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NHS England

Patient Safety Incident Response Framework supporting guidance

Oversight roles and responsibilities specification

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Contents

Introduction

The leadership and management functions of Patient Safety Incident Response Framework (PSIRF) oversight are wider and more multifaceted compared to previous response approaches.

When working under PSIRF, NHS providers, integrated care boards (ICBs) and regulators should design their systems for oversight “in a way that allows organisations to demonstrate [improvement], rather than compliance with prescriptive, centrally mandated measures”.[1] To achieve this, organisations must look carefully not only at what they need to improve but also what they need to stop doing (eg panels to declare or review Serious Incident investigations).

Oversight of patient safety incident response has traditionally included activity to hold provider organisations to account for the quality of their patient safety incident investigation reports. Oversight under PSIRF focuses on engagement and empowerment rather than the more traditional command and control.

[1] A framework for measuring and monitoring safety - The Health Foundation

Oversight mindset

The following ‘mindset’ principles should underpin the oversight of patient safety incident response:

1. Improvement is the focus

PSIRF oversight should focus on enabling and monitoring improvement in the safety of care, not simply monitoring investigation quality.

2. Blame restricts insight

Oversight should ensure learning focuses on identifying the system factors that contribute to patient safety incidents, not finding individuals to blame.

3. Learning from patient safety incidents is a proactive step towards improvement

Responding to a patient safety incident for learning is an active strategy towards continuous improvement, not a reflection of an organisation having done something wrong.

4. Collaboration is key

A meaningful approach to oversight cannot be developed and maintained by individuals or organisations working in isolation – it must be done collaboratively.

5. Psychological safety allows learning to occur

Oversight requires a climate of openness to encourage consideration of different perspectives, discussion around weaknesses and a willingness to suggest solutions.

6. Curiosity is powerful

Leaders have a unique opportunity to do more than measure and monitor. They can and should use their position of power to influence improvement through curiosity. A valuable characteristic for oversight is asking questions to understand rather than to judge.

Oversight approach

The following principles should be considered when designing and maintaining PSIRF oversight systems and processes, including when designing or using any metrics or questions implemented for patient safety incident response oversight.

1. Use a variety of data

Whether organisations are improving based on learning from patient safety incident response cannot be determined from a single measure. It is important to triangulate a mixture of qualitative and quantitative measures to get a clear understanding of the effectiveness of the patient safety incident response systems and processes in place.

Data can be outcome or process based and it is important to use both.

Outcomes data provides information after something has occurred; for example, a complaint from a bereaved family member, or a repeated patient safety incident (often referred to as ‘lagging’ data).

Process or ‘activity’ data provides information on ongoing work, such as engaging with those affected by patient safety incidents or levels of psychological safety (often referred to as leading data).

2. Reduce the information collection burden

Oversight can often lead to excessively complex or burdensome data collection, form filling and report generation. This is not the intention of incident response oversight. The focus should be on supporting an organisation’s capacity to deliver healthcare safely, rather than on purely administrative activity.

Where possible, those in oversight roles should use meaningful data from existing data streams.

3. Oversight is not ‘one size fits all’

Monitoring must be customised to local settings where appropriate. While some questions may need to be standardised, it should be recognised that a ‘one size fits all’ approach does not exist. This is particularly pertinent when designing oversight

mechanisms across different providers (eg acute and mental health providers), but also within providers (eg oversight of maternity services within acute providers).

Refer to tables 2 and 3 that outline potential oversight questions in more detail.

4. Capture meaningful insight from patients, families, and staff

Patients, families, and staff affected by patient safety incidents can provide some of the best and most pertinent warnings of poorly functioning patient safety incident response systems. Priority should be given to capturing meaningful patient, family and staff-centred metrics for learning and improvement (see also Engaging and involving patients, families and staff following a patient safety incident).

Organisations should ensure that patient safety partners are involved in developing and delivering PSIRF oversight processes, and patient groups such as local Healthwatch and Maternity Voice Partnerships should be involved to provide insight into the strength of patient safety incident response systems.

5. Metrics require clarity and purpose

The purpose of any safety metric collected for patient safety incident response oversight must be clear. All relevant stakeholders should understand what is being measured and how often. It is then easier to understand what the data collected shows, avoiding the potential for misinterpretation.

Consider the following criteria when defining safety measures (taken from A framework for measuring and monitoring safety):

- Who is each safety measure developed for?
- How and in what context will the safety measure be used?
- Is it measuring what it claims to measure?
- Can this metric be used reliably to detect or demonstrate deterioration or improvement?
- What untoward consequences will this metric have?

