North East and North Cumbria

Corporate	ICBP049 Patient Safety Incident Response Framework Oversight Policy

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1.0	16th October 2023	October 2024

Prepared By:	Director of Nursing and Midwifery, North East North Cumbria Integrated Care Board.
Consultation Process:	Executive Chief Nurse
Formally Approved:	November 2023
Approved By:	Quality and Safety Committee Executive Chief Nurse

EQUALITY IMPACT ASSESSMENT

Date	Issues
15.11.2023	None

POLICY VALIDITY STATEMENT

Policy users should ensure that they are consulting the currently valid version of the documentation. The policy will remain valid, including during its period of review. However, the policy must be reviewed at least once in every 3-year period.

ACCESSIBLE INFORMATION STANDARDS

If you require this document in an alternative format, such as easy read, large text, braille or an alternative language please contact necsu.comms@nhs.net

Version Control

Version	Release Date	Author	Update comments
1.0	November 2023	Director of Nursing and Midwifery	Reviewed Yearly

Approval

Role	Name	Date
Executive Chief Nurse	David Purdue	November 2023

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1. Introduction

This document is a policy which outlines a set of statements of principles, values, and intent in relation to the North East and North Cumbria Integrated Care Board (NENC ICB) adoption of the Patient Safety Incident Response Framework (PSIRF).

In March 2020, NHS England (NHSE) published the PSIRF. The PSIRF is a key part of the patient safety strategy (NHSE 2019) and supports the NHS to improve its understanding of safety by drawing insight and learning from patient safety incidents. The PSIRF replaces the serious incident framework (2015) and makes no distinction between 'patient safety incidents' and 'serious incidents.' 'Serious Incidents' and their associated thresholds no longer exist under PSIRF. PSIRF promotes a proportionate approach to responding to patient safety incidents by ensuring resources allocated to learning are balanced with those needed to deliver improvement (NHSE, 2022).

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

Organisations are expected to transition to PSIRF by Autumn 2023. The preparation guide divides PSIRF preparation into six phases to ease transition and provide detail around discrete activities that will set strong foundations for implementing the framework.

1.1 Status

New Policy

1.2 Purpose & Scope

This policy supports the requirements of the PSIRF and sets out the ICB approach to developing and maintaining effective systems and processes for responding to patient safety incidents and issues for the purpose of learning and improving patient safety.

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

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

- compassionate engagement and involvement of those affected by patient safety incidents.
- application of a range of system-based approaches to learning from patient safety incidents.

- considered and proportionate responses to patient safety incidents and safety issues.
- supportive oversight focused on strengthening response system functioning and improvement.

The policy applies to the ICB and all its employees and must be adhered to by all those who work for the organisation.

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

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

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

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

1.3 Who does PSIRF apply to?

The 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. Primary care providers may also wish to adopt PSIRF, but it is not a requirement at this stage.

Secondary care organisations that provide NHS funded care under the NHS standard contract which are not NHS trusts or foundation trusts (for example independent provider organisations) will also be 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 (for example due to limitations on data availability), however, processes such as stakeholder engagement in preparing plans are still required (see Appendix C).

For some smaller providers of NHS funded care, who typically report a very small number of incidents annually, a PSIRP may not be required (Appendix C). Where a full PSIRP is not intended to be completed this must be agreed with the

ICB Lead Director of Nursing and Midwifery as soon as possible during PSIRF preparation. However, where the provider and the ICB agree a full PSIRP is not required, the provider should update their incident management policy to incorporate PSIRF and the incident response process.

Grant funded independent provision, such as hospice providers, are not required to complete a PSIRP as they are not subject to an NHS Standard Contract. These providers are encouraged to complete a PSIRF or, as per Appendix C, update their incident management policy to incorporate PSIRF and incident response process.

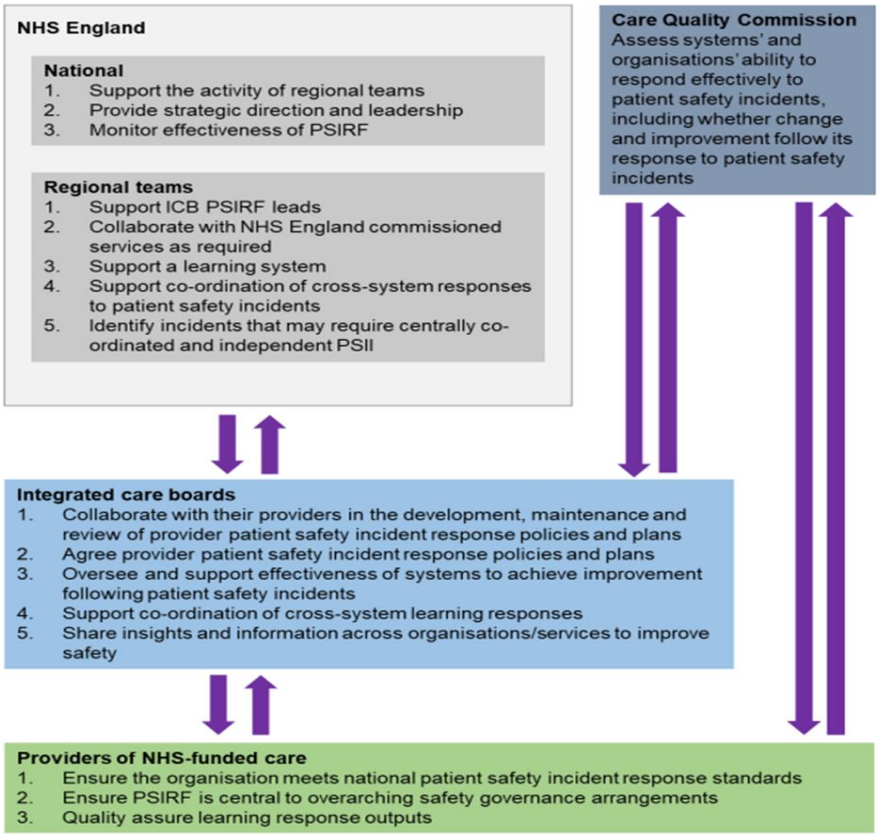
Primary care services will continue to report patient safety incidents in line with the Serious Incident Framework (SIF) until further national guidance is published regarding PSIRF and primary care. This guidance will be amended when further national guidance is received.

