, lost or unavailable records
- ✓ Re-admission following inadequate discharge planning, missed diagnosis or inappropriate medication/ treatment
- ✓ Surgical foreign body left in situ
- ✓ Theft of IT equipment
- ✓ Tissue viability problems
- ✓ Unexpected admission to HDU, ITU or transfer to another hospital
- ✓ Unexpected deaths
- ✓ Unexpected return to theatre
- ✓ Violence, abuse and harassment
- ✓ Wrong patient/ wrong body part indicated or operated on