6. Be aware of perverse incentives

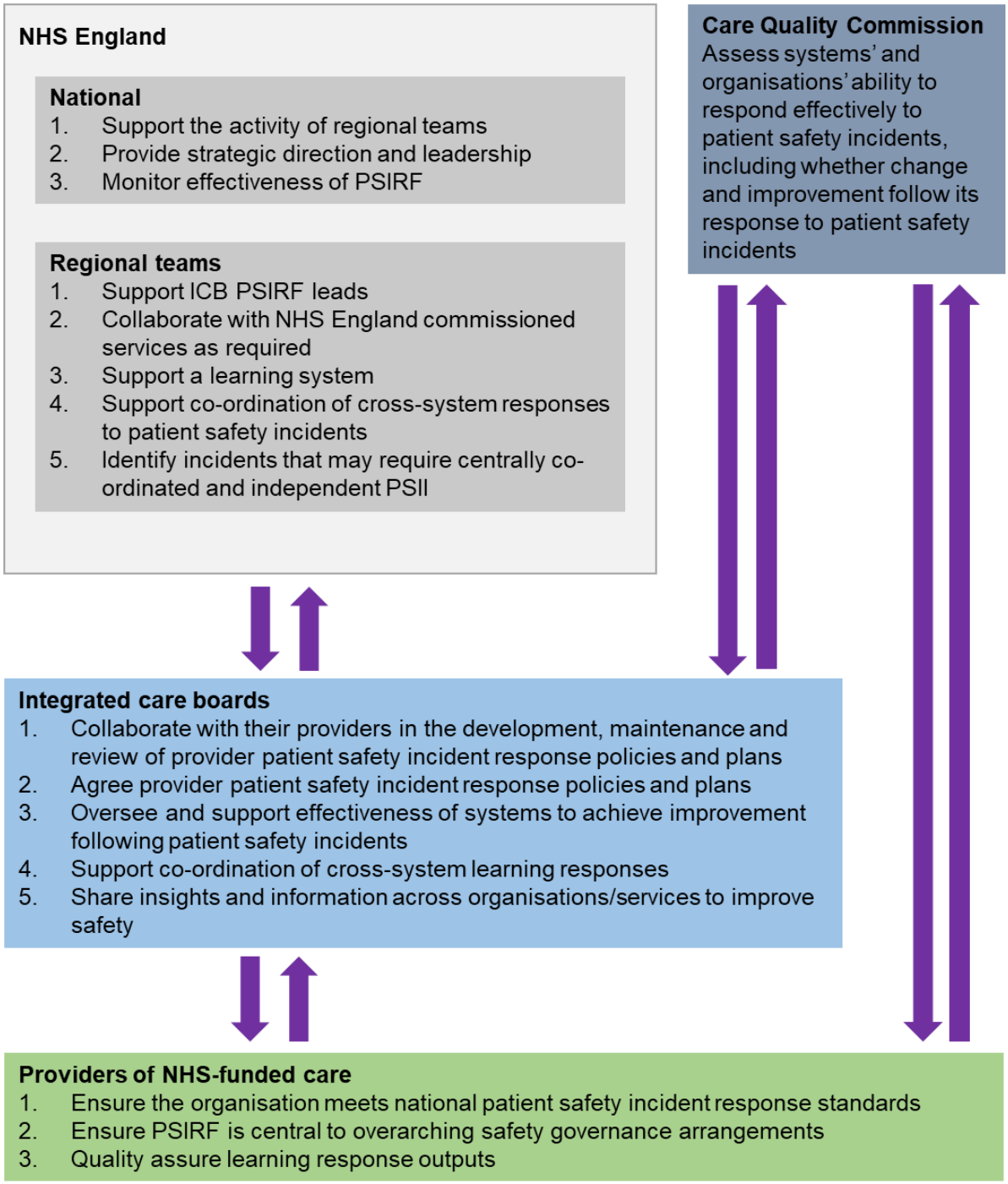
An approach that looks promising may in practice have a variety of unforeseen and unwanted consequences.

Monitoring can lead to gaming and ‘box ticking’ behaviour that misses the important purpose of incident response oversight.

Organisational responsibilities

This section describes the organisational responsibilities in relation to PSIRF oversight, an overview of which is shown in Figure 2. Appendix A gives additional detail for the oversight of maternity patient safety incident response.

Figure 2: Organisational responsibilities for an effective governance structure



Providers of NHS-funded care

The trust board (or those with delegated responsibility, including members of board quality sub-committees), or leadership team in the case of organisations without boards, is responsible and accountable for effective patient safety incident management in their organisation. This includes supporting and participating in cross-system/multi-agency responses and/or independent patient safety incident investigations (PSIIs) where required.

Appointment of a PSIRF executive lead

The trust board should identify a PSIRF executive lead to support the responsibilities outlined below. The lead must also provide direct leadership, advice, and support in complex/high profile cases, and liaise with external bodies as required.

The PSIRF executive lead may be the person with overarching responsibility for quality or, more specifically, patient safety. They must be a member of the board or equivalent leadership team and equipped (through training and professional development) with up-to-date safety skills, knowledge and experience as described in the patient safety incident response standards.

A range of open questions to generate discussion within organisations and help guide oversight by provider boards is given in Table 2 below.

PSIRF executive lead responsibilities

1. Ensure the organisation meets national patient safety incident response standards

The PSIRF executive lead, supported by the rest of the board/leadership team, must oversee the development, review and approval of the organisation's policy and plan for patient safety incident response, ensuring they meet the expectations set out in the patient safety incident response standards where relevant.

2. Ensure PSIRF is central to overarching safety governance arrangements

The board or leadership team must have access to relevant information about their organisation's preparation for and response to patient safety incidents, including the impact of changes following incidents.

