Patient safety incident response policy

NHS Somerset Integrated Care Board

November 2023 – v1.7

	Name	Title	Date
Author	Jennie Tuffin	Quality Improvement Facilitator – Patient Safety	02/11/2023
Reviewer	Emma Savage	Deputy Director of Quality & Improvement	02/11/2023
Authoriser	Shelagh Meldrum	Chief Nursing Officer & Chief Operating Officer	28/11/2023

Contents

1. Introduction

This policy supersedes the previous responsibility of NHS Somerset as commissioners in providing oversight for provider organisations for whom the Serious Incident Framework (SIF) 2015 applied.

In August 2022 NHS England published the Patient Safety Incident Response Framework (PSIRF). The PSIRF is a key part of the National Patient Safety Strategy and supports the strategy's aim to help the NHS to improve its understanding of safety by drawing insight and learning from patient safety events.

The PSIRF replaces the SIF and makes no distinction between 'patient safety events' and 'serious incidents.' 'Serious incidents' and their associated thresholds no longer exist under PSIRF. PSIRF promotes a proportionate approach to responding to patient safety events by ensuring resources allocated to learning are balanced with those needed to deliver improvement.

All secondary care organisations providing NHS-funded care nationally (primary care to follow in due course) are expected to adopt PSIRF by end of September 2023 as part of the NHS standard contract. Primary care services continue to use the Serious Incident Framework until additional national guidance is released for these organisations.

2. Purpose

This document sets out the general principles and processes for the management of patient safety events (PSEs) and Level 2 Investigations occurring within services commissioned by NHS Somerset Integrated Care Board (NHS Somerset/the ICB).

Adherence to this policy will support provider organisations and the Somerset system to transition from the SIF to PSIRF during 2023/24.

This policy will define the responsibilities of NHS Somerset as commissioners in the development and monitoring of the individual provider organisations' Patient Safety Incident Response Plans. As well as the responsibilities of the ICB for those organisations who continue to report serious incidents under the SIF, and the continued management of any serious incidents that remain open under the SIF past the implementation of PSIRF.

This policy should be read in conjunction with the following guidance:

- Revised Never Events policy and framework
- Never Events list (2018)
- The Patient Safety Incident Response Framework 2022 NHS England (2022) and its supporting guidance
- NHS England » Engaging and involving patients, families and staff following a patient safety incident

- Framework for involving patients in patient safety (June 2021)
- The National Patient Safety Strategy NHS England (July 2019)
- NHS patient safety strategy 2023 update: Ongoing deliverables and 2022/23 progress

3. PSIRF

The PSIRF sets out the NHS's approach to developing and maintaining effective systems and processes for responding to patient safety events for the purpose of learning and improving patient safety.

Patient safety events are unintended or unexpected events (including omissions), in healthcare that could have or did cause harm to one or more patients.

PSIRF fundamentally shifts how the NHS responds to patient safety events for learning and improvement. Unlike the SIF, PSIRF is not an investigation framework that prescribes what to investigate. PSIRF advocates a co-ordinated and data-driven approach to patient safety incident response that prioritises compassionate engagement with those affected by patient safety events. PSIRF embeds patient safety incident response within a wider system of improvement and prompts a significant cultural shift towards systematic patient safety management.

PSIRF focusses on improved engagement with those affected by an incident, including patients, families and staff. Ensuring they are treated with compassion and able to be part of any investigation. The Guide to engaging and involving patients, families and staff following a patient safety incident, published alongside PSIRF, sets out expectations for how provider organisations should engage with all those affected by patient safety incidents. Provider organisations should work hard to answer any questions and to involve those affected in patient safety incident investigations.

Provider organisations are required to develop a thorough understanding of their patient safety incident profile, ongoing safety actions (in response to recommendations from investigations) and established improvement programmes. To achieve this each organisation must collect and triangulate information from a wide variety of sources and collate via a wide stakeholder engagement exercise. The output of this patient safety incident response planning exercise is used to inform the selection of a proportionate response when something goes wrong. This may include a response to generate safety actions for improvement where this does not already exist, or to ensure that a safety improvement plan is put in place where learning from patient safety incident response has already been identified.

The PSIRF approach is flexible and adapts as organisations learn and improve to ensure organisations can explore patient safety events relevant to their context and the populations they serve.

The principles and practices endorsed by PSIRF are aligned with the National Patient Safety Strategy and wider initiatives under the strategy including the introduction of Patient Safety Specialists, the development of a National Patient Safety Syllabus, development of the Involving Patients in Patient Safety framework and the introduction of the Learn from Patient Safety Events service (the successor to the National Reporting and Learning System (NRLS)).

3.1. Who does PSIRF apply to?

PSIRF is a contractual requirement under the NHS Standard Contract and as such is mandatory for services provided under that contract, including acute, ambulance, mental health, and community healthcare providers. This includes maternity and all specialised services.

3.2. Secondary care providers that are not NHS Trusts

Organisations that provide NHS-funded secondary care under the NHS Standard Contract but are not NHS Trusts or Foundation Trusts (e.g. independent provider organisations) are required to adopt this framework for all aspects of NHS-funded care and may apply this approach to their other services for consistency. These organisations may not need to undertake the full analysis required for patient safety incident response planning (e.g. due to organisation size, and limitations on data availability), however processes such as stakeholder engagement in preparing plans and applying PSIRF principles when updating governance arrangements are required.

3.3. Primary Care and PSIRF

Primary care providers may wish to adopt this framework, but it is not a requirement. Primary care providers in Somerset that wish to adopt this version of the framework should work with NHS Somerset to do so. Further exploration is required to ensure successful implementation of the PSIRF approaches within primary care. The National Patient Safety Team will work with a small number of primary care early adopters to explore how the PSIRF can be adapted to this sector.

If primary care services choose not to adopt PSIRF, these services should continue to report patient safety events in line with the SIF (see section 9) until further national guidance is published regarding PSIRF and primary care. This guidance will be amended when further national guidance is received.

4. PSIRF organisational Roles and Responsibilities

See appendix 1 for further details.

4.1. NHS England National Team

NHS England National team will oversee the activity of regional teams to support effective response to patient safety events, providing strategic direction and leadership while monitoring effectiveness of PSIRF.

4.2. NHS England Regional Team

The NHS England regional teams will support ICB PSIRF leads with the learning system within NHS England and NHS Improvement. To support co-ordination of system-wide responses to patient safety events while identifying events that may require centrally co-ordinated and independent patient safety incident investigation.

4.3. Integrated Care Boards

To collaborate, develop and agree provider PSIR policies and plans while overseeing effectiveness of systems response to patient safety events, offering co-ordination support in system-wide patient safety incident investigation, sharing outcomes system-wide to continuously improve safety.

Further information pertaining to the ICB's statutory requirements for quality can be found at the following Delivering Quality functions in ICSs - update July 2023 _v2_.pdf with particular mention of PSIRF on page 15 stating that ICBs must:

- Support GP, dental, optometry and community pharmacy services to undertake relevant incident response. Support the relevant incident response in relation to NHS-funded patients in other relevant healthcare sectors (e.g. independent, CHC).
- Ensure there is a system in place to support the processing of the SI backlog identified during transition from CCG to ICB.
- Continue oversight of patient safety incident response in line with SIF, whilst transitioning to fulfil oversight requirements of PSIRF.
- Collaborate with providers in the development, maintenance, and review of the provider Patient Safety Incident Response Policies and Plans.
- Agree provider Patient Safety Incident Response Policies and Plans.
- Oversee and support effectiveness of systems in place in achieving improvement following patient safety incidents.
- Support co-ordination of cross-system Patient Safety Incident Investigations (PSIIs).
- Share insights and information across organisations/services to improve safety.
- Investigations of deaths of people with a learning disability or autistic people are managed in line with PSIRF and not as part of LeDeR which is not an investigatory process but a service and quality improvement process.

It will be the role of Somerset ICB Quality Committee to oversee the roll out, implementation and improvements made with regard to patient safety.

The Somerset System Quality Group will have a role in overseeing any high level system risks with regards to patient safety.

4.4. Providers of NHS-funded care

Ensure organisations meet national patient safety incident response standards with PSIRF central to governance arrangements, while receiving assurance of learning response outputs.

During early 2023, as part of NHS Somerset's orientation phase of implementing PSIRF, the ICB engaged with independent, charitable and voluntary and community sector organisations. Some of these provider organisations have joined the ICB for final PSIRF training or have sought their own training through a PSIRF training provider.

There should be an understanding between provider organisations and the ICB that the ICB should be notified as soon as possible of any patient safety events that occur where there is a risk of media attention or reputational damage.