2. Definitions

SIF – Serious incident framework
PSIRF – Patient Safety Incident Response Framework

3. Patient Safety Incident Response Framework Policy

Duties and responsibilities



3.1 NHSE national team
NHSE national team will oversee the activity of regional teams to support effective response to patient safety incidents, providing strategic direction and leadership while monitoring the effectiveness of PSIRF.

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

3.3 Duties within the ICB
It is the responsibility of all staff to support the delivery of the PSIRF.

ICB Executive Chief Nurse
This is the person with overall accountability for this policy.

ICB PSIRF Lead Director of Nursing and Midwifery

The ICB PSIRF Lead Director of Nursing and Midwifery is responsible for:

- Ensuring staff, providers of NHS funded activity and stakeholders are aware of this policy and processes to be followed.
- Administrative co-ordination of this policy
- Ensuring there are ICB arrangements in place for collaborating with NHS healthcare providers in the development, maintenance and review of provider patient safety incident response policies and plans.
- Recommending the approval of provider patient safety incident response policies and plans.
- Overseeing and supporting effectiveness of systems to achieve improvement following patient safety incidents.
- Supporting the co-ordination of cross-system learning responses.
- Sharing insights and information across organisations/services to improve safety.

ICB Leads
Named ICB Leads with Patient Safety Specialist experience will be identified to be responsible for:

- Collaborating with named providers/provider collaboratives.
- Overseeing and supporting effectiveness of the Place system to achieve improvement following patient safety incidents.
- Identifying learning and improvement agendas to be shared within Place at the Place Quality Group.
- Identifying incidents that require an ICS response.
- Supporting the identification of learning to be shared across the ICS.

ICB Learning Response Leads
ICB Learning Response Leads will be identified across the ICB to lead and implement Quality Improvement at Place or across the system, this role is not

specific to a job title but is identified within job planning and job descriptions/functions of roles where the staff member is required to lead quality improvement/learning responses.

ICB Learning Response Leads are responsible for:
Leading the response to learning within the ICB, across Places or Systems.

Place Quality Groups
The Place Quality Group is responsible for:

- Overseeing learning responses within Place.
- Receiving learning and identifying learning for Place.
- Identifying and recommending learning for System.

ICB PSIRF Oversight Group
The ICB PSIRF Group is responsible for:

- Ensuring compliance with the ICB Policy.
- Overseeing the discharge of the ICB's responsibilities.
- Forming an oversight statement for the Quality Committee.

ICB Quality and Safety Committee
The ICB Quality and Safety Committee is responsible for:

- The approval of this policy document.
- Seeking assurance that the ICB is discharging its duties in relation to PSIRF.

System Quality Group
The System Quality Group is responsible for:

- Overseeing ICS learning responses.
- Receiving learning and identifying learning for System.

ICB's are responsible for agreeing provider incident response plans and policies. This responsibility must be discharged prior to implementation of PSIRF, and the oversight function must be maintained post implementation.

Oversight must be:

- Proportionate
- Appropriate
- Mutually agreed.

The focus should be on collaboration and learning, and it must not add burden to any party. To support this an implementation checklist is in place (Appendix D).

3.4 Oversight role during the implementation phase.
An ICB Lead will be identified to engage with a named provider. The ICB Lead will join provider meetings to support collaboration and to enable the oversight responsibility to be discharged. The providers PSIRP and policy should be agreed via the Quality Review Group. The Provider Quality Lead and ICB Lead will mutually agree the 'ready to implement' status by reviewing the criteria and evidence against the implementation checklist. The Provider Quality Lead and ICB Lead will present

the ‘ready to implement’ case to the ICB PSIRF Oversight group and, once supported, the 'go live' date communicated to the Quality Team. Independent sector provider PSIRP and policies should be signed off at the contract meetings, and then follow the same 'ready to implement' checklist (Appendix D).

3.5 Oversight role post the implementation phase.

The ICB Leads will maintain relationships with the providers to enable the ongoing oversight of provider incident response plans and policy implementation. For each provider this is likely to be a different arrangement, which will be proportionate, appropriate, and mutually agreed. This function will usually be discharged by the ICB Lead attendance at the provider safety/learning panel and Quality Review Group. The ICB Quality and Safety Committee will receive a regular report on the discharge of the organisational responsibilities from the ICB Lead Director of Nursing and Midwifery. Independent sector oversight will occur at contract meetings.

3.6 Oversight of historic SI post implementation of PSIRF

The ICB Quality Leads will continue to attend the SI panels to review incidents registered as an SI on StEIS prior to an organisations transition to PSIRF. The panels will continue to convene to review open SI reports and outstanding actions until such a time as the historic cases have been closed. All incidents reported as PSII post PSIRF implementation will be reviewed internally by the organisation at safety/learning panels with ICB Quality representation.

3.7 Our Patient Safety Culture

The ICB supports open and transparent reporting and strives to create a climate that fosters a just and open safety culture of reflection and learning. Embracing the principle of meaningful open engagement with patients and families.

3.8 Collaboration

The National Patient Safety Incident Response Standards (NHSE, 2022) place a responsibility upon ICB’s to collaborate with Providers.

Collaboration is described as the act of working together to achieve or create something.