It is the PSIRF executive lead's responsibility to ensure:

- patient safety incident reporting and response data, learning response findings, safety actions, safety improvement plans, and progress are discussed at the board or leadership team's relevant sub-committee(s)
- roles, training, processes, accountabilities, and responsibilities of staff are in place to support an effective organisational response to incidents.

Mechanisms for the ongoing monitoring and review of the patient safety incident response plan, delivery of safety actions and improvement must form part of the overarching quality governance arrangements and be supported by clear financial planning to ensure appropriate resources are allocated to PSIRF activities and safety improvement. The board or leadership team should monitor the balance of resources going into patient safety incident response versus improvement. Repeat responses should be avoided when sufficient learning is available to enable the development and implementation of a safety improvement plan.

Updates to the policy and plan should be made as required as part of regular oversight processes. An overall review of the patient safety incident response policy and plan should be undertaken at least every four years alongside a review of all safety actions.

3. Quality assure learning response outputs

A final report should be produced for all individual PSIIs, and this reviewed and signed off as complete. Sign-off of provider-led PSIIs is the responsibility of the board/leadership team of the organisation(s) involved.

The PSIRF executive lead should be responsible for reviewing PSII reports in line with the patient safety incident response standards and signing it off as finalised. They may be supported in this by relevant colleagues as appropriate.

While a full report for submission to the board/leadership team may not be produced for learning response methods other than PSII, PSIRF executive leads should monitor the quality of all response methods. A sampling approach may be best for this.

Organisations must have processes to ensure that all safety actions implemented in response to learning or wider safety improvement plan(s) are monitored, to check they are delivering the required improvement. Progress on individual actions should be reviewed at appropriate intervals using relevant data, and an overall assessment of the delivery of all safety actions at least every four years as part of the requirements to

review patient safety incident response plans (see Guide to responding proportionately to patient safety incidents).

Questions to guide local oversight of patient safety incident response

The questions in Table 2, grouped into subject areas based on the patient safety incident response standards, can be used to guide provider boards/leadership teams in overseeing patient safety incident response. They support a formative (continuous) understanding of organisational safety, which is more meaningful than a summative (final) judgement.

Asking these questions can also be useful in PSIRF preparation and co-design.

In providing these questions our intention is not that organisations review all questions under one topic before moving onto the next one, rather that they work across a range of topics, focusing on those questions within a topic that feel most relevant to local circumstances.

Table 2: Questions to guide provider board oversight of patient safety incident management and improvement

Oversight questions	
Engagement and involvement of those affected by patient safety incidents	• How do we ensure those affected by patient safety incidents are engaged and involved in any learning response? • Does engagement include prompt and effective communication between those affected by a patient safety incident and our organisation? • Does engagement and involvement occur respectfully and according to individual needs? • How do we know how well our processes are working? What are the current barriers? • Are patients or staff with protected characteristics represented more often than others in any of our incidents and responses? What are the organisational or cultural reasons behind this?
Policy, planning and governance	• Does our patient safety incident response plan match the risks that feel tangible to us as an organisation? • Does emerging intelligence match our assumptions about the biggest risks in our plan?

	Oversight questions
	• Can we demonstrate wide collaboration and stakeholder involvement in the development and maintenance of our plan? • Does our plan demonstrate a thorough analysis of data and provide a clear rationale for the selection of patient safety incidents for further learning? • Is our ICB assisting cross-organisation working and information sharing? • How do we choose our response to a patient safety incident? • How do we support those who bring 'bad news' or surprises about organisational safety?
Competence and capacity	• Are we employing and continuously developing expertise in patient safety science for key roles? • Are our learning responses adequately resourced (including funding, time, equipment, and training)? • Are training and competence requirements met for learning response leads? • Do we have the competence within our teams to feel we can confidently have conversations with patients and families about patient safety incidents? • Does our ICB have its own continuous development plans in patient safety science training and competence to enable it to participate effectively? • Are our teams confident in having conversations with patients and families affected by an incident but where an individual learning response will not be completed in response?
Proportionate responses	• How are we triangulating insight from our responses to patient safety incidents? • Are we using recognised system-based methodologies for data collection and analysis? • Is external guidance/information used to inform patient safety responses and findings? • Do we have collaborative arrangements with our ICB to facilitate cross-system learning responses? This includes processes for recognising when support may be required and raising this with ICB colleagues.

	Oversight questions
	• Are learning responses completed in a timely manner in line with expectations of those affected?
Safety actions and improvement	• How easy is it to make an improvement in our organisation? Is time, priority and expertise given to those who need it? • Do we have and use processes to share emergent intelligence and receive support from external partners (eg ICSs, regional and national NHS teams, royal colleges, professional associations, patient groups, charities etc) • How do we assess the sustainability of our safety actions and improvements?

Examples of use

Answers to the questions in Table 2 may be obtained in numerous ways, including through conversations, observations, documentation and data review, and meetings.

The examples below guide their use; they are not an exhaustive list of potential uses.

Document review

Q: Are we employing and continuously developing expertise in patient safety science for key roles?

The board/leadership team may wish to review the job descriptions of key roles with responsibility for patient safety in their organisation. They may want to compare the essential and desirable requirements listed, and check whether these reflect the organisation's aspiration for safety maturity. The organisation may also wish to review the appraisal process for individuals, both those who qualified and those working towards a qualification in safety, to ensure it reflects professional CPD requirements and ambitions.

