NHS England

Patient Safety Incident Response Framework supporting guidance

Guide to responding proportionately to patient safety incidents

Version 1.1, September 2022

Contents

Purpose

The Patient Safety Incident Response Framework (PSIRF) is not an investigation framework: it does not mandate investigation as the only method for learning from patient safety incidents or prescribe what to investigate.

It is a framework that supports development and maintenance of an effective patient safety incident response system with four key aims:

1. compassionate engagement and involvement of those affected by patient safety incidents
2. **application of a range of system-based approaches to learning from patient safety incidents**
3. **considered and proportionate responses to patient safety incidents**
4. supportive oversight focused on strengthening response system functioning and improvement.

This guidance supports the two interlinked aims highlighted in bold above. It describes what is meant by a system-based approach to learning and taking a proportionate approach in a patient safety incident response, and how to achieve these aims through patient safety incident response planning.

This guidance should be used alongside the national patient safety incident response policy and plan templates.

What is a 'system-based approach' to learning?

The focus of a system-based approach is examining the components of a system (eg person(s), tasks, tools and technology, the environment, the wider organisation) and understanding their interdependencies (ie how they influence each other) and how those interdependencies may contribute to patient safety.

A system-based approach recognises that patient safety is an emergent property of the healthcare system: that is, safety arises from interactions and not from a single component, such as actions of people. A system-based approach therefore recognises that it is insufficient to look only at one component, such as only the people involved.

A system-based approach will identify where changes need to be made and then monitored within the system to improve patient safety.

Is root cause analysis 'system-based'?

The NHS is well versed in root cause analysis (RCA). However, although RCA was designed to be system-based and go beyond the more usual identification of fault and blame (see the London Protocol[1]), this approach to learning from patient safety incidents has been under-realised.

Evidence suggests that, despite best intentions, RCA prompts simple linear cause-and-effect analysis and has consistently failed to deliver benefits of the scale and quality needed[2].

The methods promoted by PSIRF for learning from patient safety incidents differ from RCA in the following core ways:

- They recognise that outcomes in complex systems result from the interaction of multiple factors – learning should not focus on uncovering a (root) cause, but instead should explore multiple contributory factors.

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[1] Systems analysis of clinical incidents: London Protocol
[2] Peerally, M.F., Carr, S., Waring, J. & Dixon-Woods, M. (2016) The problem with root cause analysis, BMJ Quality & Safety, 26 (5)

- They do not distinguish between care and service delivery problems. Instead, they explore contributory factors, including 'individual acts' in the context of the whole system.
- They use tools to explore multiple interacting contributory factors rather than forcing a single analytical pathway.
- A framework based on the well-established SEIPS (Systems Engineering Initiative for Patient Safety3) replaces the contributory factors classification framework. This is made up of six factors or elements that when considered together cover all elements of a 'system'.

What is SEIPS?

SEIPS is the systems-based framework endorsed by PSIRF. It is a framework for understanding outcomes within complex systems which can be applied to support the analysis of incidents and safety issues more broadly. A SEIPS quick reference guide and work system explorer is provided in the patient safety incident response toolkit. All the national PSIRF tools are based on SEIPS.

Other system-based frameworks exist; organisations can use their preferred system-based framework alongside relevant training in how apply their selected framework.

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[3] Holden, R.J., Carayon, P., Gurses, A.P., Hoonakker, P., Hundt, A.S., Ozok, A.A., & Rivera-Rodriguez, A.J. (2013). SEIPS 2.0: A human factors framework for studying and improving the work of healthcare professionals and patients. Ergonomics, 56 (11)

What does 'considered and proportionate response' mean?

PSIRF supports organisations to respond to incidents in a way that maximises learning and improvement rather than basing responses on arbitrary and subjective definitions of harm. Organisations can explore patient safety incidents relevant to their context and the populations they serve rather than exploring only those that meet a certain nationally defined threshold.

Some events in healthcare require a specific type of response as set out in policies or regulations. These responses include mandatory patient safety incident investigation (PSII) in some circumstances or review by, or referral to, another body or team, depending on the nature of the event. Appendix A summarises the guidance on nationally mandated responses to certain categories of event and sets out whether that mandated response needs to be a PSII or some other response type, including referring the event to another organisation to manage.