To enable effective collaboration:

- Trust and respect must be established.
- There must be a willingness to work together.
- Communication must be effective.
- Both parties must feel empowered.

The ICB’s responsibility to collaborate with providers will require the ICB to work with the relevant provider collaborative arrangements as well as with individual providers.

<u>Responding to/Learning from cross-system incidents/issues</u>

All providers must have a process to recognise incidents or issues that require a cross-system learning response. They must use their judgement and seek the views of local partners to ensure learning responses are co-ordinated at the most appropriate level of the system.

There is frequently more than one organisation involved in the care and service delivery in which a patient safety incident has taken place. The organisation that identifies the incident is responsible for recognising the need to alert other providers, commissioners, and partner organisations via their respective risk management or governance teams. A lead organisation should be identified to coordinate the investigation, this should be agreed by all organisations involved. The ICB Patient Safety Specialists can facilitate discussion as to the most appropriate organisation to take responsibility for co-ordinating the investigation process, to ensure there is fair division of responsibility.

The incident should be reported onto StEIS by the lead organisation until this function in the learn from patient safety events (LFPSE) system is functional. All providers are expected to respond and participate in joint 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.

If the incident involves three or more organisations, the ICB will consider coordinating the investigation process. Where there is insufficient capacity and/or capability, providers must engage early with their ICB, via their ICB Lead, who can identify the right person to support the co-ordination of a cross-system learning response, which may be via the NHSE Regional Independent Investigation Team (RIIT).

The ICB Learning Response Leads will liaise with relevant providers/provider collaboratives (and other ICBs if necessary) to 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. The learning responses may be developed through a NENC system learning event, facilitated by the ICB, to bring together all the providers who contributed to the investigation.

<u>The NHS England (North East and Yorkshire) Regional Independent Investigation Team (RIIT)</u>

RIIT supports the NHS patient safety incident response infrastructure by providing expert advice, support and/or leadership in relation to the management of independent patient safety incident investigations. This includes, advising the ICB on how to co-ordinate independently led PSIIs (where the investigation can be managed at this level) reviewing incidents reported to or identified by the RIIT for wider learning and improvement potential across healthcare system and the need for a regionally led independent PSIIs.

NHS England's regional team will commission Independent Investigations on behalf of the system.

- Where a provider or commissioner is unable to conduct an effective, objective, timely and proportionate learning response (in line with PSIRF), including being too small or too close to provide objective investigation and analysis.

- Where an incident(s) represents a significant systemic challenge within an organisation, service, or system and so the incident(s) represent significant learning potential for the wider system (regional or national)

- Where an independent process is required to ensure the confidence of relevant stakeholders in the findings

- Where an issue cuts across several providers and systems or even regions meaning there is no clear local lead and so the response must be led at a wider national level

- Following mental healthcare related homicides

Domestic homicide review
As per national guidance.

Management of mental health homicide (MHH) investigation
These incidents are a defined nationally as a priority to be investigated as a PSII (Appendix 5). These incidents often require complex, multi-agency collaboration and engagement involving internal and external stakeholder across geographical and organisational boundaries.

Advice must be sought on accessing relevant procurement frameworks from the NHSE Regional Independent Investigation Team (RIIT) for all incidents of mental health related homicide.

System Learning Responses
Providers and ICBs are expected to work together to establish and undertake cross-system learning responses, but where issues arise, support must be sought from the NHS England regional team.

The infrastructure to support learning responses to cross-system incidents is as follows:

- Place learning response required – Place based Quality Groups.
- Cross-place learning response required – System Quality Group.
- Cross-ICB learning response required – ICB Quality and Safety Committee to System Quality Group.

Where required an ICB can commission an investigation (or other learning response) that is independent of the provider. This may occur when:

- an organisation is too small (for example, does not have the workforce) to provide an objective response and analysis.
- an investigation independent of the provider is deemed necessary to ensure public confidence in the investigation integrity.
- a multi-agency incident occurs, and no single provider is the clear lead for an investigation.
- the incident(s) represent significant learning potential for the wider system (regional or national).

Advice must be sought on accessing relevant procurement frameworks from the NHSE Regional Independent Investigation Team (RIIT). All multi-agency incidents and those representing significant learning potential for the wider system should be discussed with the RIIT.

The ICB must seek to identify and share areas of good practice in relation to patient safety incident response.

Recording responses to patient safety incidents during the transition to LFPSE and PSIRF

From September 2023 all organisations who previously reported to NRLS should have made the switch to reporting to the new Learn from Patient Safety Events (LFPSE) service, which will replace the NRLS. This means there will be changes to the expectations and processes associated with recording information about the response to patient safety incidents.

Ultimately, LFPSE implementation will mean that organisations no longer use StEIS for any purposes. However, to reduce complexity during the transition period and to maintain data flows while we further enhance the LFPSE data access application, organisations are asked to continue to use StEIS for now, following the transition to PSIRF.

Providers are asked to use StEIS to record incidents that are subject to Patient Safety Incident Investigation (PSII). A new incident type has been added to StEIS that allows organisations to record incidents which are responded to using PSII.

This is the approach that has already been taken successfully by the PSIRF Early Adopter organisations.

NHS England is currently undertaking 'User Research' to support the future design of the LFPSE service, specifically regarding how best to support appropriate oversight and analysis of data once providers have transitioned to PSIRF. This will inform future versions of LFPSE and the associated Data Access Application and remove the need for use of StEIS.

Sharing and dissemination of learning across the system

The ICB have a responsibility to ensure that the insight and learning from patient safety incidents is shared and disseminated across the NENC system, to promote improvements in care and patient safety. Learning within the NENC system will be shared with, but not limited to the following:

1. The ICB Learning and Improvement steering group

This steering group's purpose is to make learning and improvement the way our ICS approaches its biggest challenges and to build a thriving learning and improvement community; one that brings people together from across the whole system to share learning and collaborate towards getting better at delivering our ICS 'Better Health and Wellbeing for All' goals. This group reports into the ICB Executive Committee and has delegated authority aligned to the Scheme of Reservation and Delegation.