Informal conversations

Q: Are we employing and continuously developing expertise in patient safety science for key roles?

The organisation may wish to understand how to support individuals who have a wealth of experience but no formal safety qualification. It may explore whether individuals wish to pursue a safety qualification and, if so, what the support needs would be.

Q: How easy is it to make an improvement in our organisation? Is time, priority and expertise given to those who need it?

The board/leadership team may wish to speak to staff who are tasked with leading improvements within the organisation, to understand the current challenges they face. Such conversations need to be psychologically safe if the challenges are to be openly and fully explored. The board/leadership team may examine if the improvement plan is achievable, likely to have the intended impact and aligns with the organisation's aspirations for safety improvement.

Data review

Q: How easy is it to make an improvement in our organisation? Is time, priority and expertise given to those who need it?

In conjunction with key stakeholders (eg patient safety specialists, patient safety partners and, trust leadership), the board/leadership team may wish to regularly review the progress of the planned implementation of improvements. The oversight of these improvements should not cease at sign-off or implementation and will need to consider sustainability of improvements and what this means for other planned changes.

Integrated care boards

ICBs have a responsibility to establish and maintain structures to support a co-ordinated approach to oversight of patient safety incident response in all the services within their system.

Appointment of an ICB lead

ICBs should appoint an appropriate lead(s) to support the responsibilities outlined below. This may be the person with overarching responsibility for quality or, more specifically, patient safety, eg an ICB patient safety specialist (see training requirements specified in Patient safety incident response standards).

Open questions to generate discussion and guide oversight of patient safety incident response by ICBs are listed in Table 3.

Responsibilities of the ICB lead

1. Collaborate with their providers in the development, maintenance and review of provider patient safety incident response policies and plans

A provider's policy should describe how it intends to deliver an effective response to patient safety incidents. The ICB lead must work with each provider in their system to develop and maintain its local patient safety incident response policy and plan, specifically to:

- review application of the national patient safety incident response standards
- establish roles, responsibilities, and processes for oversight within providers and with the ICB
- establish mechanisms for escalation of incidents and risks that may require support or action at ICB level.

A provider's plan should describe the methods it intends to use to respond to patient safety incidents for the purpose of learning and improvement. The ICB lead must work with each provider in their system as it develops its plans, specifically to:

- understand the patient safety incident profile of the provider
- understand the patient safety improvement profile of the provider
- 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.

The ICB lead should be an integral collaborator in regular reviews of provider plans as specified in the Guide to responding proportionately to patient safety incidents.

2. Agree provider patient safety incident response policies and plans

ICBs are required to approve and sign off the incident response policies and plans of the providers in their system. ICB approval acknowledges the documents have been developed according to PSIRF guidance and meet (or demonstrate a plan to meet) the patient safety incident response standards.

3. Oversee and support effectiveness of systems to achieve improvement following patient safety incidents

ICB lead(s) should collaborate with their providers to assess whether the systems and processes put in place to respond to patient safety incidents for the purpose of learning and improvement.

ICBs should support safety improvement where a provider's systems and processes to respond to patient safety incidents are not leading to improvement. This may be through seeking support from colleagues in regional teams or linking with other organisations whose systems and processes are more developed.

4. Support co-ordination of cross-system learning responses

Learning responses should be managed as locally as possible to facilitate the involvement of those affected by and those responsible for delivery of the service in which the incident or issue relates to. However, where a response involving multiple providers and/or services across a care pathway is too complex for a single provider to manage, ICBs should support the co-ordination of cross-system response.

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. Where there is insufficient capacity and/or capability, providers must engage early with their ICB, which can identify the right person to support the co-ordination of a cross-system learning response.

The ICB lead will liaise with relevant providers (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. ICB leads appointed to support cross system learning responses must have the required time and training (as described in the Patient safety incident response standards).

Providers and ICBs are expected to work together to establish and undertake cross-system learning responses, but where issues arise, they will be supported by NHS England regional teams to ensure such responses are delivered as required (see NHS England responsibilities below).

Providers, ICBs and regional teams must recognise and establish the infrastructure to support learning responses to cross-system incidents. This responsibility should be outlined in an organisation's patent safety incident response policy.

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 (ie 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).

We recommend that advice is sought on accessing relevant procurement frameworks from the NHS England 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. This includes all incidents of mental health-related homicide. See Appendix B and the 'Responsibilities of NHS England regional teams' section below for further details.

5. Share insights and information across organisations/services to improve safety

ICBs should seek to identify and share areas of good practice in relation to patient safety incident response.

Questions to guide ICB oversight of provider patient safety incident response

The questions in Table 3, grouped into subject areas based on the patient incident response standards, can be used to guide ICB oversight of provider patient safety incident response. They support a formative (continuous) understanding of organisational safety, which is more meaningful than a summative (final) judgement.

The oversight questions are:

- open – to stimulate discussion, rather than to be used to collect and collate answers for comparison. **It is not appropriate to request a report or set numerical targets against these questions**
- to be used in conjunction with other existing sources (eg the national staff survey)
- to be asked as part of conversations with a wide range of stakeholders.

