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**Patient Safety Incident Response Framework (PSIRF) Policy**

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| **Version:** | V1.1 Final |
| **Approved By:** | Executive Team (v1.0) |
| **Date of Approval:** | 06 October 2023 |
| **Date of Review:** | October 2025 |
| **Link to Strategic Objective(s):** | Priority 1: Increase healthy life expectancy and reduce inequality.  Priority 2: Give every child the best start in life.  Priority 3: Improve access to health and care services.  Priority 4: Increase the numbers of citizens taking steps to improve their wellbeing.  Priority 5: Achieve a balanced financial position annually. |

**Change and Approval History:**

|  |  |  |  |
| --- | --- | --- | --- |
| **Version** | **Revision Description** | **Reviewer / Approval Group** | **Date of Review / Approval** |
| 0.1 | Draft – to replace ‘Management of Serious Incidents Policy’. | Quality Committee recommended approval to the Executive Team | 07 September 2023 |
| 0.2 | Final draft shared with Executive Team for comments/approval, amended to include reference to the role of Health and Care Partnerships (HCPs).  Updated HSIB to HSSIB following national legislative change. | Rosie Connolly, Deputy Director Quality Improvement and Patient Safety | 04 October 2023 |
| **1.0** | **Final - Approved** | **Executive Team** | 06 October 2023 |
| 1.1 | Final – general formatting | Governance Manager – Conflicts & Policies | 02 November 2023 |
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**CONTENT**

|  |  |  |
| --- | --- | --- |
| **Section No.** |  | **Page No.** |
| **1.0** | Introduction | **4** |
| **2.0** | Purpose | **4** |
| **3.0** | Scope | **5** |
| **4.0** | Roles and Responsibilities | **7** |
| **5.0** | Addressing Health Inequalities | **11** |
| **6.0** | Engaging and Involving patients, families and staff following a patient safety incident | **11** |
| **7.0** | Provider patient safety incident response policies and plans | **12** |
| **8.0** | Approval of provider patient safety incident response policies and plans | **13** |
| **9.0** | Cross System Investigations | **13** |
| **10.0** | Patient Safety Training | **14** |
| **11.0** | Complaints and appeals | **15** |
| **Appendices** | Appendix 1 Organisational Responsibilities | **17** |
| Appendix 2 PSIRF Competencies | **18** |
| Appendix 3 ICB Provider Sign Off Process | **19** |
| Appendix 4 Equality Impact Assessment | **22** |

1. **Introduction**

This policy describes and defines the responsibility of NHS Hertfordshire and West Essex Integrated Care Board, known thereafter as the ICB, when providing oversight to organisations who have transitioned to the Patient Safety Incident Response Framework (PSIRF). Additionally, the policy outlines how the ICB will support cross-system learning responses.

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.

All organisations with an NHS standard contract are expected to adopt PSIRF in 2023/24 as part of the NHS standard contract. This includes Independent Providers of NHS funded care. Primary care services will be implementing PSIRF during the next 12 to 18 months, and will continue to work to the Serious Incident Framework (2015) in the meantime.

This policy document will be reviewed when further national PSIRF guidance is published and thereafter bi-annually.

1. **Purpose**

The leadership and management functions of the Patient Safety Incident Response Framework (PSIRF) are multifaceted. The (PSIRF) advocates oversight that enables organisations to demonstrate improvement rather than compliance with prescriptive, centrally mandated measures. To achieve this, oversight of patient safety incident response under PSIRF must focus on engagement and empowerment rather than more traditional command and control.

This policy supports the requirements of the NHS England Patient Safety Incident Response Framework (PSIRF) and sets out the ICB’s approach to fulfilling the roles and responsibilities for ICBs. This includes how the ICB will work with local Health and Care Partnerships (HCPs) to support learning and improvement.