The Learning and Improvement steering group ensures the ongoing development of a partnership approach with NHS, Local Authorities, VCSE and Independent Providers to ensure strong oversight, development, and delivery of an approach to all learning and improvement outcomes which addresses population needs, reduces health inequalities, and create a voice that will influence, challenge and support transformation to meet population need.

2. The NENC system patient safety meeting

This system wide meeting, open to those leading on patient safety in all organisations and is chaired by the ICB PSIRF Lead Director for Nursing and Midwifery. A priority of the meeting is to enable the opportunity for system partners to come together to identify and share learning and good practice from patient safety incident investigations and reviews.

The ICB recognises that an essential part of improving how organisations learn from patient safety incidents are external review which this meeting will facilitate. External review is important to help improve quality and to reduce siloed approaches to learning that can embed unintentional bias. It can also act as a means for anticipating future problems by reflecting on systems in place and anticipating risks. The NENC system patient safety meeting will facilitate external review of patient safety investigations (after an incident has been signed off by an organisation's board or delegated executive lead). This will offer the opportunity for providers to review their own practice to ascertain 'could this happen here?'.

The NENC systems patient safety meeting will provide a forum to enable identification of themes and trends, and the opportunity for anticipating future problems or risks and to support actions to be taken in mitigation. This meeting will also deliver a platform to discuss the progression of multi -agency investigations, to provide support if required and to gain insight and shared learning across the system. Concerns regarding delivery of the PSIRP will be raised at this meeting to enable the offer of cross system support. The meeting will also provide the opportunity to share investigation tools and approaches and to highlight what went well or areas for potential learning.

3. NENC system learning events.

The ICB Leads in conjunction with provider PSS and PSP's are committed to introducing a biannual learning event which will bring together multi-disciplinary partners and colleagues from across the ICB. This will be an inclusive forum to enable discussion and shared learning from patient safety incidents to be highlighted at system level. The ICB will seek to identify and share areas of good practice in relation to patient safety incident response and investigations within this forum.

4. The NENC ICB learning library

The ICB PSS in conjunction with the provider PSS, will maintain a learning library of anonymised PSII and thematic reviews for shared learning. All PSS will have access to this resource.

5. The NENC Patient Safety Improvement Network (PSIN)

The System Safety SIP (Safety Improvement Programme) commissioned by NHSE (2022/23) required the Patient Safety Collaboratives (PSCs) to set up regional

Patient Safety Improvement Networks (PSIN). This was initially to support the implementation of the Patient Safety Incident Response Framework (PSIRF) and later the improvement work related to national patient safety areas and regional priorities arising from PSIRF.

Following implementation of PSIRF, NHSE anticipated that a PSIN would undertake improvement work related to national patient safety areas and regional priorities arising from PSIRF. The PSIN will include representation from a diverse range of stakeholders aligned to the associated priority areas. Membership will be multi-professional and include those at varying levels of seniority. It is expected that members actively participate, with commitment from their host organisations and accountability for individuals remaining with their host organisation.

6. NENC Faculty of Patient Safety (FPS) Group

On behalf of Health Education England NENC (HEE), the Faculty of Patient Safety will set the strategic direction for education and training in delivering the Patient Safety Agenda, to contribute towards the delivery of high-quality compassionate patient care within the region.
The Faculty is be a multi professional, high level strategic group that will direct the Patient Safety workstream on behalf of HEE NENC. Wider stakeholders and partners will be invited and will link with the national work of HEE.

The Faculty of Patient Safety will deliver the following major work streams:
1. Simulation
2. Human Factors
3. Delirium
4. Immersive
5. Learning from Clinical Incidents and Never Events
6. MELISSA

The Faculty works closely with stakeholders setting the direction of the work streams.

7. Simulation, Immersive & Human Factors Steering Group (SIHF)

The role of the steering group is to support the HEE NENC Faculty of Patient Safety in delivering the Patient Safety agenda via simulation, immersive technologies, and human factors training, to contribute towards the delivery of high-quality compassionate patient care within the region.

8. Local maternity and neonatal system (LMNS)

The LMNSs and other local support networks play a crucial role in supporting improvement and facilitating review of patient safety incident responses. ICBs should ensure that provider organisations demonstrate their commitment to engaging with LMNSs and other local support networks as key stakeholders within their patient safety incident response plan. In addition, providers 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 incidents are reviewed. Learning should be shared via the Maternity Patient Safety Learning Network and clinical expert groups.

Patient Safety Plan
The ICB will work with providers to support the development and oversight of their Patient Safety Plans. Oversight arrangements must be focused on enabling demonstration of improvement, this function will usually be discharged by the ICB Leads attendance at the provider safety/learning panel and provider Quality Review Group.

Consultation
This policy has been formed from a national directive to implement PSIRF. PSIRF has been consulted upon nationally. Locally the ICB has engaged with ICB Quality Leads and staff with an executive responsibility for quality within provision. We intend to continue an open dialogue with stakeholders as we implement PSIRF.

4. Implementation

4.1 This policy will be available to all Staff for use in relation to the specific function of the policy.

4.2 All directors and managers are responsible for ensuring that relevant staff within their own directorates and departments have read and understood this document and are competent to carry out their duties in accordance with the procedures described.

5. Training Implications

The training required to comply with this policy are:

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

Those in system oversight roles must have knowledge of effective oversight and supporting processes, including effective use of data for assurance and patient safety incident response system development. Staff in oversight roles must be appropriately trained to support the practical application of PSIRF oversight principles and standards.