In providing these questions our intention is not that ICBs review all questions under one topic before moving on to the next one, rather that they work across a range of topics, focusing on those questions within a topic that feel most relevant to local circumstances.

Table 3: Questions to guide ICB understanding the effectiveness of provider learning response systems

	Oversight questions
Engagement and involvement of those affected by patient safety incidents	• What is the provider's understanding of engagement and involvement? • What improvement work is ongoing to facilitate quality engagement and involvement? Is there evidence of continuous work in progress? • Is compassionate engagement equitable for all? • How extensive is the evidence of a just culture (eg does 'blame', or focusing on individual actions or omissions in investigations still occur)? • What do external data sources (eg NHS staff survey, GMC training survey, Health Education England (HEE) reviews) say about staff experience? • Is the organisation aware of its successes and challenges regarding staff support in response to incidents?
Policy, planning and governance	• Is the patient safety incident response plan being updated as required and in accordance with emerging intelligence and improvement efforts? • Does the patient safety incident response plan accurately address the known patient safety-related challenges for this organisation? • Is patient safety and improvement work across the organisation aligned?

	Oversight questions
	• Is work progressing to fulfil any gaps identified in meeting national patient safety incident response standards? • What learning is emerging through collaborative external (peer) review? How is this contributing to improvement? • What is the quality management process for the outputs of patient safety incident response (eg PSII reports)? • Does quality management involve key stakeholders (eg safety experts, patient safety partners, staff representatives)?
Competence and capacity	• Are oversight training and competence requirements met within the ICS? • Can the organisation describe its capacity to effectively deliver its patient safety incident response plan? • Is staff time protected or dedicated full-time roles in place for patient safety incident response? • Do the organisational stakeholders (eg patient safety partners, clinical teams, support staff) have continuous professional development opportunities to enable them to participate effectively? • Can the organisation describe where the capacity is to implement improvement based on patient safety incident response? • Are learning response leads empowered to act independently? • Is access to expertise and support provided?
Proportionate responses	• Is the organisation's leadership clear in communicating to teams that an individual learning response should not be conducted for every incident that results in moderate or more severe harm? And do leaders support teams where this policy is challenged? • Is there evidence that teams are attempting to conduct a learning response to every incident, and therefore resources are spread too thinly? • Are there opportunities for teams to learn from when things do and do not go well? • Is there evidence of filtering or censorship of findings or suggested improvements? • Is learning and improvement work adequately balanced? (ie balance of horizon scanning, thematic work, and individual learning responses)

	Oversight questions
	• Are learning responses completed in a timely manner in line with expectations of those affected?
Safety actions and improvement	• Is learning triangulated across the range of incident response methods used to inform improvement? • Can the organisation describe safety improvement in progress, what they aim to achieve and their interim successes and challenges? • What is the provider board doing to support local teams on challenges in patient safety improvement?

Examples of use

Answers to the questions in Table 3 may be obtained in numerous ways, including through conversations, observations, documentation and data review, and meetings.

The examples below guide their use; they are not an exhaustive list of potential uses.

Review meeting

Q: Is compassionate engagement equitable for those affected?

The ICB lead, with an individual or team from the provider, may wish to walk through how a patient group with a particular protected characteristic would experience engagement following an incident. They may also wish to understand what training the team have had in conducting the variety of engagement options available.

Informal conversations

Q: Is compassionate engagement equitable for those affected?

The ICB lead may wish to speak to patients and families with a particular protected characteristic to understand their experience of engagement following a patient safety incident. They may ask the provider to identify a range of patients and families for the ICB to speak with. Providers may also gather feedback from conversations with patients and families to share with the ICB.

Q: Is the organisation clear in communicating to teams that an individual learning response should not be conducted for every incident that results in moderate or more severe harm?

The ICB lead may wish to understand the pressures teams face to provide a learning response following an incident (eg from within the organisation and from coroners, patients, regulators, and professional bodies). It should help ensure that those in decision-making positions can determine which incidents will and which will not require an individual learning response. The ICB may wish to speak to different department leads and support those divisions that may be under pressure to investigate every incident.

Data review

Q: Is the organisation clear in communicating to teams that an individual learning response should not be conducted for every incident that results in moderate or more severe harm?

ICB may wish to compare the volume of learning responses against the organisation's patient safety incident response plan and determine if and where improvement plans are not being progressed because repeat response remains the focus.

Local support networks including local maternity and neonatal systems

Local support networks including Local maternity and neonatal systems (LMNSs) should play a crucial role in supporting improvement and facilitating review of patient safety incident responses.

Organisations should engage with their local support networks as key stakeholders in the development of their patient safety incident response plan.

Organisations should use their support networks to facilitate review of incident responses between peers, so that they can learn from each other's incident response approaches and reduce the risk of becoming isolated and accepting lower quality incident response standards.

NHS England

NHS England must appoint or assign appropriate leads to support the below responsibilities. A lead may be a person(s) with overarching responsibility for quality or patient safety more specifically. They must be able to connect (either directly or through other colleagues) with relevant governance groups/committees including system quality groups, regional quality groups and (together with the national team) the executive quality group as required.