4.5. Local Maternity and Neonatal system (LMNS)

The Somerset LMNS and other local support networks play a crucial role in supporting improvement and facilitating review of patient safety incident responses. The ICB should ensure that partner organisations demonstrate their commitment to engaging with the LMNS and other local support networks as key stakeholders within their Patient Safety Incident Response Plan. In addition, partner organisations should use their LMNS and support networks to facilitate review of incident responses between peers. This will support organisations to learn from each other's incident response approaches and reduce the risk of organisations becoming isolated and help to bring a level of standardisation regarding how patient safety events are reviewed.

4.6. Care Quality Commission (CQC)

The Care Quality Commission's assessment of a provider's leadership and safety considers an organisation's ability to respond effectively to patient safety events, including consideration of whether change and improvement follow its response to patient safety events. CQC teams will apply the PSIRF and associated Patient Safety Incident Response standards as part of their assessment of the strength of an organisation's systems and processes for preparing for and responding to patient safety events.

4.7. Healthcare Safety Investigation Branch (HSIB)

HSIB investigations identify the contributory factors that have led to harm or have the potential to cause harm to patients. HSIB recommendations aim to improve healthcare systems and processes to reduce risk and improve safety. HSIB aims to improve patient safety through effective and independent investigations that do not apportion blame or liability.

4.8. Patient safety partners

In line with the NHS Patient Safety Strategy, the NHS is committed to the recruitment of patient safety partners and anticipates that these posts will be recruited to by September 2022. Patient Safety Partners play an important role on oversight committees where patient safety events or concerns regarding patient safety are discussed. More information is provided in the framework for involving patients in patient safety.

NHS Somerset ICB appointed two patient safety partners who started at the beginning of August 2023.

4.9. Safeguarding

Everyone has the right to live their lives free from abuse, neglect, violence and exploitation. Some people, because of their circumstances, may not be able to exercise this right and are unable to protect themselves from abuse and neglect. The ICB has a duty to take appropriate steps to support and protect babies, children, young people and adults who may be at risk of abuse or neglect. As part of a response to any patient safety event, it is expected that any safeguarding concerns will be identified and that the appropriate response will be provided in line with:

- the provider's own safeguarding policies and procedures.
- the ICB's safeguarding policies and procedures.

When any patient event raises concern about abuse or neglect arising from the actions of paid staff, the employing organisation will follow their own policy and procedure for responding to allegations made against staff. This must include consideration of whether to refer to the local authority designated officer for children. For adults the organisation will consider whether to refer to the council officer responsible for overseeing allegations made against people in positions of trust.

In the ICB we ensure we are able to discharge our duties to respond to safeguarding concerns that arise from a patient safety incident by providing ICB lead or designated professional oversight of all relevant patient safety events and attendance at system partners' patient safety meetings. The lead and designated professionals will also provide information and advice on responding to concerns about abuse or neglect.

5. NHS Somerset Patient Safety Incident Response

5.1. NHS Somerset PSIRF aims

NHS Somerset is aligned to the development and maintenance of an effective patient safety incident response system across Somerset which integrates four key aims:

5.2. Compassionate engagement and involvement of those affected by patient safety incidents including patients, families, carers and staff

NHS Somerset will ensure that PSIR plans and policies for Somerset organisations seek to work with those affected by patient safety incidents and to involve them meaningfully in the investigation process.

NHS Somerset promotes and embraces a just culture to ensure that staff are treated fairly and appropriately following patient safety events. When providing system oversight for patient safety reviews and investigations NHS Somerset will ensure that processes for the engagement from staff are in place and used to inform investigations.

When considering provider organisations' PSIR plans NHS Somerset will ensure that organisations have systems and structures in place to enable managers and wider staff to:

- be confident about which incidents are being investigated and why.

- understand the potential impact of patient safety events on staff.
- recognise and help to manage the signs and symptoms of stress (including those associated with post-traumatic stress disorder) in themselves and colleagues.
- have access to support following patient safety events.

5.3. Application of a range of system-based approaches to learning from patient safety events:

PSIRF promotes a range of system-based approaches for learning from patient safety events, rather than methods that assume simplistic, linear identification of a single cause.

Several national system-based learning response tools and guides have been developed to encourage a system-based approach which explores contributory factors in relation to patient safety events to inform improvement. NHS provider organisations are encouraged to apply national tools or similar system-based equivalents.

NHS Somerset will ensure that PSIR plans detail the provision of education and training for staff to ensure that they have the specific knowledge and experience required to lead patient safety incident investigations or reviews. NHS Somerset will also ensure that those involved in the oversight of PSIRF have the knowledge and skills required to undertake this role effectively.

As a Somerset system we have collaborated together since the PSIRF was published in August 2022 from engaging with all partners, project managing the roll out of PSIRF and the training to undertake patient safety incident investigations at both provider and system level.

5.4. Considered and proportionate responses to patient safety events:

NHS Somerset recognises that organisations have finite resources available for patient safety incident response. PSIRF supports organisations to use their incident response resources to maximise improvement rather than repeatedly responding to patient safety events based on subjective thresholds and definitions of harm where limited new learning is possible.

If an organisation is satisfied that improvement work is ongoing to address known contributory factors in relation to an identified patient safety event and that safety actions are being monitored, it is acceptable to not undertake a detailed investigation into an incident other than engaging with those affected and recording that it occurred.

5.5. Supportive oversight focused on strengthening response system functioning and improvement:

NHS Somerset will work collaboratively, with a common understanding of the aims of the PSIRF, to provide an effective governance structure around the Somerset system response to patient safety events. NHS Somerset will facilitate collaboration at both place and local system level to support provider PSIR plans to be strong and effective.

6. NHS Somerset PSIRF process

6.1. The appointment of an ICB Patient Safety Specialist (PSS) lead

NHS Somerset has two PSSs who will work collaboratively with partners across the system to develop, maintain and review each provider's Patient Safety Incident Response Policy and Plan.

NHS Somerset's PSS leads will work as an integral collaborator with system providers to:

- review the application of the national PSIRF standards.
- establish roles, responsibilities, and structures for oversight within the system.
- establish mechanisms for escalation of incidents and risks that may require support or action at system or regional level.

NHS Somerset when considering PSIR plans must ensure that it is clearly stated how the provider organisation intends to deliver an effective response to patient safety events. The response methods the organisation intends to use to respond to patient safety events for the purpose of learning and improvement must also be detailed.

The designated ICB PSSs will work collaboratively with partners across the system as they develop and review their PSIR plans to:

- understand the patient safety incident and improvement profile of provider organisations.
- support the selection of appropriate response methods for anticipated patient safety events based on an understanding of potential for new learning and ongoing safety improvement work.
- support provider organisations to work in collaboration to identify themes and trends across the wider system to inform learning.

6.2. Agreement of provider Patient Safety Incident Response Policies and Plans

NHS Somerset is required to approve and sign off the incident response policies and plans for provider organisations in their system. Approval of an organisation's Policy and Plan demonstrates NHS Somerset's acknowledgement that the documents have been developed according to PSIRF guidance and meet (or demonstrate a plan to meet) PSIRF standards.

NHS Somerset's PSSs, PSPs and quality leads will collaborate with partner organisations to assess whether the systems and processes put in place to respond to patient safety events have achieved demonstrable improvement.

Considerations for ICB oversight includes ensuring:

- patient safety response teams are being trained/resourced appropriately and in line with standards.
- responses to patient safety events are timely (i.e. completed within the expected/planned timeframe).

- the experience of those affected is sought and is positive/improving (e.g. via verbal feedback, interviews, review of complaints data, survey response).
- incident response output is high quality (e.g. blame is avoided, contextual factors prioritised).
- areas for improvement and safety actions identified are systems-based.
- evidence that insight from incident response is being used to inform improvement (locally, across the system, and nationally as appropriate).
- safety improvement plans are being strategically developed (e.g. is there strategic alignment with other areas of the business/ QI strategy?).
- clear plan for criteria of incidents requiring Patient safety incident investigation (PSII) including nationally defined incidents, (see appendix 2.1 and 2.2).

6.3. NHS Somerset responsibility when PSIR plans are challenged

Where a partner's systems and processes for responding to patient safety events are challenged NHS Somerset will provide support for safety improvement. This may be through seeking support from colleagues in regional teams, by sharing expertise or by linking with other organisations whose systems and processes are more developed.