	Frequency	All Staff	Board Members	Staff leading learning responses	Those in a PSIRF oversight role
Patient safety syllabus level 1: Essentials for patient safety	**Annual**	**X**	**X**	**X**	**X**

Patient safety syllabus level 1: Essential of patient safety for boards and senior leadership teams	**Annual**		**X**		
Patient safety syllabus level 2: Access to practice	**Annual**			**X**	**X**
Continuing professional development (CPD)	**Annual**			**X**	**X**
Systems approach to learning from patient safety Incidents	**Once**			**X**	**X**
Oversight of learning from patient safety incidents	**Once**				**X**
Involving those affected by patient safety incidents in the learning process	**Once**			**X**	**X**

6. Documentation

6.1 Other related policy documents.

6.2 Legislation and statutory requirements

- https://www.england.nhs.uk/nhs-standard-contract/

6.3 Best practice recommendations

- https://www.england.nhs.uk/patient-safety/the-nhs-patient-safety-strategy/
- https://www.england.nhs.uk/publication/patient-safety-incident-response-framework-and-supporting-guidance/#heading-1
- https://www.england.nhs.uk/wp-content/uploads/2022/08/B1465-2.-Engaging-and-involving...-v1-FINAL.pdf
- https://www.england.nhs.uk/wp-content/uploads/2022/08/B1465-3.-Guide-to-responding-proportionately-to-patient-safety-incidents-v1.1.pdf
- https://www.england.nhs.uk/wp-content/uploads/2022/08/B1465-4.-Oversight-roles-and-responsibilities-specification-v1-FINAL.pdf
- https://www.england.nhs.uk/wp-content/uploads/2022/08/B1465-5.-Patient-Safety-Incident-Response-standards-v1-FINAL.pdf
- https://www.england.nhs.uk/wp-content/uploads/2022/08/B1465-6.-PSIRF-Prep-Guide-v1-FINAL.pdf

7. Monitoring, Review and Archiving

7.1 Monitoring

The ICB Board will agree with the Director of Nursing and Midwifery, North East North Cumbria Integrated Care Board a method for monitoring the dissemination and implementation of this policy. Monitoring information will be recorded in the policy database.

7.2 Review

7.2.1 The ICB Board will ensure that this policy document is reviewed in accordance with the timescale specified at the time of approval. **No policy or procedure will remain operational for a period exceeding three years without a review taking place.**

7.2.2 Staff who become aware of changes in practice, changes to statutory requirements, revised professional or clinical standards and local/national directives that affect, or could potentially affect policy documents, should advise the sponsoring director as soon as possible, via line management

arrangements. The sponsoring director will then consider the need to review the policy or procedure outside of the agreed timescale for revision

7.2.3 For ease of reference for reviewers or approval bodies, changes should be noted in the 'document history' table on the front page of this document.

NB: If the review consists of a change to an appendix or procedure document, approval may be given by the sponsor director and a revised document may be issued. Review to the main body of the policy must always follow the original approval process.

7.3 **Archiving**

The ICB Board will ensure that archived copies of superseded policy documents are retained in accordance with the NHS Records Management Code of Practice.

Schedule of Duties and Responsibilities

Through day to day work, employees are in the best position to recognise any specific fraud risks within their own areas of responsibility. They also have a duty to ensure that those risks, however large or small, are identified and eliminated. Where it is believed fraud, bribery or corruption could occur, or has occurred, this should be reported to the CFS or the chief finance officer immediately.

Council of Members	The council of members has delegated responsibility to the ICB Board (GB) for setting the strategic context in which organisational process documents are developed, and for establishing a scheme of governance for the formal review and approval of such documents.
Accountable Officer	The accountable officer has overall responsibility for the strategic direction and operational management, including ensuring that ICB process documents comply with all legal, statutory, and good practice guidance requirements.
Executive Chief Nurse	The Executive Chief Nurse has overall responsibility for the policy.
Director of Nursing & Midwifery	The Director of Nursing and Midwifery will: Ensure staff, providers of NHS funded activity and stakeholders are aware of this policy and processes to be followed. Ensure there are ICB arrangements in place for collaborating with NHS healthcare providers in the development, maintenance and review of provider patient safety incident response policies and plans.
Commissioning Support Staff.	Whilst working on behalf of the ICB NECS staff will be expected to comply with all policies, procedures and expected standards of behaviour within the ICB, however they will continue to be governed by all policies and procedures of their employing organisation. **(This paragraph to be included in all policies)**

All Staff	All staff, including temporary and agency staff, are responsible for: • Compliance with relevant process documents. Failure to comply may result in disciplinary action being taken. • Co-operating with the development and implementation of policies and procedures and as part of their normal duties and responsibilities. • Identifying the need for a change in policy or procedure as a result of becoming aware of changes in practice, changes to statutory requirements, revised professional or clinical standards and local/national directives, and advising their line manager accordingly. • Identifying training needs in respect of policies and procedures and bringing them to the attention of their line manager. • Attending training / awareness sessions when provided.

Appendix A

Equality Impact Assessment

Initial Screening Assessment (STEP 1)

As a public body organisation we need to ensure that all our current and proposed strategies, policies, services and functions, have given proper consideration to equality, diversity and inclusion, do not aid barriers to access or generate discrimination against any protected groups under the Equality Act 2010 (Age, Disability, Gender Reassignment, Pregnancy and Maternity, Race, Religion/Belief, Sex, Sexual Orientation, Marriage and Civil Partnership).

This screening determines relevance for all new and revised strategies, policies, projects, service reviews and functions.

Completed at the earliest opportunity it will help to determine:

- The relevance of proposals and decisions to equality, diversity, cohesion and integration.
- Whether or not equality and diversity is being/has already been considered for due regard to the Equality Act 2010 and the Public Sector Equality Duty (PSED).
- Whether or not it is necessary to carry out a full Equality Impact Assessment.