Responsibilities of NHS England regional teams

1. Support ICB PSIRF leads

The appointed regional lead should support ICBs to establish systems and processes for responding to and overseeing patient safety incidents, including by facilitating patient safety incident response policy and plan development where required.

In most cases this role will focus on supporting collaboration within and between ICBs, other commissioning leads, and/or regional leads (such as Regional Chief Midwives) as required, and advising on the development of relevant skills and capacity to deliver PSIRF (see training requirements in the Patient safety incident response standards).

Where a system, or provider(s) within a system, experience significant challenges in responding to patient safety incidents (eg a breakdown of governance infrastructure across local systems), regional teams will work with relevant teams/individuals to determine how best to address to identified problems.

2. Collaborate with NHS England commissioned services as required

In some cases, particularly where NHS England regional teams maintain their commissioning function of specific services (such as specialised services or Health and Justice), staff may need to be more closely involved in the development, monitoring and improvement of patient safety incident response policies and plans instead of, or together with, ICB leads. Relevant leads within the region and ICB must jointly agree how they will work together to support their respective functions.

3. Support a learning system

Regional leads should collaborate in sharing insights and information between organisations and services to improve patient safety incident response systems and improvement activity.

4. Support co-ordination of cross-system responses to patient safety incidents

Regional leads should work with ICBs to develop the relevant systems to support cross-system learning responses at a local system level. Regional teams will also support co-ordination of system-focused responses to high profile or complex incidents where this activity cannot be managed at a local system level (by the ICB).

5. Identify incidents that may require centrally co-ordinated and independent PSII

Within each NHS England region, Regional Independent Investigation Teams (RIITs) will support 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 investigation. This includes:

- advising ICBs 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 widespread learning and improvement potential across healthcare systems and the need for a regionally-led independent PSII
- escalating systemic or systematic risks across services that require a national response
- advising, guiding, and maintaining the independent PSII supplier framework available to all NHS-commissioned services and ICBs.

NHS-funded care providers and quality and safety leads within ICBs must ensure that NHS England RIITs are involved in commissioning decisions relating to investigation of incidents that:

- require the involvement of and liaison between multiple external agencies (eg the police and/or local authorities) and/or ICBs and NHS England regions but the organisation(s) does not have the capability to manage this (eg mental health related homicides)
- have significant and widespread learning and improvement potential for multiple health systems and for which collaboration across relevant care providers, pathways and/or local health systems needs to be facilitated at a broader level.

The need for an NHS England regionally commissioned independent PSII should be considered at the earliest opportunity so that the process can be initiated as soon as practicable. In some cases, it may be agreed that the investigation can be managed by the provider(s) and/or ICB(s) with advice and direction from the NHS England regional team as required.

Multiple parallel patient safety incident investigations (eg locally led and independently commissioned PSIIs) into the same incident must be avoided: wherever possible one PSII should be undertaken. In circumstances when an internal response has been undertaken before the decision to undertake an independent PSII is made, the NHS England regionally commissioned PSII should use any information and insight gathered through local processes wherever this is available.

The remit of any commissioned independent PSII is the same as any other – to learn and improve – and it must adhere to the patient safety incident response standards. They are not undertaken to make judgement about avoidability, predictability, cause of death or culpability. Investigation reports must be signed off by a formally constituted group.

Appendix B provides further details on the RIIT incident response process.

NHS England National Patient Safety Team

National considerations to support monitoring of **PSIRF effectiveness** include reviewing:

- effectiveness and usability of PSIRF documentation, tools, templates, and guidance
- quality of training offered by suppliers on the NHS training and development framework
- the impact of PSIRF on patient safety incident reporting
- wider evaluation on the long-term outcomes of patient safety incident response systems including:
  - engagement and involvement of those affected
  - quality of system-based learning responses
  - evidence of local system improvement in relation to patient safety incidents

as well as advising on support and interventions to respond to issues relating to the effectiveness of patient safety incident response systems.

Care Quality Commission

The Care Quality Commission's (CQC's) assessment of a provider's leadership and safety considers an organisation's ability to respond effectively to patient safety incidents, including 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 its assessment of the strength of an organisation's systems and processes for preparing for and responding to patient safety incidents.

CQC will expect to be informed (via the regional relationship lead) of high profile and complex incidents as part of the co-ordinated response, as well as being provided with all statutory notifications as required by the Health and Social Care Act (2008) and set out in CQC's guidance on statutory notifications.

CQC will assess how the provider can support the needs of those affected and take meaningful action in response to patient safety incidents. CQC is developing its approach to regulating ICSs and intends to implement this from April 2023.

Where it specifically considers PSIIs, CQC's review will consider how these meet the national patient safety incident response standards. CQC will assess, in partnership with the NHS England PSIRF team, the specific training requirements for those undertaking reviews of PSIIs.

Other types of review and/or investigation

Certain types of incident trigger mandated specific responses. PISRF does not change existing requirements for these.

In some circumstances learning responses under PSIRF will coincide with other responses, and when they, do co-operation and collaboration between partner agencies is essential to minimise duplication, uncertainty and/or confusion relating to the different processes, particularly for those affected.