Where a provider organisation or the ICB identifies a recurrent theme of patient safety events occurring and ongoing improvement work does not appear to be having the desired effect, a decision to escalate to either NHS Somerset or to the relevant provider organisation's Patient Safety Lead can be made. This escalation can occur at the organisation's patient safety meetings where there is NHS Somerset representation, or if it is felt the escalation cannot wait for a scheduled meeting, the organisation can choose to contact NHS Somerset's Quality, Safety & Improvement Team as soon as possible. A decision should then be made in collaboration between the provider organisation and NHS Somerset as to how NHS Somerset can best support the provider organisation with safety improvement. See NHS Somerset's *Procedure for Escalation When Improvements Not Effective* for further details.

6.4. NHS Somerset support for co-ordination of cross-system PSIIs

Sometimes there is more than one organisation involved in the care and service delivery in which a patient safety event has taken place, all providers must have a process in place to recognise events that require a cross-system learning response. The organisation that identifies the event is responsible for recognising the need to alert other providers, the ICB and other commissioners, and partner organisations via their respective risk management/governance teams. Alerts of such a nature should be sent to somicb.psirf@nhs.net. Once identified, the alert should be sent to the other organisations within 72 hours, NHS Somerset is here to support providers with this process if needed.

A lead organisation should be identified to coordinate the investigation, this could be NHS Somerset or someone else, but it should be agreed by all organisations involved. The ICB's Quality Team can facilitate discussion of which is the most appropriate organisation to take responsibility for co-ordinating the investigation process. Where no

one provider organisation is best placed to assume responsibility for co-ordinating an investigation, the ICB will lead this process.

The incident should be reported onto StEIS by the lead organisation until the LFPSE (Learning From Patient Safety Events System) is launched nationally. All providers are expected to respond and participate in joint SI/PSII investigations when requested. Responses should be managed as locally as possible to facilitate the involvement of those affected by the incident and those responsible for delivery of the service where the incident occurred.

However, where a PSII involving multiple providers and/or services across a care pathway is too complex or costly to be managed by a single provider NHS Somerset will support the co-ordination of a cross-system PSII. Further detail can be found in NHS Somerset's *Standard operating procedure for undertaking end to end learning reviews for people with complex needs and/or involvement of multiple system partners*.

The NHS Somerset PSS will liaise with relevant providers (and other ICSs if appropriate) to agree how the PSII will be led and managed and how actions will be monitored.

NHS Somerset will also ensure that partners have systems in place to support a co-ordinated and measured, systems-based response to high profile or complex events such as mental health homicides (MHH) which includes how to support the needs of those affected during the investigation. Provider organisations and NHS Somerset will work together to establish and undertake cross-system PSIIs. NHS England and NHS Improvement regional teams are available to provide support if challenges arise (see NHS England and NHS Improvement responsibilities in appendix 1).

6.5. PSII/SI Interface with other types of review and/or investigation

Certain types of patient safety events trigger specific responses described in other legislation (e.g. where a person dies in prison or an incident that affects patients participating in a national screening programme). NHS Somerset is committed to contributing to and supporting system partners to engage in external PSIIs or investigations led by agencies such as the police, coroners, Health and Safety Executive, HSIB. etc (see appendix 2.1 and 2.2).

NHS Somerset acknowledges that there are occasions where the PSIRF processes will coincide with other procedures, such as a Domestic Homicide Review, Mental Health Homicide, child rapid review or child safeguarding practice review, child death review or a Safeguarding Adult Review (SAR), a Safeguarding Adult Enquiry or another externally led investigation. In such circumstances, co-operation and collaborative working between partner agencies is essential for minimising duplication, uncertainty and/or confusion relating to the investigation process. Ideally, only one investigation should be undertaken (by a team comprising representatives of relevant agencies) to meet the needs/requirements of all parties. However, in practice this can be difficult to achieve as investigations may have different aims/purposes which may inhibit joint investigations.

The undertaking of parallel processes may also be required by law. Where this is the case NHS Somerset will make every effort to ensure duplication of effort is minimised. In such cases, a strategy discussion should take place to agree how the interfaces between reviews will be managed.

In the event of criminal proceedings, wherever possible, patient safety investigations should continue alongside criminal proceedings to maximise patient safety learning. Any immediate actions required to keep people safe should not be delayed if a delay would mean people experiencing significant and avoidable harm. It is important that any patient safety enquiries do not prejudice any investigations undertaken by agencies who have powers of prosecution. This includes but is not limited to the police, Care Quality Commission (CQC), Office for Standards in Education (Ofsted) and the Medication and Healthcare Products Regulation Agency (MHRA). If there is a possibility that any agency may be undertaking a process of criminal investigation the ICB safeguarding team must be contacted for advice.

A request must be sent to any involved agencies to request a strategy meeting to coordinate all investigations. This meeting should clarify and agree which agency has primacy in relation to the investigation. It should also clarify if the patient safety investigation should be put on hold or continued and under what parameters. If a decision is made to suspend progress, arrangements to review this position must also be agreed. It is recognised that the timing of the reviews is not within the control of NHS organisations. However, the NHS has a duty of care to future patients and should therefore not unduly delay any necessary action pending the outcome of separate reviews. This principle should always be applied to any decisions regarding parallel processes. The patient safety event report may be utilised to form the basis of other reports. In these cases a conversation needs to be had as soon as possible between the Provider's Head of Governance, Provider's Risk Manager, NHS Somerset lead safeguarding designate who is the head of nursing, and Patient Safety Specialists to ensure all parties are clear regarding terms of reference and the approach being taken.

7. Management of Mental Health Homicide (MHH) investigations

In April 2013 NHS England (NHSE) became responsible for commissioning independent investigations into homicides (sometimes referred to as mental health homicide reviews) that are committed by patients being treated for mental illness. The purpose of an independent investigation is to review thoroughly the care and treatment received by the patient so that the NHS can:

- be clear about what, if anything, went wrong with the care of the patient.
- minimise the possibility of a reoccurrence of similar events.
- make recommendations for the delivery of health services in the future.

Homicides committed by those in receipt of mental health care have devastating consequences for the family of the victim(s), the patient(s) who committed the homicide, and their families, and a profound impact for all parties involved. These events are defined nationally as a priority to be investigated as a PSII (see appendix 2.1 and 2.2).

In the event of a MHH, duty of candour must be undertaken by the reporting organisation to the patient (the alleged perpetrator), the patient's family, and the victim's family. And as with the PSIRF core values, the aforementioned will all be offered the opportunity to participate in each stage of the investigation, to inform system learning.

When a MHH occurs, the event is referred to NHSE's Regional Independent Investigation Team (RIIT) who may choose to commission a regional level independent investigation, or agree a locally-led patient safety incident investigation (PSII).

MHHs often require complex, multi-agency collaboration and engagement involving internal and external stakeholders across geographical and organisational boundaries. Where a locally-led PSII is agreed by the RIIT, NHS Somerset will support the provider organisation if required to engage external organisations and provide investigation support where needed, i.e. terms of reference setting, arranging a multi-agency meeting.

Following completion of any locally-led MHH PSII, the report will be shared with the RIIT who will consider if a further external investigation is needed.

An independent investigator must be given access to all the information and reports about the alleged perpetrator's care and treatment (within the usual patient confidentiality rules), and can also request interviews with any NHS staff involved.

The criteria for an independent investigation to be carried out is:

- to investigate the care and treatment of patients and establish whether or not a homicide could have been prevented and if any lessons were learned for the future.
- to increase public confidence.
- to provide an assurance framework for those trusts providing specialist mental health services and a platform for demonstrating learning from action plans.

Where the RIIT agree a PSII should be managed at an independent regional level, the RIIT will:

- commission and manage the investigation in line with the national procurement framework, patient safety incident response standards and independent PSII operating procedures
- determine the terms of reference for the PSII and ensure that the patient safety incident response standards are followed
- manage the interface with other statutory investigations (eg domestic homicide reviews (DHRs), special case reviews (SCRs), safeguarding adult reviews (SARs)), and work with other bodies to support a collaborative approach
- ensure agreement with internal and external stakeholders, including the police, probation, local authorities, Health and Safety Executive, local safeguarding boards and/or other agencies as required regarding:
    - timing of investigations

- sharing of information and confidentiality issues
- involvement, support and communication with families, carers, staff and the media. The standards outlined in Engaging and involving patients, families and staff following a patient safety incident must be upheld
- completion and sign-off of the PSII report
- PSII report publication strategy (including assessment of the impact of publishing sensitive, confidential, and identifiable information)
- arrangements for the ongoing monitoring and/or escalation of actions and delivery of improvement
- dissemination of learning and subsequent improvement efforts.

Please see appendix 6 for a MHH process flow chart.

8. Sharing and dissemination of learning across the system

NHS Somerset have a responsibility to ensure that the insight and learning from patient safety events is shared and disseminated across the Somerset system, to promote improvements in care and patient safety.