Incidents meeting the [Never Events criteria (2018)](#) or its replacement, and deaths thought more likely than not to have been due to problems in care (ie incidents meeting the [learning from deaths](#) criteria for PSII) require a locally-led PSII. The resources required to support PSII following such incidents should be predicted based on previous reporting patterns/ incident trends and included within an organisation's patient safety incident response plan.

Appendix B outlines national requirements in relation to maternity patient safety incident response.

The PSIRF sets no further national rules or thresholds to determine what method of response should be used to support learning and improvement. Instead, organisations are now able to **balance effort between learning through responding to incidents or exploring issues and improvement work.**

Responding proportionately to balance learning and improvement efforts requires a thorough understanding of the local patient safety incident profile and ongoing

improvement work. In the next section we describe the PSIRF planning process that enables organisations to proactively allocate patient safety incident response resources through the development of a patient safety incident response plan.
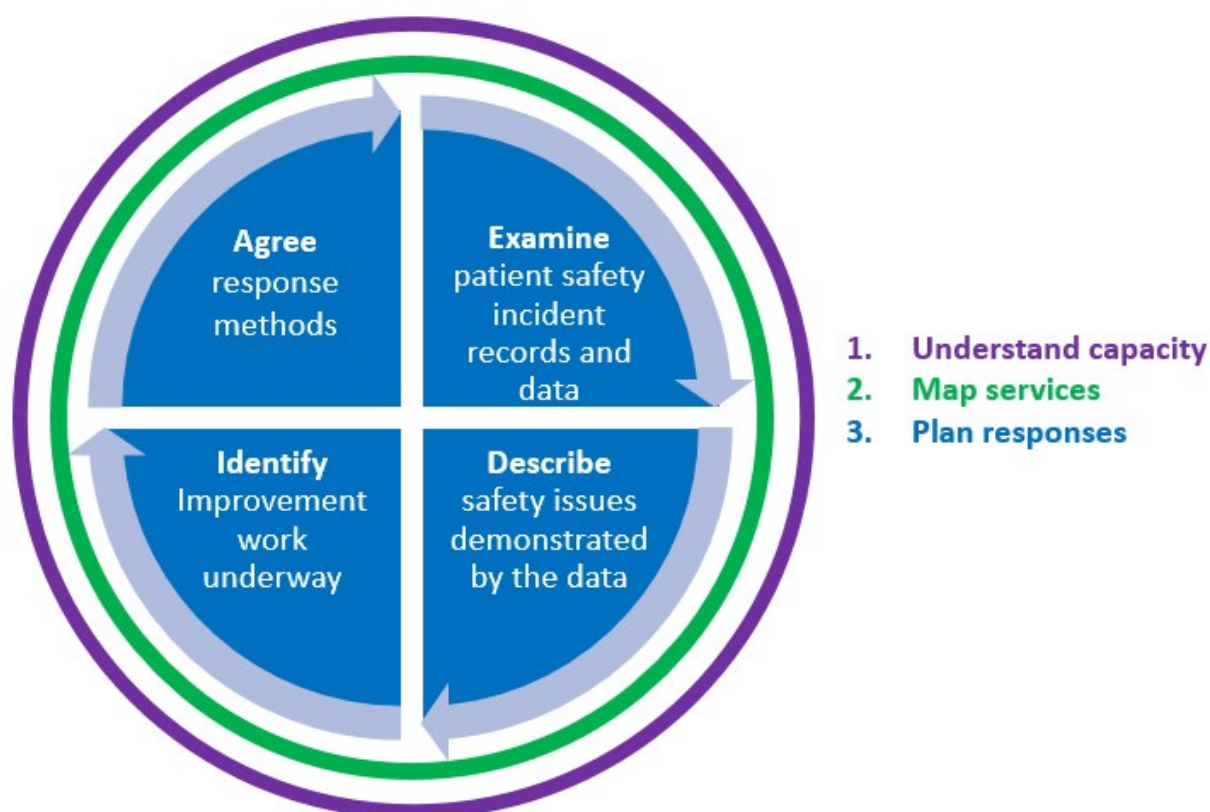
Patient safety incident response planning

Organisations are required to develop a patient safety incident response plan in line with the national template. The plan sits alongside an organisation's patient safety incident response policy to guide responses to patient safety incidents.