Ideally, one investigation should be undertaken (by a team comprising representatives of relevant agencies) that meets the needs/requirements of all parties. In practice this can be difficult to achieve because investigations have different aims/purposes, and none must be conflated to accommodate others. Where it is not possible to undertake a single investigation, duplication of effort should still be minimised, particularly with regards to communication with and requests made to those affected. In some circumstances the NHS England RIIT can advise and/or support investigative work where multiple external agencies are involved (see Appendix B).

An organisation's patient safety incident response policy should set out how the interface with the trust-led response to patient safety incidents and other investigations will be managed.

Healthcare Safety Investigation Branch

HSIB investigations do not apportion blame or liability but aim to identify the factors that have led to harm or have the potential to cause harm to patients. Its recommendations aim to improve healthcare systems and processes to reduce risk and improve safety.

HSIB undertakes patient safety investigations through two programmes.

1. **National investigations:** can encompass any patient safety concern that occurred within NHS-funded care in England after 1 April 2017. Incidents for

national investigation are selected based on the scale of risk and harm, the impact on individuals involved and on public confidence in the healthcare system, as well as the potential for learning to prevent future harm.

2. **Maternity investigations:** From 1 April 2018, HSIB became responsible for all patient safety investigations of maternity incidents occurring in the NHS that meet the criteria of the Each Baby Counts programme. The purpose of this programme is rapid learning and improvement in maternity services, and to identify common themes that offer opportunity for system-wide change.

The Health and Care Act established HSIB as the Health Services Safety Investigations Body (HSSIB), a non-departmental public body of the Department of Health and Social Care (DHSC), operating with full independence by spring 2023. HSIB maternity investigations will transfer to a new special health authority, which will be funded for up to five years from April 2023.

Coroners

A coroner investigates unnatural or violent deaths, where the cause of death is unknown, or because the death took place in prison, police custody or another type of state detention, such as a mental health hospital. The investigation may include an inquest hearing. The coroner's role is to find out who died and how, when, and where they died.[2]

Organisations should establish good relationships with their coroner, involve them in patient safety incident response plan development and respond when they ask for information. PSRIF requires all deaths to be investigated **where the death is thought more likely than not to have been due to problems in care**

In their work with coroners, organisations should:

- Ensure they comply with the Notification of Deaths regulations that require registered medical practitioners to notify the senior coroner of a death if one or more of the circumstances set out in the regulations applies, including where they "suspect" that the person's death was due to "undergoing any treatment or procedure of a medical or similar nature".

[2] A Guide to Coroner Services for Bereaved People (publishing.service.gov.uk)

- Ensure they provide coroners with any requested documents, such as PSII reports, learning from other response methods and any other relevant supporting materials. Where the healthcare provider has not generated a specific report, they should still gather information to respond to coroners' questions (this may not require an investigation). If a coroner suggests there may have been patient safety issues, the provider should consider if an investigation or other response method would be appropriate.
- Advise the coroner of any relevant documents they hold, even if these are not specifically requested.
- Advise the coroner that the NHS omits person identifiable information from local patient safety investigation reports to allow for wider sharing without inadvertently impacting on family members and NHS staff, or damaging safety culture with inappropriate blame. Organisations should request that the coroner also has concern for the potential impact of any shared investigative supporting materials entering the public domain.
- Ensure the remit of any learning response method under PSIRF focuses on learning and improvement and not other external requirements such as the coroner's role to make judgements about cause of death.

Medical examiner system

Medical examiners, supported by medical examiner officers, work to:

- listen to the bereaved, increasing transparency and offering them the opportunity to raise concerns about care
- improve the quality and accuracy of the Medical Certificate of Cause of Death
- ensure notification of deaths to the coroner where appropriate.

Medical examiners do not carry out in-depth reviews, but when they identify concerns, they refer them to appropriate governance leads. This may include the trust mortality lead and/or the trust PSIRF lead. These leads will then ensure the death is considered for a response in line with the trust's learning from deaths policy and patient safety incident response plan. Where evidence, however identified, suggests problems in care were more likely than not to have led to the death occurring at the time that it did, a PSII must be undertaken.

Improving incident response through collaborative external review

An essential part of improving how organisations learn from patient safety incidents is external peer review of a sample of learning response reports that have been signed off by an organisation's board/leadership team (or delegated executive lead). Organisations should specify the proportion of responses to be externally reviewed and note in their patient safety incident response policy how this will be facilitated.

Where possible, services with similar characteristics (including the population they serve) should partner with one another to review reports to support collaborative learning.

External review improves quality and reduces siloed approaches to learning that can embed unintentional bias. It can also anticipate future problems by reflecting on systems in place and any risks they carry. For example, from reviewing incident findings, areas for improvement and safety actions developed in other organisations, providers can review their own practice to ascertain if 'this happen here'.

Appendix A: Oversight of maternity patient safety incident response

Developing the approach to accountability, oversight and improvement of maternity patient safety incident response is an essential part of implementing a perinatal quality surveillance and improvement model. As with all aspects of incident response under PSIRF, a provider board/leadership team are accountable for the quality of incident response and most importantly for reducing risk as a result. This is particularly relevant to the organisation's board-level maternity safety champion and the non-executive appointed to work alongside them.

ICBs are responsible for overseeing their providers' systems for responding to incidents and should identify and provide support where improvement is needed. They are responsible for agreeing and signing off an organisations' patient safety incident response plan, including relevant maternity content.