9. Serious Incident Framework - for primary care organisations

Primary care are required to comply with the SIF until additional PSIRF guidance is launched nationally unless otherwise agreed with the commissioner as there may be exceptions where complex arrangements are in place with certain primary care organisations.

NHS Somerset, as a commissioner of these services, is accountable for quality assuring the robustness of serious incident investigations and the subsequent actions arising from lessons learnt. This involves gaining assurance from the provider organisation that incidents are properly identified and reported and then investigated to identify lessons learnt. Lessons should then be used to ensure that the risk of a similar incident happening again is minimised.

It is a requirement of all registered organisations to report serious incidents to the Care Quality Commission (CQC). This process in no way replaces this requirement.

9.1. Serious Incident Definitions – for those primary care organisations who will continue to report under the SIF

In broad terms, serious incidents are events in health care where the potential for learning is considered significant, or the consequences to patients, families and carers, staff or organisations are so significant, that they warrant using additional resources to mount a comprehensive response. Serious incidents can extend beyond incidents which affect patients directly and include incidents which may indirectly impact patient safety or an organisation's ability to deliver ongoing healthcare.

In accordance with the SIF there is no definitive list of events/incidents that constitute a serious incident and lists should not be created. Every incident must be considered on a case-by-case basis using the description below and reported to NHS Somerset:

- Acts and/or omissions occurring as part of NHS-funded healthcare (including in the community) that result in:
    - Unexpected or avoidable death of one or more people. This includes suicide/self-inflicted death and homicide by a person in receipt of mental health care within the recent past
    - Unexpected or avoidable injury to one or more people that has resulted in serious harm.
    - Unexpected or avoidable injury to one or more people that has requires further treatment by a healthcare professional to prevent death or serious harm.
    - Actual or alleged abuse; sexual abuse, physical or psychological ill-treatment, or acts of omission which constitute neglect, exploitation, financial or material abuse, discriminative and organisational abuse, self-neglect, domestic abuse, human trafficking, and modern-day slavery where healthcare did not take appropriate action/intervention to safeguard against such abuse occurring or where abuse occurred during the provision of NHS-funded care.
- An incident (or series of incidents) that prevents, or threatens to prevent, an organisation's ability to continue to deliver an acceptable quality of healthcare services (full details are provided in the SI Framework).
- Major loss of confidence in the service, including prolonged adverse media coverage or public concern about the quality of healthcare or an organisation.
- A Never Event – all Never Events are defined as serious incidents. Not all Never Events result in serious harm or death and the Never Events List 2018 (updated February 2021) remains relevant.

9.2. Reporting of a serious incident to NHS Somerset

Providers are required to report serious incidents on StEIS (Strategic Executive Information System) within two working days of the incident being identified. Once the serious incident has been reported on StEIS an automated email will be sent to Somerset ICB which provides a unique identifier number.

This policy in no way interferes with existing lines of accountability and does not replace the duty to inform the police and/or other agencies/organisations where appropriate.

A no harm/near miss event in relation to any of the above should also be recorded by NHS provider organisations and potential aggregated trends and clusters analysed using root cause analysis. Any emerging trends, which constitute a significant risk in any of the above categories, should be reported using this policy.

9.3. Decommission of serious incidents

All incidents meeting the threshold of an SI must be investigated and reviewed according to the principles set out in the SIF.

If, after initial investigation, the provider organisation feel that it no longer meets the criteria for a serious incident, then a request should be submitted to the ICB in writing

requesting downgrade, stating the reason for this. The downgrade request will be considered by Quality Team staff from NHS Somerset; if the request and rationale are considered appropriate, the serious incident will be downgraded from the StEIS database. The ICB may request that any ongoing investigation and learning is shared to inform any themes or trends.

9.4. SIF Reporting requirements

The SIF indicates that an initial update should be sent to the ICB within three working days of reporting the incident. This is to provide more detail to the ICB with regards to immediate action taken, Duty of Candour and Terms of Reference.

The investigation should be completed, and a final report and action plan submitted to the ICB. Action plans should be submitted with the final report with clear actions described, responsibilities and action deadlines set and plans to monitor and review, including planned follow-up audits to gain assurance that the learning has been implemented and changes embedded into practice.

10. Approach to managing serious incidents that have been reported under the SIF alongside implementing PSIRF

10.1. Pragmatically closing serious incidents ahead of PSIRF implementation

NHS Somerset is taking the approach to get as many of the open serious incidents closed prior to adoption of PSIRF so that the ICB and our providers can smoothly transition to, and focus on, the new way of working. There will be such a change to how future patient safety events will be responded to, monitored, learned from, and closed, that trying to run the old framework alongside the new framework could prove challenging.

The proposal is for ICB Quality, Safety & Improvement team colleagues to get together with our various provider colleagues in what has been termed a ‘round table day’. The aim is to have the right people in the room to review and feedback, and to ask and answer questions about investigation reports and action plans face to face in real time. Reducing the back and forth feedback via email.

This will allow discussion to take place about what a report may still be missing from an ICB perspective, and a space for our provider colleagues to respond there and then. With multiple people in the room, it will allow healthy conversation and the ability to check and challenge each other if felt we as an ICB are asking for too much and veering away from that pragmatic approach to closure.

Each serious incident report and action plan being put forward for potential closure should be shared by the provider ahead of time, whether it be in draft format or final, to allow the ICB Quality team time to review them ahead of the round table day. A deadline should be given to the provider for them to provide these reports and then ample reading time should be carved out in the ICB Quality Team’s diaries for leads to review the submitted reports.

During the round table day, the ICB can recommend changes to any of the reports which would make them more suitable for closure, and any conditional closure steps for each serious incident should be agreed between the ICB and the provider. The ICB should then trust that the organisation's own governance processes will take those agreed steps forward. There should not be a need for the ICB to revisit whether these steps have been completed, but rather this responsibility will be transferred to the provider, similar to how the governance of future patient safety events will be managed under the new PSIRF. After the round table day, those serious incidents where conditional closure steps were agreed should be closed by the ICB on StEIS after filling in the relevant StEIS fields.

Terms of reference for the round table day will be agreed ahead of time. A governance closure template will be developed and agreed by the ICB, which will be completed on the round table day for each serious incident that is pragmatically closed.

A cut-off date for when reporting serious incidents to StEIS must cease should be agreed between NHS Somerset and all reporting organisations.

10.2. Quality assurance and closure of serious incidents that remain open after PSIRF implementation goes live

NHS Somerset support the approach of handing over the quality assurance and closure of serious incidents that remain open after PSIRF adoption to the provider, underpinning the principles of PSIRF.

This will be reviewed and discussed with providers on an individual basis and a formal agreement will then be developed.

The ICB may choose to retain the quality assurance role for specific serious incidents where required.

Following the implementation of PSIRF, from October 2023, the ICB Deputy Director of Nursing and Inclusion and/or the Deputy Director of Quality and Improvement will become part of our main provider's (Somerset NHS Foundation Trust's) Patient Safety Board. Assurance will be sought through this Board. ICB attendance at our other provider organisations' equivalent meetings will also be sought, and similar agreements put in place with each provider.

10.3. Monitoring of action plans for serious incidents that were reported under the SIF once PSIRF implementation goes live

NHS Somerset must agree with our providers whether the ICB will continue to seek assurance of embedded action implementation for any serious incidents that were commissioned under the SIF or whether this assurance should now sit with providers' internal governance teams.

NHS Somerset support the approach of handing over the ongoing monitoring of serious incident action plans to the provider, underpinning the principles of PSIRF.

This will be reviewed and discussed with providers on an individual basis and a formal agreement will then be developed.

The ICB may choose to retain the monitoring role for specific serious incident action plans where required.

Where actions to mitigate recurrence of a patient safety issue do not appear to be having the desired effect, the ICB may choose to collaborate with the provider to make any necessary interventions for improvement. Further information can be found in NHS Somerset ICB's *Procedure - Escalation When Improvements Not Effective*.

11. NHS Somerset patient safety training requirements

NHS Somerset recognises that those involved in the review of patient safety events and investigations and those providing an oversight function require specific knowledge and skills. This includes knowledge of systems thinking and system-based approaches to learning from patient safety events.

Those involved in the quality assurance of patient safety incident response (i.e. provider boards/executive leads) must have knowledge to constructively challenge the strength and feasibility of recommendations and safety actions to improve underlying system issues. They must be able to recognise when safety actions following patient safety incident response do not take a system-based approach, for example, inappropriately focusing on individual behaviours or not appreciating why an adaptation to the system was necessary with recommendations targeted at 'retraining' or additional policies and checklists.