An organisation's plan represents a proposal for how the organisation intends to respond to patient safety incidents over a period of 12 to 18 months. **The plan is not a permanent rule** that cannot be changed. Organisations must remain flexible and consider each patient safety incident in light of the specific circumstances in which it occurred and the needs of those affected, as well as the plan.

Figure 1. suggests a process to follow when creating or revising a patient safety incident response plan.

Figure 1. Patient safety incident response planning process

Before planning

Organisations must first:

1. **Understand their capacity for responding to patient safety incidents:** The [patient safety incident response standards](#) describe how patient safety incident responses should be resourced, including the training and competencies those undertaking these responses require. Organisations must be able to describe their capacity to respond to patient safety incidents for learning and improvement, and how they meet the national standards or, if standards are not currently met, their plan for doing so.
2. **Map their services:** Organisations deliver different services and pathways and there are often organisations within organisations. Mapping services will help ensure that the shape and structure of an organisation's plan reflects patient safety concerns for the variety of services offered.

Further information is provided in the patient safety incident response plan and policy templates.

Planning guidance

Planning how to respond to patient safety incidents is a collaborative process. Organisations should work with a range of stakeholders to create a list of patient safety incident types that are jointly identified as areas of interest in terms of risk and potential learning and improvement. Organisations can list as many incident 'types' as deemed appropriate.

The stakeholders that organisations should work with should be diverse and include, but not limited to:

*   patient safety partners and/or patient and public representative groups such as local Healthwatch and Maternity Voice Partnerships.
*   ICB patient safety specialists
*   CQC and other professional regulators
*   specific and distinct clinical governance teams, clinicians, and safety champions wherever they exist, including maternity

Table 1. describes each stage of the process shown in Figure 1 to inform response planning; further detail is provided in the national plan template.

Table 1: Four steps to planning response methods

Planning stage	Description
1. Examine patient safety incident records and safety data	Organisations should review a variety of their data (including investigation reports, complaints, inequalities data) to determine their patient safety incident profile. Conversations and discussions (ie qualitative information) should inform this work alongside the collection of quantitative information. Special consideration should be given to reviewing inequalities data.
2. Describe safety issues demonstrated by the data	Initially there is likely to be a mixture of issues, such as broad incident types (eg medication incidents) and safety concerns (eg safe discharge) as well as more discrete incident types (eg missed diagnosis of cauda equina). Specific outcomes may also be described. The list may need to be reviewed several times before stakeholders accept it as the agreed 'incident profile'.
3. Identify improvement work underway	Identify national, regional, and locally designed patient safety improvement work that is underway or being developed within your organisation. If improvement work relates to patient safety issues or incidents identified and agreed as part of step 2 above, consider the balance of effort between improvement work and additional learning responses to individual incidents. Wherever possible and appropriate, individual actions in response to recommendations from existing reports and investigations should be consolidated and incorporated as part of organisational improvement plans. Consider producing an overarching organisational safety improvement plan that can be reviewed and developed over time.
4. Agree response methods	Plan how to use incident response resources to respond proportionately to the issues and/or incident types listed in the organisation's patient safety incident profile to maximise learning and improvement (see also Patient safety incident response activity below). **Note:** it may be appropriate to use a combination of methods in response to an issue.

Unplanned responses

While planning supports proactive allocation of patient safety incident response resources, there will always need to be a reactive element in responding to incidents.

A response should always be considered for patient safety incidents that signify an unexpected level of risk and/or potential for learning and improvement but fall outside the issues or specific incidents described in an organisation's plan.

Publishing your plan

An organisation's patient safety incident response plan must be agreed by the integrated care board (ICB), other commissioning leads where required, and the board (or leadership group if they do not have a board) of the organisation for sign-off. Finalised plans must be published on the organisation's external facing website alongside its patient safety incident response policy.

Reviewing your plan

An organisation's plan is a 'living document' that should be appropriately amended and updated as the organisation uses it to respond to patient safety incidents. Organisations are expected to review their plan every 12 to 18 months to ensure their focus remains up to date; with ongoing improvement work their patient safety incident profile is likely to change. This will also provide an opportunity to re-engage with stakeholders to discuss and agree any changes made in the previous 12 to 18 months. Any updates to the plan at this point should be published on the organisation's website replacing any previous versions of the plan.