This policy supports development and maintenance of an effective patient safety incident response system that integrates the four key aims of the PSIRF and which we can also align to our existing principles:

* **Integration of health, care, and wellbeing services**
* **Priority towards prevention and early intervention**
* **Targeted work to reduce health inequalities.**
* **Involving our residents and our workforce**

The following principles underpin the oversight of patient safety incident response:

1. Improvement is the focus.
2. Blame restricts insight.
3. Learning from patient safety incidents is a proactive step towards improvement.
4. Collaboration is key.
5. Psychological safety allows learning to occur.
6. Curiosity is powerful.
7. **Scope**

This policy is specific to roles and responsibilities in relation to patient safety incident responses conducted solely for the purpose of learning and improvement across Hertfordshire and West Essex.

Patient safety incidents 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 incidents for learning and improvement. PSIRF is not an investigation framework to determine the cause of death or to hold any individual or organisation to account. PSIRF advocates a co-ordinated and data-driven approach to patient safety incident response that prioritises compassionate engagement with those affected by patient safety incidents. PSIRF embeds patient safety incident response within a wider system of improvement and prompts a significant cultural shift towards systematic patient safety management.

**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.**

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

* claims handling,
* human resources investigations into employment concerns,
* professional standards investigations,
* information governance concerns
* estates and facilities concern
* financial investigations and audits
* safeguarding concerns
* coronial inquests and criminal investigations
* complaints (except where a significant patient safety concern is highlighted)

For clarity, the ICB considers these processes as separate from any patient safety investigation. 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.

During the transition from the Serious Incident Framework (2015) to PSIRF providers will have some open investigations under the Serious Incident Framework (2015). These should be concluded under the Serious Incident Framework (2015), with all new incidents being managed under the PSIRF from the date of implementation agreed between the provider and the ICB.

**4.0 Roles and Responsibilities**

**4.1 NHS England National Team**

NHS England (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 effectiveness of PSIRF.

**4.2 NHS England 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

**4.3 Integrated Care Board**

* Assess effectiveness of systems and processes to respond to patient safety incidents in NHS funded provider services as demonstrated by the behaviours of openness and transparency; the existence of a just culture; evidence of continuous learning and improvement.
* Collaborate with providers in the development, maintenance and review of provider patient safety incident response policies and plans
* Agree provider patient safety incident response policy and plans including regular review of updated plans and progress against improvement plans (see sections 7 and 8 for further details)
* Oversee and support effectiveness of systems to achieve improvement following patient safety incidents
* Work with local Health and Care Partnerships (HCPs) to identify and share system and local themes and learning to drive improvement.
* Support co-ordination of cross-system learning responses where activity cannot be managed at the provider level because the incident is unusually complex, difficult or costly to manage due to multiple providers and or services being involved across a care pathway.
* Provide improvement advice where weaknesses are identified in a provider’s systems and processes for responding to patient safety incidents.
* Share insights and information across organisations/services to improve safety including examples where providers have demonstrably improved care or reduced risk
* Work with providers to identify high profile incidents or issues that are likely to attract media attention and support coordinated communication across relevant stakeholders. This includes communication teams at organisational, system and regional level as well as external stakeholders such as safeguarding leads or police.

**4.4 ICB Patient Safety Specialist**

The ICB Patient Safety Specialist (PSS), with support from the wider Nursing and Quality Team, will work collaboratively with the provider services across the system to develop, maintain and review each provider’s patient safety incident response policy and plan.

The ICB PSS lead 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 at provider, HCP and ICB level.
* establish mechanisms for escalation of incidents and risks that may require support or action at system or regional level.

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

* understand the patient safety improvement profile of provider organisations.
* support the selection of appropriate response methods for anticipated patient safety incidents based on an understanding of potential for new learning and ongoing safety improvement work.
* support provider organisations to work in collaboration.

**4.5 ICB Patient Safety Partners**

Patient Safety Partners (PSP) are a key element of the National Patient Safety Strategy relating to the involvement of patients, carers, families and lay people as partners in improving the quality and safety of NHS care.