Those in system oversight roles (i.e. provider board PSIRF leads, ICS PSIRF leads, CQC relationship managers and inspectors) must have knowledge of effective oversight and supporting processes including effective use of data for assurance and patient safety incident response system development.

Staff in oversight roles must receive appropriate training to support the practical application of PSIRF oversight principles and standards.

11.1. Training procurement framework

An NHS suppliers training framework has been developed to assist with identifying training suppliers for the following required PSIRF training courses:

- Systems approach to learning from patient safety incidents
- Involving those affected by patient safety incidents in the learning response process
- Oversight of learning from patient safety incidents

11.2. Patient Safety Syllabus

As part of the NHS Patient Safety Strategy, work is underway to develop and deliver NHS-wide patient safety training. The National Patient Safety Syllabus was published

by Health Education England in May 2021 covering five levels of training. Level 1 (essentials for patient safety) and level 2 (access to practice) became available for all NHS staff via the eLearning for health platform in October 2021. In June 2022, the ICB (former CCG) mandated the requirement for all staff to complete Level 1 training and this is monitored via the Electronic Staff Record.

See below table for a breakdown of training requirements and further information can be found in appendix 3.

11.3. Table – Training requirements for those in PSIRF oversight roles

Topic	Minimum duration	Content
Systems approach to learning from patient safety Incidents	2 days/12 hours	• Introduction to complex systems, systems thinking and human factors • Learning response methods: including interviewing, and asking questions, capturing work as done, data synthesis, report writing, debriefs and after-action reviews • Safety action development, measurement, and monitoring
Involving those affected by patient safety incidents in the learning process	1 day/6 hours	• Duty of Candour • Just culture • Being open and apologising • Effective communication • Effective involvement • Sharing findings • Signposting and support
Systems approach to learning from patient safety Incidents oversight training	1 day/6 hours	• Effective oversight and supporting processes • Improvement focussed culture • Commissioning and planning investigations • Complex investigations and stakeholder boundaries
Patient Safety Syllabus Level 1: Essentials for patient safety	eLearning (30 minutes)	• Listening to patients and raising concerns • The systems approach to safety, where instead of focusing on the performance of individual members of staff, we try to improve the way we work • Avoiding inappropriate blame when things don't go well • Creating a just culture that prioritises safety and is open to learning about risk and safety
Patient Safety Syllabus Level 2: Access to Practice	eLearning	• Introduction to systems thinking and risk expertise • Human Factors • Safety culture

Continuing professional development	At least annually	• To stay up to date with best practice (e.g. through conferences, webinars etc.)

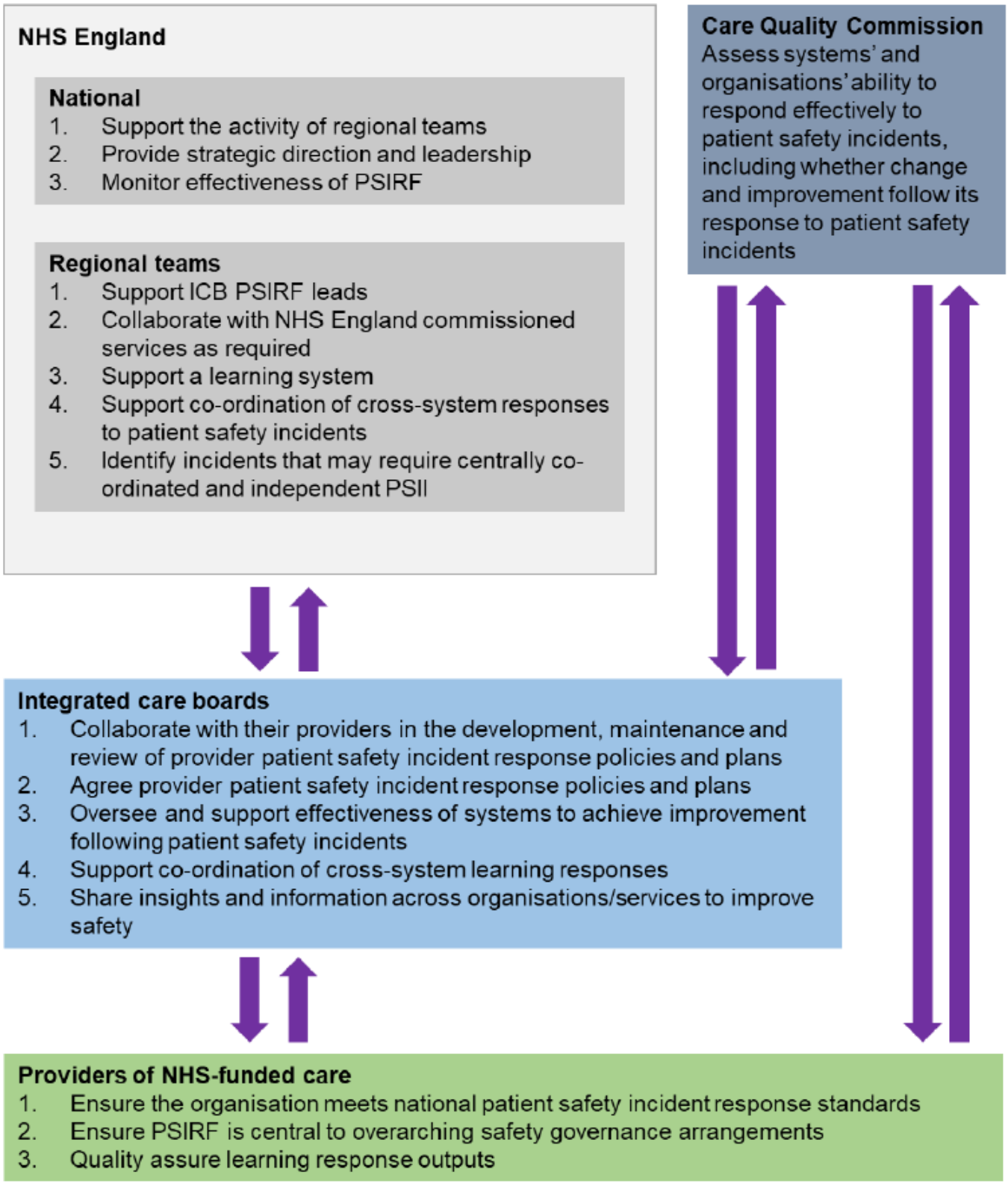
12. Update and review

The Deputy Director of Quality and Improvement is responsible for ensuring that this policy reflects current national guidance.

The Patient Safety Quality Committee will have responsibility for the governance of this policy.

Annual review and monitoring of provider organisation's Patient Safety Incident Response Plans will indicate the effectiveness of this policy at system level.

Appendix 1: Overview of organisational responsibilities



Appendix 2.1: Priorities for PSII review

1. Nationally defined priorities for external PSII review
    - Maternity and neonatal for HSIB led PSII
    - Mental health related homicides
    - Child deaths
    - Death of a person with a learning disability
    - Safeguarding
    - Incidents in screening programmes
    - Deaths of patients in custody, in prison or on probation where healthcare was/is NHS funded and delivered through an NHS contract. These are reviewed by the Prisons and Probation Ombudsman who will work with NHS England and NHS Improvement to commission an independent clinical review of the healthcare received.

2. Nationally defined priorities for local PSII review
    - Never events
    - Learning from deaths
    - Death of a person with mental illness
    - Learning disability death where patient safety incident may have contributed
    - Suicide/self-harm of person in state care
    - Deaths of patients in custody, in prison or on probation where there is reason to believe problems in healthcare may have impacted

3. Locally defined priorities for PSII review
    - Emergent incidents which justify a heightened level of response because the consequences for patients, families and carers, staff or organisations are so significant and the potential for learning is so great
    - Locally predefined incidents prioritised based on all of the following criteria: • actual and potential impact of incident • likelihood of recurrence • potential for learning.

See further detail of national event response requirements in table on following page in appendix 2.2.