A rigorous planning exercise that includes a review of data (including PSII reports, improvement plans and reporting data) and wider stakeholder engagement should happen at a minimum every four years and more frequently if appropriate (as agreed with the organisation's integrated care board (ICB)) to ensure efforts continue to be balanced between learning and improvement. Four years is suggested before performing a rigorous planning exercise to allow enough time for safety actions and subsequent improvement to have effect.

When conducting a rigorous planning exercise, organisations should collaboratively assess:

- allocation of resources – were they correctly balanced?
- ongoing improvement efforts – are they achieving the desired impact? Should efforts continue or stop (where they are not delivering any improvement)?

- stakeholder views, including those of patients and the public
- where thematic work may be needed to develop a safety improvement plan.

Plans must be updated in accordance with the above assessment and agreed with the organisation's ICB before being signed-off by the organisation's board.

Organisations may need to review their plans more frequently during the early stages of transition to PSIRF as they adapt to the new approach.

Patient safety incident response activity

Patient safety incident response activity can be divided into three overarching categories depending on the key objective (see Table 2).

Table 2: Application of patient safety incident response activity according to key objectives

	Key objective of patient safety incident response activity		
	Learning to inform improvement	**Improvement based on learning**	**Assessment to determine required response**
Circumstances in which to apply activity type	Where contributory factors are not well understood and local improvement work is minimal, a learning response may be required to fully understand the context and underlying factors that influenced the outcome.	Where a safety issue or incident type is well understood (eg because previous incidents of this type have been thoroughly investigated and national or local improvement plans targeted at contributory factors are being implemented and monitored for effectiveness) resources are better directed at improvement rather than repeat investigation.	For issues or incidents where it is not clear whether a learning response is required

Learning to inform improvement

Several system-based learning response methods are available for organisations to respond to a patient safety incident or cluster of incidents (see Table 3). We recommended that these are applied where contributory factors are not well

understood and local improvement work is minimal – that is, there is the greatest potential for new learning and improvement.

Full method guides are provided in the [patient safety incident response toolkit](#).

Table 3: National learning response methods

Method	Description
Patient safety incident investigation (PSII)	A PSII offers an in-depth review of a single patient safety incident or cluster of incidents to understand what happened and how.
Multidisciplinary team (MDT) review	An MDT review supports health and social care teams to learn from patient safety incidents that occurred in the significant past and/or where it is more difficult to collect staff recollections of events either because of the passage of time or staff availability. The aim is, through open discussion (and other approaches such as observations and walk throughs undertaken in advance of the review meeting(s)), to agree the key contributory factors and system gaps that impact on safe patient care.
Swarm huddle	The swarm huddle is designed to be initiated as soon as possible after an event and involves an MDT discussion. Staff 'swarm' to the site to gather information about what happened and why it happened as quickly as possible and (together with insight gathered from other sources wherever possible) decide what needs to be done to reduce the risk of the same thing happening in future.
After action review (AAR)	AAR is a structured facilitated discussion of an event, the outcome of which gives individuals involved in the event understanding of why the outcome differed from that expected and the learning to assist improvement. AAR generates insight from the various perspectives of the MDT and can be used to discuss both positive outcomes as well as incidents. It is based around four questions: What was the expected outcome/expected to happen? What was the actual outcome/what actually happened? What was the difference between the expected outcome and the event? What is the learning?

It is important to supplement finding out what happened using the methods described in Table 3 with an understanding of 'everyday work'. Everyday work describes the reality of how work is done and how people performing tasks routinely adjust what they do to match the ever-changing conditions and demands of work.

Exploring everyday work shifts the focus from developing quick fixes to understanding wider system influences and is central to any learning response conducted to inform improvement. In this sense learning response methods provide a "window on the system"[4] and an attempt to look to the future by exploring what a patient safety incident reveals about gaps in and inadequacies of the healthcare system in which it occurred.

Table 4 describes national tools we have developed for exploring everyday work. Organisations should use these together with the learning response methods to explore the context in which work is conducted.