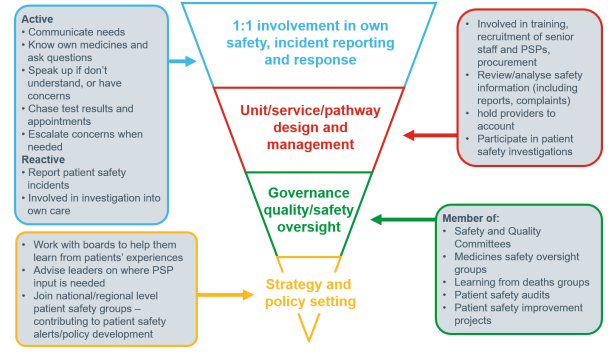
PSPs have an important role with the PSIRF, bringing the patient perspective to patient safety investigation and learning alongside the role of those directly involved in incidents.

The ICB PSPs will support the PSIRF process through active involvement in PSIRF system learning forums, and where appropriate working with provider PSPs to support learning and improvement. All ICB PSPs supporting PSIRF work will have undertaken the specific PSIRF training alongside relevant staff.

The ICB PSPs will also work with the ICB, in line with the national guidance, in wider areas linked to patient safety improvement. These include;

* **Service and pathway design**. Patients should be involved in service and pathway design, in some cases this may be a PSP or a wider patient representative.
* **Safety governance**. PSPs can contribute and add value to safety governance by, for example, sitting on relevant committees to support compliance monitoring, responding to safety issues, reviewing data and reports, and providing appropriate challenge to ensure learning and change. The ICB PSPs are members of both the ICB Quality Committee and the ICS System Quality Group.
* **Strategy and policy**. PSPs can ensure patients’ perspectives are considered and provide valuable insights on the risks to patients; for example, where transitions in care and integration of care pathways are being considered.

The potential roles of PSPs within organisations, as outlined in the National Patient Safety Strategy, has been described below;



**4.6 Providers of NHS funded care**

Providers who have transitioned to PSIRF must ensure organisations meet national patient safety incident response standards with PSIRF central to governance arrangements, while receiving assurance of learning response outputs. Providers must ensure that standards for the legal duty of candour are adhered to for patient safety incident investigations and reviews.

**4.7 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.

**4.8 Care Quality Commission (CQC)**

The CQC’s assessment of a provider’s leadership and safety considers an organisation’s ability to respond effectively to patient safety incidents, including consideration of whether change and improvement follow its response to patient safety incidents. 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 incidents.

**4.9 Health Services Safety Investigations Body (HSSIB)**

HSSIB investigations identify the contributory factors that have led to harm or have the potential to cause harm to patients. HSSIB recommendations aim to improve healthcare systems and processes to reduce risk and improve safety.

**5.0 Addressing health inequalities**

The ICB recognises that there is a no one-size-fits-all-approach to support patients, families including unpaid carers and staff in response to a patient safety incident.

The ICB is committed to providing equality of opportunity for all individuals involved in an incident and recognise effective engagement and involvement, taking into account different needs of individuals, will enable opportunities for learning as well as embedding needed quality improvements at both a local and system levels.

Further benefits of the PSIRF include supporting the development of a just culture. This will help to reduce the ethnicity gap in rates of disciplinary action across the NHS workforce in relation to patient safety incidents.

The flexible approach for PSIRF also supports addressing concerns specific to health inequalities. It provides an opportunity to learn from patient safety incidents that do not meet the previous definition of a ‘Serious Incident’, whilst tools made available in the patient safety incident response toolkit also prompt consideration of inequalities in the development and maintenance of patient safety incident response plans.

**6.0 Engaging and Involving Patients, Families and Staff following a Patient Safety Incident**

The ICB will ensure that those affected by patient safety incidents have the opportunity to participate in patient safety investigations to understand what has happened and answer any questions they have in relation to the incident and to be signposted to support as required. The ICB will ensure that PSIRF plans and policies for provider organisations seek to work with those affected by patient safety incidents and to involve them meaningfully in the investigation process.

In addition to involvement and engagement with patients and families, the ICB will look to ensure that providers are fulfilling their regulatory and professional requirements for Duty of Candour.

The ICB promotes and embraces a just culture to ensure that staff are treated fairly and appropriately following patient safety incidents. When providing system oversight for patient safety reviews and investigations the ICB will ensure that engagement from staff has been sought and used to inform each investigation.