Name(s) and role(s) of person completing this assessment:

Name: Jenna Wall
Job Title: Director of Nursing and Midwifery
Organisation: North East and North Cumbria ICB

Title of the service/project or policy: Patient Safety Incident Response Framework Oversight Policy

Is this a;
Strategy / Policy ☒ **Service Review** ☐ **Project** ☐
Other Click here to enter text.

What are the aim(s) and objectives of the service, project or policy:
This policy supports the requirements of the PSIRF and sets out the ICB approach to developing and maintaining effective systems and processes for responding to patient safety incidents and issues for the purpose of learning and improving patient safety.

Who will the project/service /policy / decision impact?
(Consider the actual and potential impact)

- **Staff** ☒
- **Service User / Patients** ☐
- **Other Public Sector Organisations** ☐

- **Voluntary / Community groups / Trade Unions** ☐
- **Others, please specify** Click here to enter text.

Questions	Yes	No
Could there be an existing or potential negative impact on any of the protected characteristic groups?	☐	☒
Has there been or likely to be any staff/patient/public concerns?	☐	☒
Could this piece of work affect how our services, commissioning or procurement activities are organised, provided, located and by whom?	☐	☒
Could this piece of work affect the workforce or employment practices?	☐	☒
Does the piece of work involve or have a negative impact on: • Eliminating unlawful discrimination, victimisation and harassment • Advancing quality of opportunity • Fostering good relations between protected and non-protected groups in either the workforce or community	☐	☒

If you have answered no to the above and conclude that there will not be a detrimental impact on any equality group caused by the proposed policy/project/service change, please state how you have reached that conclusion below:

This is an interna; Standard Operating Procedure (SOP) based on national guidance. It applies equally to all staff. No staff are disadvantaged by this procedure.

If you have answered yes to any of the above, please now complete the 'STEP 2 Equality Impact Assessment' document

Accessible Information Standard	Yes	No
Please acknowledge you have considered the requirements of the Accessible Information Standard when communicating with staff and patients. https://www.england.nhs.uk/wp-content/uploads/2017/10/accessible-info-standard-overview-2017-18.pdf	☒	☐
Please provide the following caveat at the start of any written documentation: **"If you require this document in an alternative format such as easy read, large text, braille or an alternative language please contact necsu.comms@nhs.net**		
If any of the above have not been implemented, please state the reason: N/A		

Governance, ownership and approval

Please state here who has approved the actions and outcomes of the screening		
Name	**Job title**	**Date**
Jenna Wall	Director of Nursing and Midwifery	15/11/2023

Publishing

This screening document will act as evidence that due regard to the Equality Act 2010 and the Public Sector Equality Duty (PSED) has been given.

If you are not completing 'STEP 2 - Equality Impact Assessment' this screening document will need to be approved and published alongside your documentation.

Please send a copy of this screening documentation to: NECSU.Equality@nhs.net for audit purposes.

Appendix B

NENC ICB Patient Safety Response Framework (PSIRF) sign off process for smaller and independent providers.

Relevant to: Independent and smaller providers of NHS funded care and ICB leads.

The NHS Patient Safety Incident Response Framework (PSIRF) was launched in 2022 and is intended for full implementation by Autumn 2023. The 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. PSIRF will replace the Serious Incident Framework 2015 (SIF 2015) and change the way that patient safety incidents are responded and investigated.

PSIRF requires ICB's to work collaboratively with providers to develop a Patient Safety Incident Response Plan (PSIRP) and Patient Safety Incident Response Policy.

Within the PSIRP, each organisation must work with their ICB and other stakeholders to identify how it will respond proportionately to all incidents requiring investigation. This includes, where applicable, priority incidents for Patient Safety Incident Investigation (PSII) and those meeting the national requirements for investigation such as those within the Learning from Deaths Framework and Never Events. Providers are advised to mine the following types of data sources to profile these patient safety incident risks: patient safety incident reports; complaints; whistleblowing incidents; Patient Safety Incident Investigations (PSII); mortality reviews; case note reviews; staff survey results; claims; and risk assessments.

The PSIRP is essentially a strategic plan to address the findings of the above data review and outline how incidents should be responded to within the organisation. It should also identify the appropriate resource to ensure the requirements within each PSIRP can be achieved.

Once the provider and ICB are satisfied with the plan, they can agree transition to the new Framework. When providers transition to PSIRF requirements under the SIF 2015 will cease to apply in relation to incidents reported after the agreed date of transition.

PSIRP changes the way incidents are responded to, for smaller providers, the focus will be ensuring incidents with greater potential for learning receive a response that explores system issues in greater depth (e.g., patient safety incident investigation, with the appropriate thematic analysis, and a plan for how all other incidents with lower potential for learning will be responded to. There will be circumstances where no individual response is required including where there is ongoing improvement work which is being monitored or because the risk(s) represented by the incident is believed to be managed (i.e., it is as low as reasonably practicable). For all providers, there is a broader range of patient safety incident response methods under PSIRF than seen under the SIF 2015 which can include:

- incident timelines

- Structured judgement review/case note review/clinical review.
- After-action review
- Patient Safety Incident Investigation (PSII)

Traditional Root Cause Analysis is not recommended under PSIRF in favour of safety investigations and alternative system-based methods. It is important to note that patient safety investigations are conducted for systems learning and improvement rather than for (or in relation to) individual patients, families, or staff. Other investigation types are designed with differing remits to meet any other types of investigation-related requirements e.g.

- HR investigations (for concerns about individual competency/ performance)
- legal investigations (for concerns surrounding liability, avoidability, etc).
- Coroner's investigations (to determine cause of death)

As part of PSIRF transition, all providers will need to review training requirements for safety investigation.