Table 4: Tools for capturing everyday work

Tool	Description
Observation guide	Observations help us move closer to an understanding of how work is actually performed, rather than what is documented in training, procedures or equipment operating manuals (work as prescribed), how we imagine work is conducted (work as imagined) or how people tell us work is performed (work as disclosed).
Walkthrough guide	Walkthrough analysis is a structured approach to collecting and analysing information about a task or process or a future development (eg designing a new protocol). The tool is used to help understand how work is performed and aims to close the gap between work as imagined and work as done to better support human performance.
Link analysis guide	Link analysis creates a visualisation of the frequency of interactions observed in a specific location or environment. It can be used to highlight frequently used paths within an environment that are critical for safety. This can inform the design of the environment to locate items or areas based on what tasks are carried out most frequently.

[4] Vincent, C.A. (2004). Analysis of clinical incidents: a window on the system not a search for root causes. BMJ Quality & Safety, 13 (4)

Interview guide	This interview planning guide contains questions that help plan an interview with staff involved in a patient safety incident or with patients, families or carers.

We have developed other national tools to inform information gathering and to support synthesis of information (see Table 5).

Table 5: Tools for mapping and synthesising information gathered

Tool	Description
Timeline mapping	A working document to help create a narrative understanding of a patient safety incident. This can be added to as further information is collected.
	It is useful for understanding any gaps in information and defining early thoughts on lines of enquiry.
Work system scan	A checklist and documentation tool to ensure the full breadth of the work system is considered.
	The tool is used to indicate any aspects of the system design that hinder or support people in the work system to do their job (ie barriers and facilitators).

Improvement based on learning from incident response

Where an incident type is well understood – for example, because previous incidents of this type have been thoroughly investigated and national or local improvement plans targeted at the contributory factors are being implemented and monitored for effectiveness – resources may be better directed at improvement rather than repeat investigation (or other type of learning response).

Risks or broad patient safety issues may also be identified during patient safety incident response planning that could benefit from focused improvement efforts rather than further incident responses.

Organisations may wish to consider conducting a thematic review of past learning responses to inform the development of their safety improvement plan.
Alternatively, a 'horizon scan' may be useful where pathway issues are identified or predicted regardless of whether or not an incident has occurred. Guides to the tools described in Table 6 are provided in the patient safety incident response toolkit.

Table 6: Tools to respond to broad patient safety issues

Tool	Description
Thematic review tips	A thematic review may be useful for understanding common links, themes or issues within a cluster of investigations, incidents or patient safety data. Themed reviews seek to understand key barriers or facilitators to safety. The 'top tips' document provides guidance on how to approach a thematic review.
Horizon scanning	The Horizon Scanning Tool supports health and social care teams to take a forward look at potential or current safety themes and issues. It can be used to proactively identify safety risks.

Organisations may wish to apply methods to support proactive risk assessment or develop specialised reviews to enable systematic data collection to inform wider improvement work. Examples include falls reviews and infection prevention and control reviews.

If an organisation and its ICB are satisfied risks are being appropriately managed and/or improvement work is ongoing to address known contributory factors in relation to an identified patient safety incident type, and efficacy of safety actions is being monitored, it is acceptable **not** to undertake an individual learning response to an incident other than recording that it occurred and ensuring those affected are engaged as outlined in the [Engaging and involving patients, families and staff following a patient safety incident guidance](). A learning response may not be required or may not be the best way to address concerns and questions raised by those affected. If an affected patient, family or staff member requests a learning response, organisations should carefully consider their request.

If such incidents involve moderate or greater harm organisations must fulfil their Duty of Candour obligations.

Assessment to determine if a learning response is required

If an organisation cannot easily identify where an incident fits in relation to their plan (ie whether a learning response is required), it may need to perform an assessment to determine whether there were any problems in care that require further exploration and potentially action.

Assessment methods include structured judgement reviews or similar (eg case record or note reviews) that can determine whether there were any problems in care that require further exploration.

Developing safety actions

Organisations should follow an integrated process for developing, implementing, and monitoring safety actions. Further information is provided in the safety action development guide.

Acting in response to a patient safety incident may take different forms. Sometimes rapid action is needed to respond to imminent risk eg removing broken/faulty equipment. These actions should be completed as soon as practicable and should be captured as part of specific incident response.