When considering organisation’s PSIRF plans the ICB 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 incidents 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 incidents.

**7.0 Provider patient safety incident response policies and plans**

The ICB will work collaboratively with providers to support development and review of their patient safety incident response plan and policy ahead of formal approval by the provider Board and ICB.

Where a provider has multiple commissioners of services, the lead commissioner will lead discussion with the provider and involve associate commissioners and wider stakeholders (eg LMNS) proportionate to their level of interest in the provider.

The ICB when considering PSIRF plans must ensure that it is clearly stated how the organisation intends to deliver an effective response to patient safety incidents. The response methods the organisation intends to use to respond to patient safety incidents for the purpose of learning and improvement must also be detailed as well as how they will engage with, and support, those directly involved in the incident.

The ICB will also seek assurance that there has been engagement with staff and patients in the drafting and reviewing of their plan and policy, including identification of local priorities.

Monitoring and regular review of the PSIRP must form part of the overarching quality governance arrangements and be supported by clear financial planning to ensure that appropriate resources are allocated to review, investigation and improvement activities.

The ICB PSS and quality leads will collaborate with the provider to assess whether the systems and processes put in place to respond to patient safety incidents have achieved demonstrable improvement.

Where a regulator or oversight organisation has concerns regarding the safety of NHS commissioned services, additional information and assurance will be sought from the provider. If this involves the commissioning of an independent investigation or review, this will be additional to those in the provider’s PSIRP.

**8.0 Approval of Provider patient safety incident response policies and plans**

The ICB is required to approve and sign off the incident response policies and plans for provider organisations within the Hertfordshire and West Essex system, or where is has been agreed that the ICB is the lead commissioner. Approval of an organisation’s policy and plan demonstrates the ICB acknowledgement that the documents have been developed according to PSIRF guidance and meet (or demonstrate a plan to meet) PSIRF standards.

The ICB Provider sign off process can be found in Appendix 3.

**9.0 Cross System Investigations**

There is frequently more than 1 organisation involved in the care and service delivery in which a patient safety incident has taken place; all providers and commissioners must have a process in place to recognise incidents that require a cross system learning response.

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.

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 the ICB will support the co-ordination of a cross system PSII; working with local HCPs where appropriate.

The ICB will seek the views of local system partners to ensure that learning responses are co-ordinated at the most appropriate level of the system. Where there is insufficient capacity and or capability, providers should engage early with the ICB who will support the co-ordination of a cross system learning response.

The ICB PSS will liaise with relevant providers (and other ICBs or ICSs if appropriate) to agree how the PSII will be led and managed and how actions will be monitored. Where necessary this will include appropriate record sharing across organisations.

The incident should be reported onto STEIS by the lead organisation until the learn from patient safety events (LFPSE) system is launched nationally. All providers are expected to respond and participate in joint investigations when requested.

The ICB will also ensure that providers have systems in place to support a co-ordinated and measured, systems-based response to high profile or complex incidents such as mental health homicides which includes how to support the needs of those affected during the investigation. The ICB will work with the NHS England Regional Independent Investigations Team where appropriate, including working with providers to ensure referral of relevant cases.

**10.0 Patient Safety Training**

**10.1 Patient Safety Syllabus Training**

The Patient Safety Syllabus, Curriculum Guidance and e-learning has been developed following the publication of the NHS Patient Safety Strategy. The syllabus sets out a new approach to patient safety emphasising a proactive approach to identifying risks to safe care while also including systems thinking and human factors.

**Level 1 and 2**

Level 1 and 2 training has been made mandatory for all ICB staff. Completion of the training will help to ensure health and care services are as safe as possible for patients and service users.

## **Levels 3 and 4**

In addition to the level 1 and 2 training, all Patient Safety Specialists working in NHS organisations and registered with NHS England will be required to undertake level 3 and 4 training via a blended learning approach and will commence in the autumn of 2023.

**10.2 PSIRF Specific Training**

The ICB recognises that those involved in the review of patient safety incidents 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 incidents.