For smaller independent providers, ICB's will need to ensure as part of the sign-off process that each provider can demonstrate that full organisational data has been reviewed to determine a workable incident response plan which prioritises significant risks for more robust and detailed systems-based responses (e.g. PSII). Additionally, there must be a rationale for determining which incident types will be responded to using alternative methods, and how decision will be made for an unexpected incident which is not represented by the plan but offers significant opportunities for learning and system improvement.

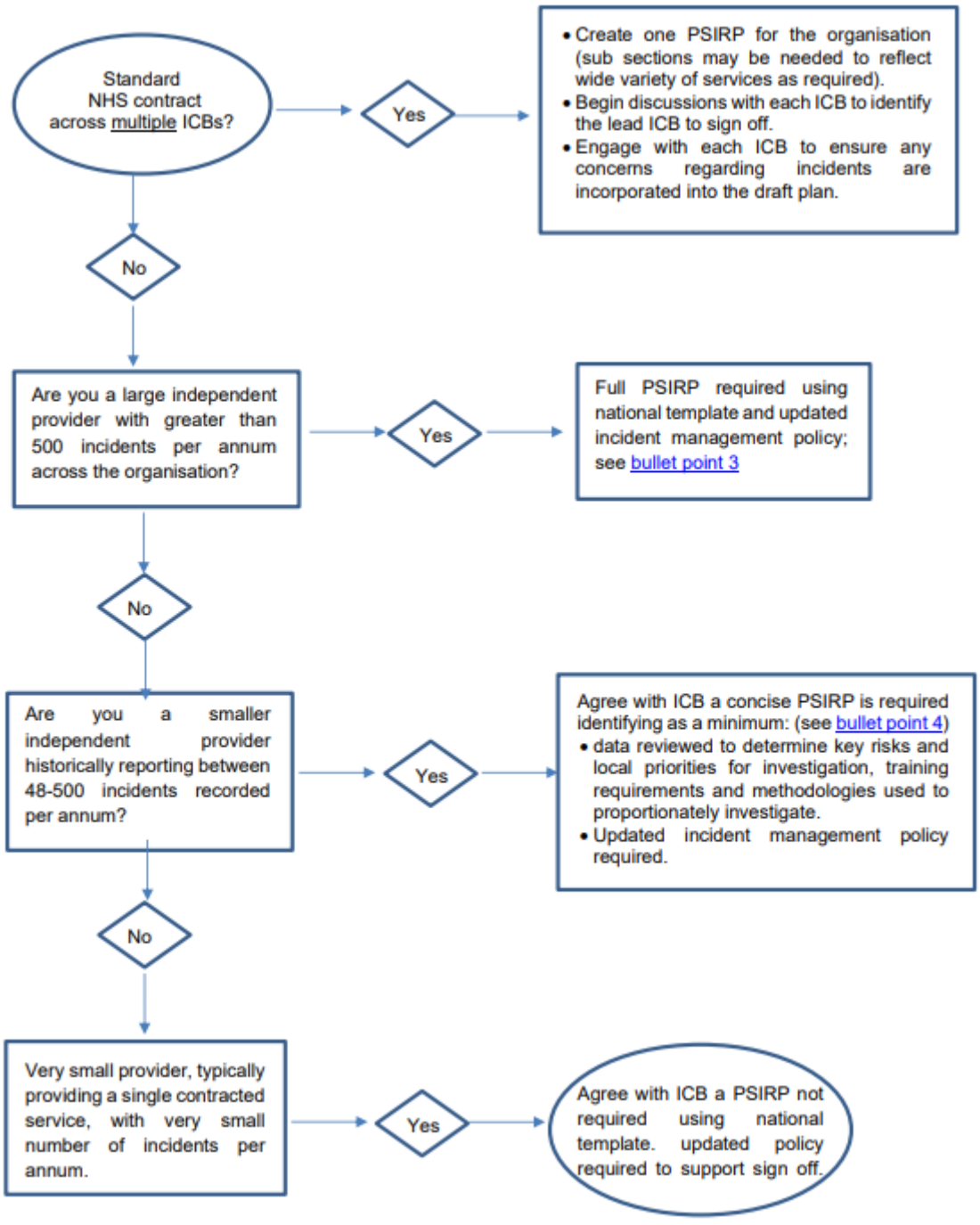
Independent and smaller providers of NHS funded care.

For some smaller providers, who typically report a very small number of incidents annually, a patient safety incident response plan may not be required (see below). Where a full PSIRP is not intended to be completed this must be agreed with the ICB as soon as possible during PSIRF preparation. However, where provider and ICB agree a full PSIRP is not required, that organisation should update their incident management policy to incorporate PSIRF and the incident response process. This should be in place by Autumn 2023 to evidence preparedness for transition to PSIRF.

For larger independent providers, who may also have standard contracts with multiple ICBs, one PSIRP may be appropriate for the entire organisation. Providers will need to co-ordinate with ICBs to determine which ICB is best placed to collaborate in the development of and to sign off the plan to enable transition to PSIRF. The provider should inform each ICB of how they intend to produce their plan for the whole organisation.

NENC ICB proposes each small provider considers the following process map in order to fulfil requirements for PSIRF.

PSIRF process map



NENC ICB propose the following sign off process for independent smaller providers across the North East and North Cumbria. This process is not intended to apply to larger providers of acute services such as NHS Trusts.

1.ICB will work collaboratively with its smaller providers during 2023 to support PSIRF transition. Network meetings will be scheduled to allow for support and troubleshooting during the implementation phase of PSIRF, including development of patient safety incident response plan.

2.Any associated PSIRF implementation papers taken to the organisations public boards should be shared with the ICB. Each organisation may wish to invite the ICB to attend any governance discussions or internal meeting where the PSIRP is presented for internal sign off. This will help evidence PSIRF preparedness.