Regional maternity teams should be involved in developing and agreeing organisations' patient safety incident response plan, as should LMNSs. Organisations should also use their LMNSs to facilitate peer review of maternity incident responses, so that organisations can learn from each other's incident response approaches and reduce the risk of isolated organisations accepting lower quality incident response standards. Services with similar characteristics (including the population they serve) should partner with one another to support collaborative learning wherever possible. This may mean linking services across different LMNSs.

Appendix B: RIIT incident response process

Where the Regional Independent Investigation Team (RIIT) agree a PSII should be managed at a regional level, they 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; see below)
  - arrangements for the ongoing monitoring and/or escalation of actions and delivery of improvement
  - dissemination of learning and subsequent improvement efforts.

Publication of sensitive and confidential information in independent patient safety investigation reports

Independent PSII reports must be shared with internal and external stakeholders, including the affected individuals and families, and should be written in a clear and

accessible way as described in the Patient safety incident response standards. Where possible independent PSIIs will be published in full.

The impact of publishing an independent PSII report can have on those affected must be carefully considered, especially when individuals may be identifiable.

Where a patient, the family of a deceased patient or another affected person does not consent to publication, their rights must be balanced against the wider public interest when deciding whether to publish. If publication could prevent a similar patient safety incident, the wider public interest could outweigh the rights of individuals to privacy. However, this right for both individual and family life, provided under Article 8 of the European Convention on Human Rights (ECHR), must be considered.

Where risks to individuals outweigh the wider public interest, other approaches can be considered, such as publishing a summary report of the investigation and/or thematic work, or system improvement plans relating to similar incident types/issues.

A contemporaneous written record of the factors considered in the decision to publish sensitive material or not must be retained.

Responsibility for openness, Duty of Candour and responding to immediate risk

Regardless of whether an independent PSII is required, the organisation identifying the incident is expected to be open with those affected, explaining what has happened, listening to any questions and/or concerns, and explaining what will happen next. Any immediate risks to the patient(s) or others and actions that may be required to mitigate those risk must be considered.

The requirement to comply with Duty of Candour regulations is unchanged: that is, all providers must inform the patient/family/carers of any notifiable patient safety incident and follow all the requirements of the Duty of Candour. In cases of mental health-related homicide, this will be both the patient and their family, and the victim's family. While legal obligations associated with Duty of Candour apply to those in receipt of care, the moral obligation to be open, honest, supportive, and inclusive must be upheld for all affected. Further information is included within Engaging and involving patients, families and staff following a patient safety incident.

Reporting to the National Reporting and Learning System (NRLS) and Strategic Executive Information System (StEIS)

Until NRLS and StEIS are replaced by the Learn From Patient Safety Events service (LFPSE), all patient safety incidents must be reported to NRLS via the trust's local risk management system, and all patient safety incidents for which an independent or provider-led PSII is undertaken must be reported to StEIS.

Once an independent PSII report is finalised and shared with the provider, the provider can complete the uploading of investigation findings to StEIS for sharing and learning purposes, ahead of closure of the incident.

Reporting to the Learn From Patient Safety Events service (LFPSE)

The LFPSE service will replace NRLS and StEIS. Reporting to LFPSE is the equivalent of reporting to NRLS and StEIS but once an organisation starts reporting to LFPSE, it only needs to make one incident report – that is, it no longer needs to report to NRLS or StEIS.

Implications of the Human Rights Act

The Human Rights Act 1998, which gives the European Convention on Human Rights (ECHR) effect in the UK, may impact investigations carried out in relation to patient safety incidents. The relevant Article of the ECHR is Article 2 – right to life.

Article 2 has been interpreted in the case law of UK courts and the European Court of Human Rights as imposing both positive and procedural (investigative) obligations on the State: the state must never arbitrarily take someone's life and must also safeguard the lives of those in its care. In addition, the state must carry out an effective investigation when an individual dies following the state's failure to protect the right to life, or the use of force by government officials.[3]

Not all incidents being investigated under PSIRF will trigger a duty for the investigation to be Article 2 compliant. The duty does not, for example, arise for every death in hospital, but it almost always will where there is an unexpected death in custody

[3] Guide on Article 2 - Right to life (coe.int)

(including those detained under the Mental Health Act (1983)) and where real concerns exist that there were failings in care. It may also arise because of the control of and responsibility assumed for the individual, so Article 2 could apply to the death of an informal psychiatric patient. However, every case will depend on its circumstances and legal advice should be sought.

Any duty to carry out an Article 2 compliant investigation covers the span of investigations following an incident and is not restricted to an investigation under the PSIRF in isolation. Normally, a coroner's inquest will ensure Article 2 compliance either for its own purposes or for an investigation under PSIRF and/or civil or criminal proceedings. An investigation under PSIRF may contribute towards the coroner's inquest as part of the State's overall response to its Article 2 obligations. Again, legal advice may be needed to determine the scope of and proper procedures for any investigation under PSIRF that involves significant Article 2 issues.

Contact us:
patientsafety.enquiries@nhs.net

NHS England
Wellington House
133-155 Waterloo Road
London
SE1 8UG

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