Developing safety actions that respond to underlying system issues starts with identifying and understanding aspects of the work system that need to change to reduce risk and potential for harm (ie areas for improvement or system issues). Actions to reduce risk (ie safety actions) are then generated in relation to each defined area for improvement.

The recommended process for developing safety actions is described in the safety action development guide, which emphasises a collaborative approach. A **debrief tool** is provided in the patient safety incident response toolkit that can help with communicating findings and developing safety actions in a collaborative way.

Organisations should seek to reduce duplicative and/or disconnected safety actions, for example, by maintaining a wider safety action log that is referred to when developing safety actions and/or conducting regular reviews of ongoing safety actions as part of patient safety incident response planning.

Safety improvement plans

Safety improvement plans bring together findings from various responses to patient safety incidents and issues. They can take different forms, for example, organisations might consider:

- creating an organisation-wide safety improvement plan summarising improvement work

- creating individual safety improvement plans each focusing on a specific service, pathway, or location
- reviewing output from learning responses undertaken in relation to single incidents collectively, when it is felt that there is sufficient understanding of the underlying, interlinked system issues
- creating a safety improvement plan to tackle broad areas for improvement (ie overarching system issues)

Organisations should consider which approach is best suited to the data they have, and insight gained. The key is to demonstrate why a specific safety improvement plan approach is the right one for the organisation based on available data, stakeholder views, improvement priorities, patient safety incident profile and insight from patient safety incident responses.

There are no thresholds for when a safety improvement plan should be developed; for example, after completing a certain number of learning responses. The decision to do so must be based on knowledge gained through the learning response process and other relevant data.

Timeframes for learning response methods

Timescales must be set where possible for all response methods.

A response must start as soon as possible after an incident is identified, and usually completed within one to three months.

The timeframe for completing a PSII should be agreed with those affected by the incident, as part of setting the terms of reference for the PSII, provided they are willing and able to be involved in that decision. PSIIs (and other local response) should take no longer than six months, but this must not become a new default target. If an organisation's local responses are often taking more than 6 months, or exceeding timeframes set with those affected, then processes should be reviewed to understand how timeliness can be improved.

In exceptional circumstances (eg when a partner organisation requests an investigation is paused), a longer timeframe may be needed to respond to an incident. In this case, any extension to timescales should be agreed with those affected (including the patient, family, carer, and staff).

The time needed to conduct a response must be balanced against the impact of long timescales on those affected by the incident, and the risk that for as long as findings are not described, action may not be taken to improve safety or further checks will be required to ensure the recommended actions remain relevant.

Where external bodies (or those affected by patient safety incidents) cannot provide information, to enable completion within six months or the agreed timeframe, the local response leads should work with all the information they have to complete the response to the best of their ability; it may be revisited later, should new information indicate the need for further investigative activity.

Appendix A: National event response requirements

Table A1: Events requiring a specific type of response as set out in policies or regulations

Event	Action required	Lead body for the response
Deaths thought more likely than not due to problems in care (incidents meeting the learning from deaths criteria for PSII)[5]	Locally-led PSII	The organisation in which the event occurred
Deaths of patients detained under the Mental Health Act (1983) or where the Mental Capacity Act (2005) applies, where there is reason to think that the death may be linked to problems in care (incidents meeting the learning from deaths criteria)	Locally-led PSII	The organisation in which the event occurred
Incidents meeting the Never Events criteria 2018, or its replacement.	Locally-led PSII	The organisation in which the Never Event occurred

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[5] Unless the death falls under another more specific category in Table A1, in which case that response must be followed.