Appendix 2.2: National event response requirements including Level 2 Investigations

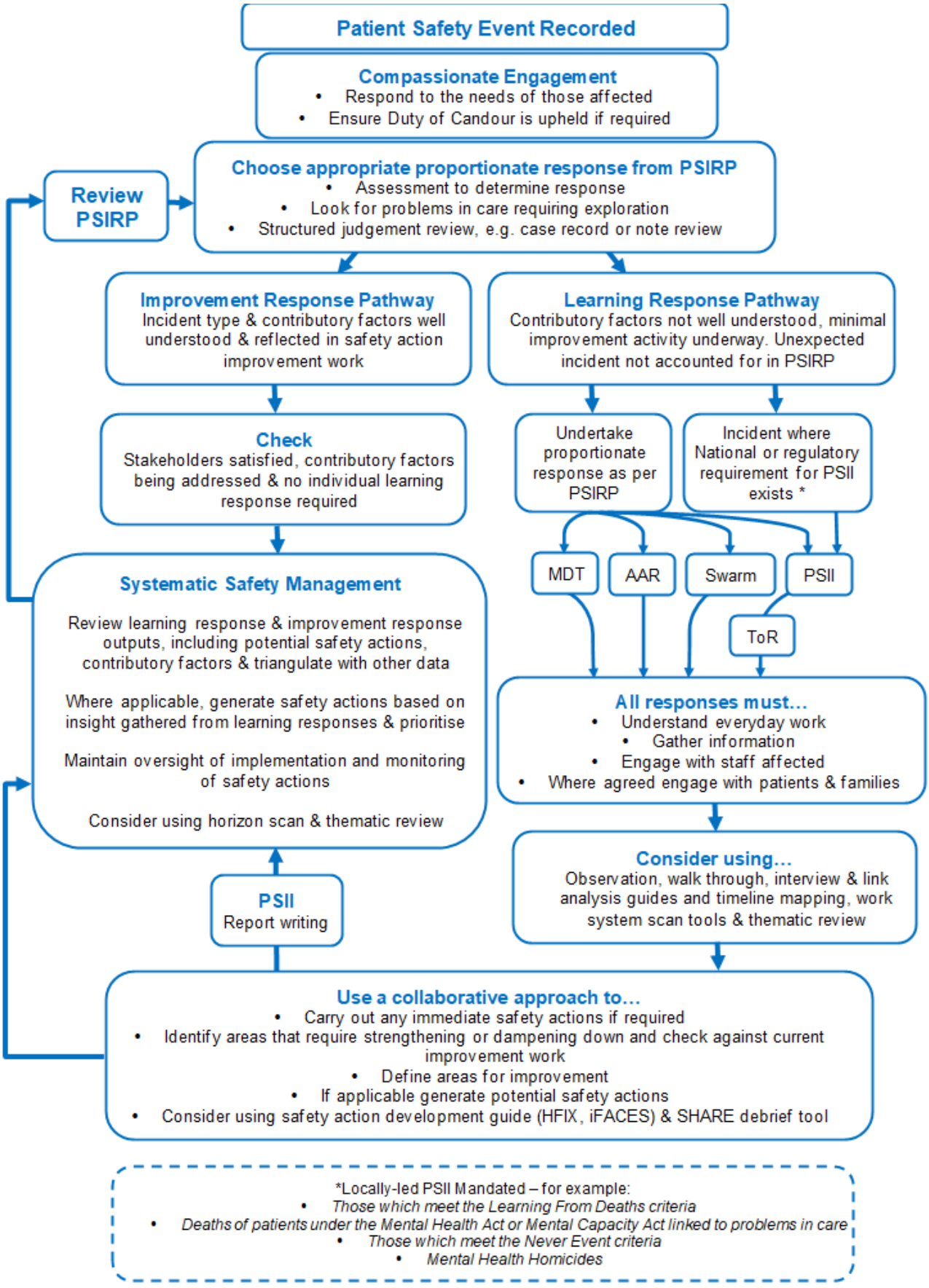
Event	Action required	Lead body for the response
Deaths thought more likely than not due to problems in care	• Locally-led **PSII.**	The organisation in which the event occurred
Deaths of patients detained under the Mental Health Act (1983) or where the Mental Capacity Act (2005) applies, where there is reason to think that the death may be linked to problems in care	• Locally-led **PSII**.	The organisation in which the event occurred
Incidents meeting the Never Events criteria 2018, or its replacement	• Locally-led **PSII**.	The organisation in which the Never Event occurred
Mental health-related homicides	• Referred to the NHS England Regional Independent Investigation Team (RIIT) for consideration for an independent **PSII**. • Locally-led **PSII** may be required.	As decided by the RIIT
Maternity and neonatal incidents meeting Healthcare Services Safety Investigation Branch (HSSIB) criteria	• Refer to HSSIB or SpHA (or Special Healthcare Authority (SpHA) when in place) for independent **PSII**.	HSSIB (or SpHA)
Child deaths.	• Refer for Child Death Overview Panel review. • Locally-led **PSII** (or other response) may be required alongside the panel review – organisations should liaise with the panel.	Child Death Overview Panel
Deaths of persons with learning disabilities	• Refer for Learning Disability Mortality Review (LeDeR). • Locally-led PSII (or other response) may be required alongside the LeDeR – organisations should liaise with this.	LeDeR programme
Safeguarding incidents in which: **• babies, children, or young people are on a child protection plan; looked after plan or a victim of wilful neglect or domestic abuse/violence** **• adults (over 18 years old) are in receipt of care and support needs from their local authority** **• the incident relates to FGM, Prevent (radicalisation to terrorism), modern slavery and human trafficking or domestic abuse/violence**	• Refer to local authority safeguarding lead. • Healthcare organisations must contribute towards domestic independent inquiries, joint targeted area inspections, child safeguarding practice reviews, domestic homicide reviews and any other safeguarding reviews (and inquiries) as required to do so by the local safeguarding partnership (for children) and local safeguarding adults boards.	Refer to your local designated professionals for child and adult safeguarding
Incidents in NHS screening programmes	• Refer to local screening quality assurance service for consideration of locally-led learning response.	The organisation in which the event occurred
Deaths in custody (eg police custody, in prison, etc) where health provision is delivered by the NHS	• Any death in prison or police custody will be referred (by the relevant organisation) to the Prison and Probation Ombudsman (PPO) or the Independent Office for Police Conduct (IOPC) to carry out the relevant investigations. • Healthcare organisations must fully support these investigations where required to do so.	PPO or IOPC
Domestic homicide.	• A domestic homicide is identified by the police usually in partnership with the community safety partnership (CSP) with whom the overall responsibility lies for establishing a review of the case. • Where the CSP considers that the criteria for a domestic homicide review (DHR) are met, it uses local contacts and requests the establishment of a DHR panel. • The Domestic Violence, Crime and Victims Act 2004 sets out the statutory obligations and requirements of organisations and commissioners of health services in relation to DHRs.	CSP