NHS England has developed training for staff in PSIRF specific roles, and a national procurement framework has been developed and training suppliers identified. Training includes two days training for staff involved in reviewing and investigating systems incidents, one day training for those staff that will engage with both staff and patients involved in incidents and one day training for those staff that have organisational wide oversight roles.

The ICB is committed to ensuring that all relevant staff have access to appropriate, high quality patient safety training in line with national requirements.

In addition to the training, clear competencies were also developed for those staff involved in patient safety in either leading learning responses, patient and staff engagement and involvement and oversight. These can be found in Appendix 2.

**11.0 Complaints and Appeals**

The ICB recognises that there will be occasions when patients, service users or carers are dissatisfied with aspects of the care and services provided or commissioned.

It is important to understand that there is a distinction made between complaints and concerns as the use of the word complaint should not automatically mean that someone expressing a concern enters the complaints process.

The ICB is committed to dealing with any complaints that may arise as quickly and as effectively as possible as set out in the Local Authority Social Services and National Health Service Complaints (England) Regulations 2009.

All complaints and concerns received are managed in line with the ICB’s Complaints Concerns and Patient Feedback Policy which can be found at: <https://hertsandwestessex.icb.nhs.uk/downloads/file/146/complaints-concerns-and-patient-feedback-policy>

Complaints can be valuable aids in developing and maintaining standards of care and that lessons learnt from complaints can be used positively to improve services. The ICB Nursing and Quality Directorate will work to ensure learning from complaints, concerns and patient feedback is triangulated with patient safety learning to support system improvement.

**Appendix 1: Overview of organisational responsibilities**

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**Appendix 2: PSIRF Competencies**

**Learning response leads**

Apply human factors and systems thinking principles to gather qualitative and quantitative information from a wide range of sources.

Summarise and present complex information in a clear and logical manner and in report form.

Manage conflicting information from different internal and external sources.

Communicate highly complex matters and in difficult situations.

**Engagement and involvement competencies**

Communicate and engage with patients, families, staff, and external agencies in a positive and compassionate way.

Listen and hear the distress of others in a measured and supportive way.

Maintain clear records of information gathered and contact with those affected.

Identify key risks and issues that may affect the involvement of patients, families, and staff.

Recognise when those affected by patient safety incidents require onward signposting or referral to support services.

**Oversight roles training and competencies**

Be inquisitive with sensitivity (that is, know how and when to ask the right questions to gain insight about patient safety improvement).

Apply human factors and systems thinking principles.

Obtain (e.g. through conversations) and assess both qualitative and quantitative information from a wide range of sources.

Constructively challenge the strength and feasibility of safety actions to improve underlying system issues.

Recognise when safety actions following a patient safety incident response do not take a system-based approach (eg inappropriate focus on revising policies without understanding ‘work as done’ or self-reflection instead of reviewing wider system influences).

Summarise and present complex information in a clear and logical manner and in report form.

**Appendix 3: ICB Provider Sign Off Process**

The ICB process for managing the sign off of provider Patient Safety Incident Response Plan (PSIRP) and Policy should be followed. The review group should assess if the policy and plan meet the required standards. Ultimately the **policy** should describe the provider’s approach to responding to patient safety incidents for the purpose of learning and improvements. The **plan** should set out the organisations patient safety profile and detail the methods it will use to respond in a way to maximise learning and improvement. The “criteria” below are intended to guide thinking and form an understanding if the requirements have been met.

Once the policy and plan are supported, they can be submitted to the ICB for approval. The below checklist will be used to review and approve the plan and policy.