3.**Where a full PSIRP is required using the national template**:
The agreed lead ICB will be an important collaborator during the development of the patient safety incident response plan. The draft should be shared with all ICBs (including the lead ICB) prior to submission at the organisations board for internal sign off. The lead ICB, in collaboration with other ICBs, will comment on the draft prior to sign off by the organisation internal board and help ensure it is robust. A meeting between the provider and ICB(s) may be required to discuss the plan in detail to support the completion of an effective response plan. Following this meeting further revisions of the PSIRP may be required. Where a meeting takes place and it is deemed the PSIRP requires revision, the updated version should be re circulated to the lead ICB for further comment prior to submission to the organisations board for final approval. Collaboration during the development of the plan may reduce the need for further meetings. Following this the plan should then be submitted to the organisations Board for review and agreement. The draft PSIRP should only be submitted to the provider board for final approval when the lead ICB is has agreed the draft PSIRP is proportionate and supports a robust level of patient safety incident response. After Board review and agreement, the plan will be reviewed at the contract meeting and ratified, a copy should be sent to the ICB Lead Director for Nursing and Midwifery who will share the PSIRP with the ICB PSIRF Oversight Group for information.

A formal sign off letter will be issued determining a mutually agreed ‘go live’ date for PSIRF implementation. The ICB cannot sign off any PSIRP without assurance this has first been reviewed and agreed by the provider board. An updated organisational policy should also be completed to support PSIRF sign off.

The PSIRP should then be published on the providers website.

4. **Where a concise PSIRP is required using the national template as a guide**
A draft plan, using the national template as a guide, should be discussed, and agreed at the contract meeting. It will need to contain evidence that the appropriate organisational data has been reviewed for significant risks, resources have been reviewed to ensure compliance against the plan and any priorities for safety investigation have been identified and the types of incidents which will be investigated utilising the most proportionate level of patient safety incident response. An updated organisational policy should also be completed to support

PSIRF sign off. The PSIRF Oversight Group should be informed once this has occurred. The final documentation should be published on the providers website.

Appendix C

NENC ICB Patient Safety Response Framework (PSIRF) ready to implement process for all providers.

Relevant to: All providers under Standard NHS Contract.

The NHS Patient Safety Incident Response Framework (PSIRF) was launched in 2022 and is intended for full implementation by Autumn 2023. The 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. PSIRF will replace the Serious Incident Framework 2015 (SIF 2015) and change the way that patient safety incidents are responded and investigated.

PSIRF requires ICB's to work collaboratively with providers to develop a Patient Safety Incident Response Plan (PSIRP) and Patient Safety Incident Response Policy. For smaller and independent providers, the **'NENC ICB Patient Safety Response Framework (PSIRF) sign off process for smaller and independent providers'** SOP should be followed.

- The NHS Trust providers PSIRP and policy should be signed off via the Quality Review Group.
- Independent sector provider PSIRP and policies should be signed off at the contract meetings.

The following process should then be followed to mutually agree the 'ready to implement' status.

Provider Quality Lead and ICB Patient Safety Specialist will mutually agree the 'ready to implement' status by reviewing the criteria and evidence against the implementation checklist. The ICB Patient Safety Specialist will present the 'ready to implement' case to the ICB PSIRF Oversight group and, once supported, the 'go live' date communicated to the Quality Team. For the independent and smaller providers this should be discussed at contract meetings and then the same 'ready to implement' checklist followed.

Implementation Checklist

- Is there a clear plan for engaging and involving those affected by patient safety incidents?

- Is there a PSIRF policy in place? Does the PSIRF policy articulate how PSIRF is embedded into the organisations governance arrangements? Will the Policy be published on the providers website?

- Is a Patient Safety Plan in place? Does the plan demonstrate a thorough analysis of relevant organisational data? Is there a clear rationale for each response to each patient safety incident type? Has the plan been agreed at executive level?

- Is there a plan for the management and closure of legacy Serious Incidents? What is the plan for operating a dual system?

- Is there a planned arrangement to enable the ICB to discharge their responsibility regarding 'ongoing' oversight and collaboration?

- Are there dedicated learning response leads?

- Is there a dedicated staff resource to support engagement and involvement of those affected?

- Is there a training needs analysis and training plan?

- Is there a plan for enabling proportionate responses to be met?

- Is there a plan to implement LFPSE?

Where a full PSIRP is required using the national template
A formal sign off letter will be issued determining a mutually agreed ‘go live’ date for PSIRF implementation. Inform Quality Team of 'go live' date.

Where a concise PSIRP is required using the national template as a guide
The mutually agreed 'go live' date for PSIRF implementation should be recorded in the minutes of the Contract meeting. The PSIRF Oversight Group should be informed once this has occurred. Inform Quality Team of the 'go live' date.

Where a PSIRP is not required
Updated policy should be ratified at contract meeting, this should be included in the minutes and communicated to the PSIRF Oversight Group.

Management and closure of legacy/historic Serious Incidents post implementation of PSIRF

The ICB Quality Leads will continue to attend the SI panels to review incidents registered as an SI on StEIS prior to an organisations transition to PSIRF. The panels will continue to convene to review open SI reports and outstanding actions until such a time as the historic cases have been closed. PSII are not managed through this process.

Oversight of PSII post implementation of PSIRF

Providers are asked to use StEIS to record incidents that are subject to Patient Safety Incident Investigation (PSII). A new incident type has been added to StEIS that allows organisations to record incidents which are responded to using PSII.

Although recorded on StEIS PSII do not need to be managed through an SI panel process and there is no requirement for 72 hour reports or oversight through the SI panel mechanism.

All incidents reported as PSII post PSIRF implementation will be reviewed internally by the organisation at safety/learning panels with ICB Quality/PSS representation.

The provider should communicate when the PSII can be closed on StEIS, there is no requirement for ICB sign off or assurance documents.