Appendix 3: Training requirements for providers, commissioners, and executives

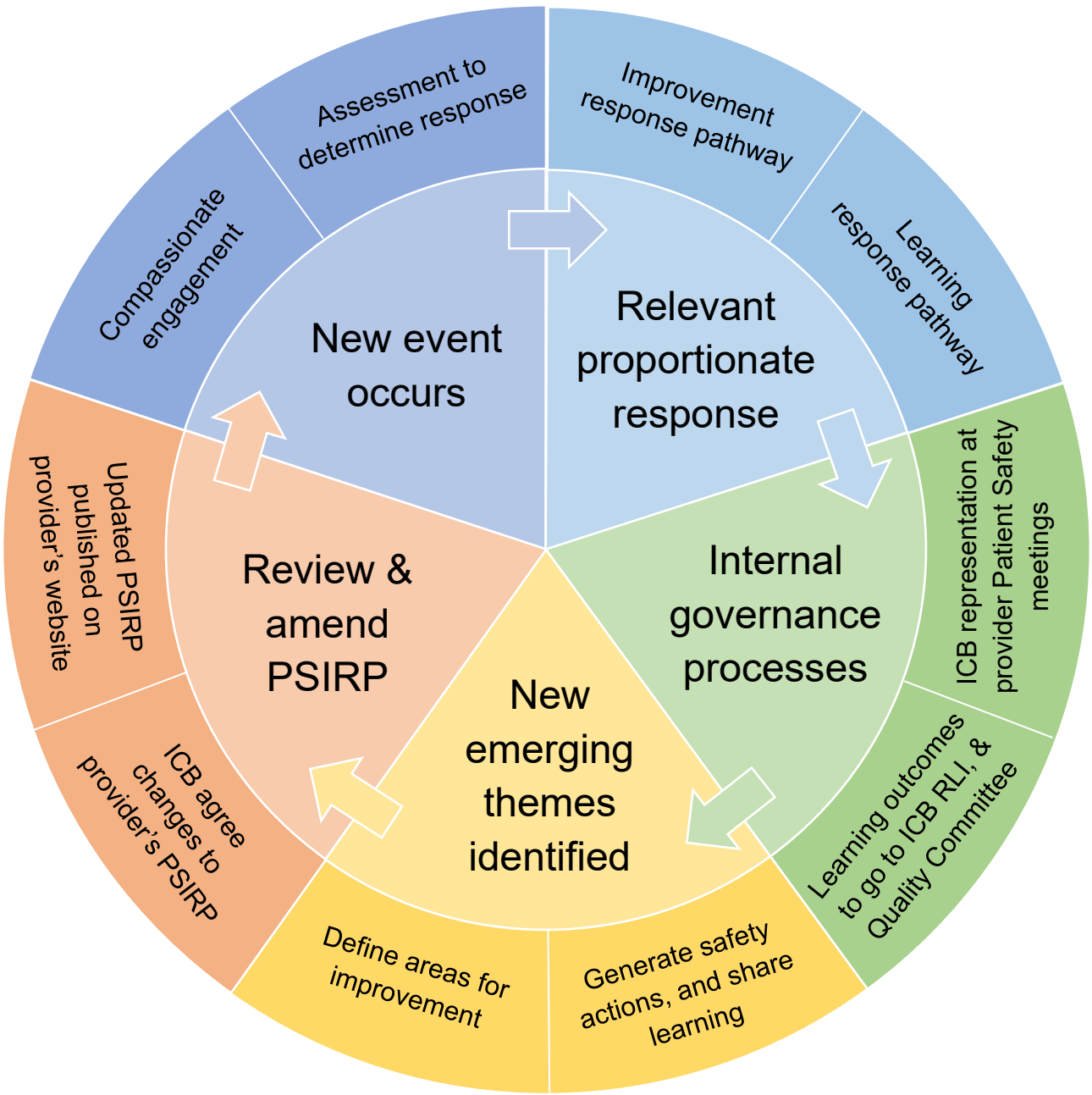
Systems approach to learning from patient safety incidents training for health and social care providers, commissioners, and executives					
LOT 4a		**LOT 4b**		**LOT 4c**	
Systems approach to learning from patient safety incidents		**Systems approach to learning from patient safety incidents oversight training**		**Engaging with patients, families, and staff following a patient safety incident training**	
2-day/12 hours (minimum duration)		**1-day/6 hours (minimum duration)**		**1-day/6 hours (minimum duration)**	
For: • **All** learning response leads • **All** those in PSIRF oversight roles (see Lot 4b)		**For:** All those in PSIRF oversight roles: Provider boards; Integrated care boards; NHS England regional leads		**For:** • **All** engagement leads • **All** those in PSIRF oversight roles (see Lot 4b)	
Description	**Requirements** of **all** presenters delivering training	**Description**	**Requirements** of **all** presenters delivering training	**Description**	**Requirements** of **all** those delivering training
Training to support the development of core understanding and application of systems-based patient safety incident response throughout the healthcare system - in line with NHS guidance, based upon national and internationally recognised good practice. **Delivery of:** Thorough, credible, systems-based patient safety incident response training, based upon the NHS PSIRF and to include: General content: • Purpose of patient safety incident response • Introduction to complex systems, system thinking and human factors • Just culture	• Training must be conducted by those who have attended courses in learning from safety incidents amounting to more than 30 days, are up to date in learning response best practice and have both conducted and reviewed learning responses. • Accreditation with a recognised organisation (such as a Chartered Human Factors Specialist (CErgHF) or similar) is preferred. • Must demonstrate evidence of recent CPD **Relevant training and qualifications in** • Systems-based approaches to patient	*Training to support the development of expert understanding and oversight of systems-based patient safety incident response throughout the healthcare system - in line with NHS guidance, based upon national and internationally recognised good practice.* **Delivery of:** Thorough, credible, systems-based patient safety incident response oversight training, based on the NHS PSIRF and to include: • Effective oversight and supporting processes related to incident response • Maintaining an open, transparent and improvement focused culture • Patient safety incident investigation (PSII)	• Training must be conducted by those who have attended courses in learning from safety incidents amounting to more than 30 days, are up to date in learning response best practice and have both conducted and reviewed learning responses. • Must demonstrate evidence of recent CPD **Relevant training and qualifications in** • Systems-based approaches to patient safety incident response • Complex systems, systems thinking and human factors • Improvement science/quality improvement	*Training to support the development of expertise in engaging and involving patients, families, carers and staff affected by patient safety incidents, in line with NHS guidance, based upon national and internationally recognised good practice. To include the duty of candour, and 'Engagement' principles* **Delivery of:** Thorough, credible, training, based on the NHS PSIRF to include: • Duty of Candour regulations • Being open and apologising • Effective communication including dealing with conflict and difficult conversations • Engaging with patients, families, carers, and staff	• Training must be conducted by those who are up to date in engagement best practice and have both conducted and reviewed learning responses. • Must demonstrate evidence of recent CPD **Skills and experience in:** • Applying duty of candour • Applying Being Open or PSIRF principles • Effective communication including dealing with conflict and difficult conversations • Engaging with patients, families, carers, and staff following a patient safety incident

• Improvement science and developing system improvement plans Response techniques • Interviewing and asking questions • Conducting observations, understanding work as done • Systems frameworks • Must include Patient Safety Incident Investigation • Learning response planning • Analysis • Report writing Contingency/backup cover required, consistent with the requirements for trainer knowledge, skills, and expertise	safety incident response • Complex systems, systems thinking and human factors • Improvement science/quality improvement • Teaching, coaching, feedback and/or delivery of learning **Skill and experience** • Conducting high quality, complex investigations spanning different organisations, settings, and stakeholder boundaries • Providing high quality training in systems-based safety incident response • Presenting to executive board members, clinicians, and multi-disciplinary teams **Up to date knowledge of relevant:** • NHS patient safety incident response policy and guidance • NHS and organisation policies and processes	commissioning and planning • Complex investigations spanning different organisational, care setting, and stakeholder boundaries Contingency/backup cover required, consistent with the requirements for trainer knowledge, skills, and expertise	• Teaching, coaching, feedback and/or delivery of learning **Skill and experience** • Conducting high quality, complex investigations spanning different organisations, settings, and stakeholder boundaries • Providing high quality training in systems-based safety incident response • Presenting to executive board members, clinicians, and multi-disciplinary teams • Measurement and monitoring safety using both qualitative and quantitative data **Up to date knowledge of relevant**: • NHS patient safety incident response policy and guidance • NHS and organisation policies and processes	following a patient safety incident • Effective involvement of those affected by a patent safety incident throughout the incident response process to ensure a thorough and richer learning response Contingency/backup cover required, consistent with the requirements for trainer knowledge, skills, and expertise	• Effective involvement of those affected by a patent safety incident throughout the incident response process to ensure a thorough and richer learning response • Systems-based approaches to learning from patient safety incidents • Complex systems, systems thinking and human factors • Providing high quality training / coaching in engagement or related subjects **Up to date knowledge of relevant**: • NHS patient safety incident response policy and guidance • NHS and organisation policies and processes