A transition plan will be agreed between the ICB and the provider relating to switch over from the Serious Incident Framework (2015) to PSIRF, as well as agreeing the management of active/current Serious Incidents. The transition plan must address:

* a cut-off date for accepting incidents for investigation under the Serious Incident Framework (2015)
* a date for completing investigations under the Serious Incident Framework (2015) or agreement on an overlap phase
* ensuring that all relevant staff know the transition date/phase and what they are required to do/how this affects them (e.g., changing how to report on StEIS

The full SOP for the approval process can be found below;



# **Patient Safety Incident Response Plan**

|  |  |
| --- | --- |
| Criteria | Comments |
| The safety profile is described, providing an accurate reflection of the safety issues within the organisation. There should be a clear description of the data sources used. |  |
| Specific service/department plans or elements should be defined. |  |
| Clear evidence of engagement with a wide range of stakeholders (internal and external) within safety profile. |  |
| The organisation describes its own safety culture and how it reaches this conclusion. There is a plan to improve cultural/behavioural elements of PSIRF. |  |
| Planned and current improvement work in place across the organisation is mapped. |  |
| Planned incident response methods are defined. These reflect the national mandatory responses. The local responses planned are sensible and proportionate. |  |
| PSIRP should include leading learning responses to multi-organisation, or cross-system patient safety incidents. |  |
| PSIRP should include how the organisation plans to support patients/ families and staff |  |
| PSIRP should include learning responses from good or positive care |  |

# **Patient Safety Incident Response Policy**

|  |  |
| --- | --- |
| Criteria | Comments |
| Clear description of the proactive efforts made to promote a positive safety culture, including a reporting culture and a just culture. |  |
| The role of Patient Safety Partners within the patient safety incident response policy and plan is defined. |  |
| Description of how patient safety incident response processes support health equality and reduce inequality. |  |
| Description of how those affected by a patient safety incident will be supported – this includes patients, families and staff. |  |
| Duty of Candour within PSIRF is described. |  |
| Staff capacity and time to respond to Patient Safety Incidents are described. |  |
| Staff training requirements and accessing these are described. |  |
| The process to review the PSIRP is defined to keep it amended and updated. |  |
| Review date for the PSIRP is defined. |  |
| A process for reporting cross-organisational or cross-system issues is defined, and in line with local arrangements with the ICB. |  |
| PSI decision making processes are described – reflecting proactive learning responses and reactive learning responses – these are proportionate. |  |
| Timeframes for learning responses are defined. |  |
| The process of development of safety actions following a learning response is defined. |  |
| The process to develop safety improvement plans is described, including where it is overseen. |  |
| Provider’s internal approach to oversight of Patient Safety should be defined – this should include evidence of collaboration & involvement of ICB |  |
| Patient Safety Incident Response Standards are met. |  |

**Appendix 4**

**Equality Impact Assessment and Health Inequality Impact Assessment**

|  |  |
| --- | --- |
| **Title of policy, service, proposal etc being assessed:**  Patient Safety Incident Reporting Framework (PSIRF) Policy | |
| **What are the intended outcomes of this work?**  The key outcome for this policy is the introduction of the PSIRF framework across the HWE system for all Providers that deliver services under the NHS Standard Contract. It is anticipated that PISRF will be rolled out to primary care over the next 12-18 months.  In addition, the policy outlines the role of the ICB in supporting the system and providing oversight of individual providers’ PSIRF processes and aligning these to the National Patient Safety Strategy. | |
| **How will these outcomes be achieved?**  These outcomes will be achieved by working with and supporting all Providers in developing their PSIRF plans and individual policies and their implementation. Furthermore, it will be about ensuring we have oversight of Patient safety across the HWE system. | |
| **Who will be affected by this work?**  Patients, carers, families and staff. | |
|  | |
| **Evidence** | |
| **Impact Assessment Not Required**  We are fully implementing the new national PSIRF framework and standards in line with the national policy template and national PSIRF standards without local deviation. Therefore, no local impact assessment is required.  The ICB will continue to monitor progress in relation to PISRF to understand any positive or negative impact relating to inequalities; the national framework is expected to support reduction in inequalities for patients and staff. | |
|  |
| **For your records**  **Name of person(s) who carried out these analyses:** Chris Harvey, Assistant Director Nursing and Quality (ICB Deputy Patient Safety Specialist) |
| **Date analyses were completed:** 16/08/2023 |
| **Equality and Diversity Lead Sign off** |
| Confirmation received from Paul Curry that no local impact assessment is required where a national policy is being adopted without local interpretation. 23/08/2023 |