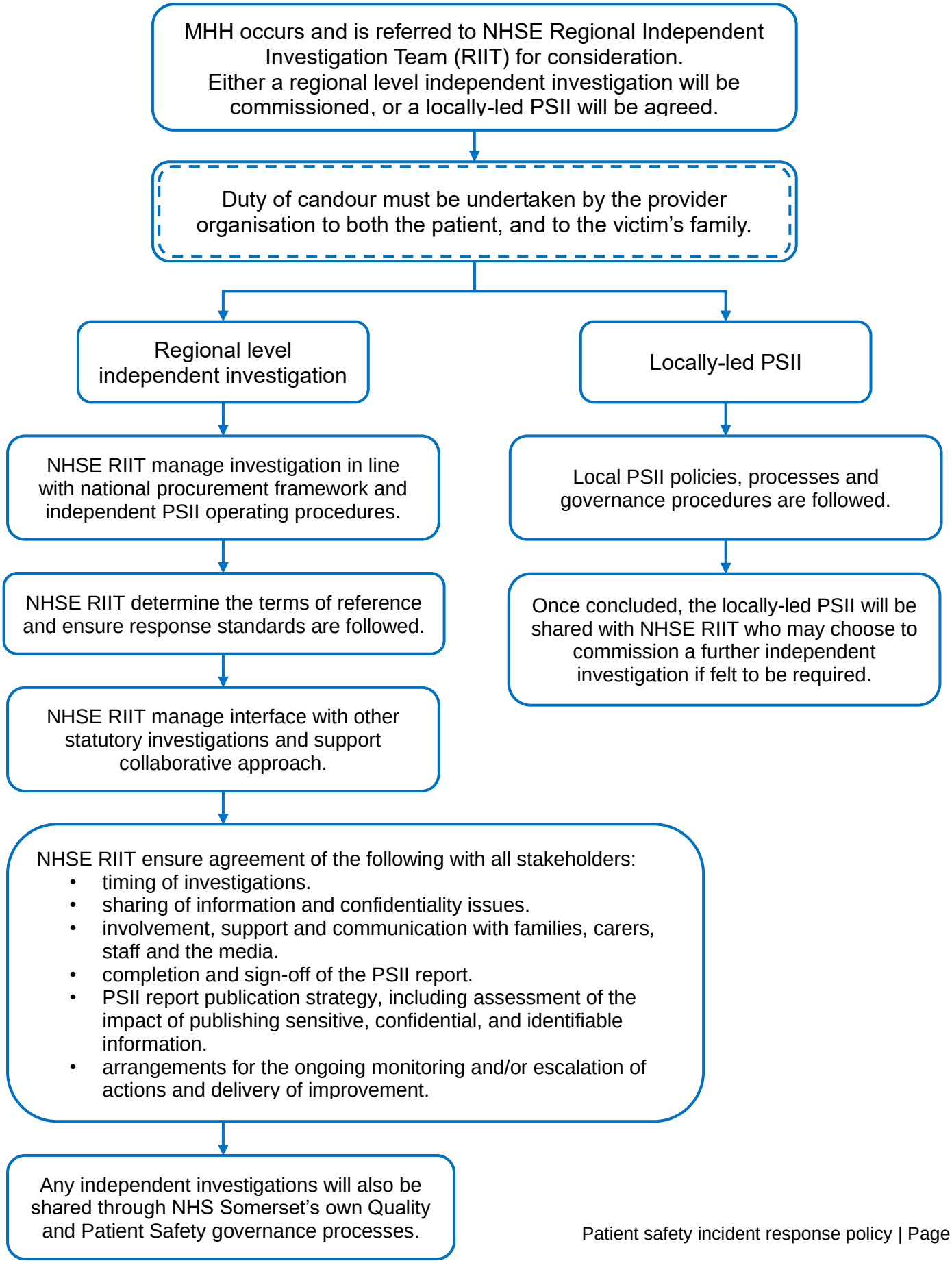
Appendix 4: Patient Safety Event Response Pathway



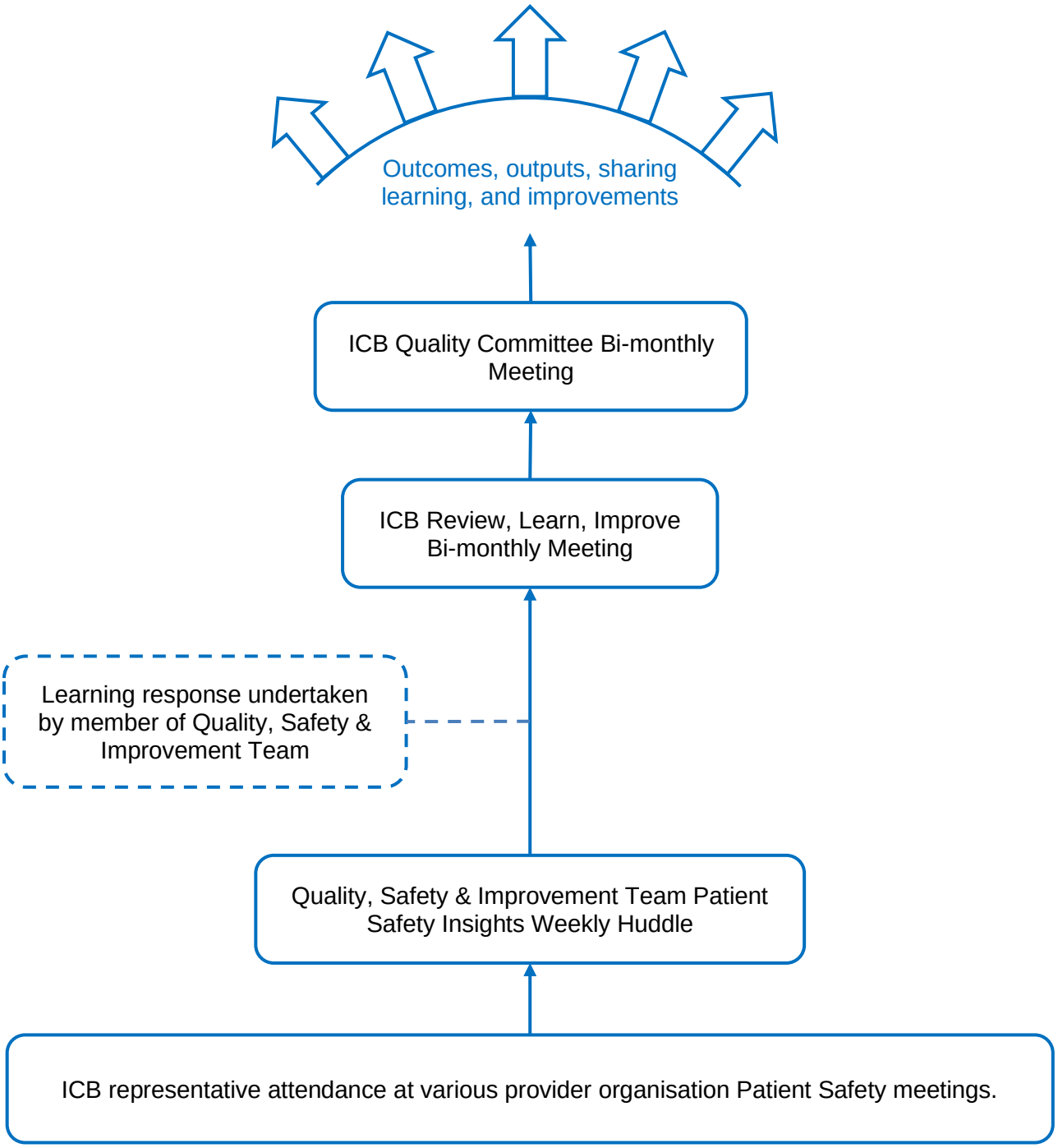
Appendix 5: Patient Safety Event Process Wheel



Appendix 6: Mental Health Homicide (MHH) management process



Appendix 7: NHS Somerset ICB's Internal Governance Reporting Structure



Appendix 8: NHS Somerset Patient Safety Governance Meetings

Meeting	Basic info	Purpose of meeting	Where this meeting feeds onto
Weekly Patient Safety Events Huddle	• Meeting held weekly. • No formal minutes but decisions made are captured within an excel log. • Attended by representatives from across the ICB Quality, Safety & Improvement Team.	• Share new patient safety insights from that week. • Agree any action to be taken – decisions to be logged. • Provide updates in response to previously shared patient safety insights. • Triangulate emerging themes and intelligence from other sources besides patient safety events.	Escalations to the Review, Learn, Improve Meeting
Review, Learn, Improve Meeting	• Formal meeting held bi-monthly. • Formal minutes and action tracker. • Attended by representatives from across the ICB Quality, Safety & Improvement Team, as well as a representative from NHSE, and a lay member (Patient Safety Partner).	• To review what is happening in focussed areas of the Quality, Safety & Improvement Team's work. • To identify and triangulate emerging themes, trends and risks from reported data and soft intelligence, and take appropriate action where needed. • To share identified learning with team members. • To seek support and challenge from team members where needed. • To identify any shared learning to be cascaded wider, whether across county, regionally, or nationally. • To formally take policies, reports, and procedures through internal governance sign-off processes. • To make decisions in relation to the completion and sign off of our own (NHS Somerset reported) Patient Safety Events. • To review RIIT commissioned independent investigations prior to them going into the public domain.	Escalations to the ICB Quality Committee
ICB Quality Committee	• Formal meeting held bi-monthly. • Formal minutes and action tracker. • Attended by representatives from across the ICB Quality, Safety & Improvement Team, the Chief Nursing Officer/Chief Operating Officer, the ICB's Quality and Safety Non-Executive Directors, and a lay member (Patient Safety Partner).	• To provide the ICB with assurance that it is delivering its functions in a way that secures continuous improvement in the quality of services, against each of the dimensions of quality set out in the Shared Commitment to Quality and in the Health and Care Bill 2021. • To promote a culture within Somerset Integrated Care System (ICS) that focuses on Patient Safety, Patient Experience, Safeguarding and Quality Improvement. • To provide assurance on all NHS Provider services' governance arrangements and patient safety performance, through receiving exception reports on quality and safety issues, patient experience and safeguarding concerns and alerts for health services. • To note closure of our own (NHS Somerset reported) Patient Safety Events. • To note RIIT commissioned independent investigations prior to them going into the public domain.	System risks with regard to patient safety escalated to Somerset ICS Quality Group

Appendix 9: Flow chart for providers and PSIRP expectations