Event	Action required	Lead body for the response
Mental health-related homicides	Referred to the NHS England Regional Independent Investigation Team (RIIT) for consideration for an independent PSII Locally-led PSII may be required	As decided by the RIIT
Maternity and neonatal incidents meeting Healthcare Safety Investigation Branch (HSIB) criteria or Special Healthcare Authority (SpHA) criteria when in place	Refer to HSIB or SpHA for independent PSII See also Appendix B	HSIB (or SpHA)
Child deaths	Refer for Child Death Overview Panel review Locally-led PSII (or other response) may be required alongside the panel review – organisations should liaise with the panel	Child Death Overview Panel
Deaths of persons with learning disabilities	Refer for Learning Disability Mortality Review (LeDeR) Locally-led PSII (or other response) may be required alongside the LeDeR – organisations should liaise with this	LeDeR programme
Safeguarding incidents in which: • babies, children, or young people are on a child protection plan; looked after plan or a victim of wilful neglect or domestic abuse/violence	Refer to local authority safeguarding lead Healthcare organisations must contribute towards domestic independent inquiries, joint targeted area inspections, child safeguarding practice reviews, domestic homicide reviews and any other safeguarding reviews (and inquiries) as required to do so by the local safeguarding partnership (for children) and local safeguarding adults boards	Refer to your local designated professionals for child and adult safeguarding

Event	Action required	Lead body for the response
• adults (over 18 years old) are in receipt of care and support needs from their local authority • the incident relates to FGM, Prevent (radicalisation to terrorism), modern slavery and human trafficking or domestic abuse/violence		
Incidents in NHS screening programmes	Refer to local screening quality assurance service for consideration of locally-led learning response See: Guidance for managing incidents in NHS screening programmes	The organisation in which the event occurred
Deaths in custody (eg police custody, in prison, etc) where health provision is delivered by the NHS	Any death in prison or police custody will be referred (by the relevant organisation) to the Prison and Probation Ombudsman (PPO) or the Independent Office for Police Conduct (IOPC) to carry out the relevant investigations Healthcare organisations must fully support these investigations where required to do so	PPO or IOPC
Domestic homicide	A domestic homicide is identified by the police usually in partnership with the community safety partnership (CSP) with whom the overall responsibility lies for establishing a review of the case	CSP

Event	Action required	Lead body for the response
	Where the CSP considers that the criteria for a domestic homicide review (DHR) are met, it uses local contacts and requests the establishment of a DHR panel The Domestic Violence, Crime and Victims Act 2004 sets out the statutory obligations and requirements of organisations and commissioners of health services in relation to DHRs	

Appendix B: Requirements for maternity services

Once an organisation that provides maternity services begins working under the PSIRF, its maternity services will be subject to the PSIRF in the same way that all other secondary care services in that organisation are. This means that organisations must consider maternity services, maternity safety improvement and how to respond to maternity incidents as part of their PSIRF preparation, planning and implementation. Organisations must use insight and intelligence, including that obtained via the perinatal quality oversight tools and structures, to support the PSIRF planning process.

Organisations should ensure that their collective and collaborative approach to developing their patient safety incident response plan (which may include a specific maternity section) includes input from regional maternity teams, local maternity and neonatal systems (LMNSs) and Maternity Voice Partnerships.

Maternity patient safety incidents requiring referral to HSIB for investigation

Patient safety incidents meeting the 'Each Baby Counts' and maternal deaths criteria listed below are national requirements for PSII. As such they must be referred to the Healthcare Safety Investigation Branch (HSIB) or Special Healthcare Authority when in place, through the web portal provided to all trusts, for an independent PSII, and an organisation's patient safety incident response plan must make clear which maternity incidents will be referred to HSIB.

HSIB investigates the following maternity patient safety incidents:

- Intrapartum stillbirth: the baby was thought to be alive at the start of labour but was born showing no signs of life.
- Early neonatal death: the baby died, from any cause, within the first week of life (0 to 6 days).
- Potentially severe brain injury diagnosed in the first seven days of life and the baby was diagnosed with grade III hypoxic–ischaemic encephalopathy; or was

therapeutically cooled (active cooling only); or – had decreased central tone, was comatose and had seizures of any kind.

- Maternal deaths: death while pregnant or within 42 days of the end of the pregnancy from any cause related to or aggravated by the pregnancy or its management, but not from accidental or incidental causes (excludes suicides).

Where such an investigation is undertaken, a separate local patient safety learning response is not required. However, organisations should complete Duty of Candour requirements (ahead of handover to HSIB for further involvement of patients/families in the investigation) as set out below, and report on the relevant incident reporting system(s) as described below.

Organisations must also take any immediate actions identified as necessary to avoid and/or mitigate further serious and imminent danger to patients, staff and the public.

In relevant cases, the organisation should also use the Perinatal Mortality Review Tool (in parallel with and with the assistance of HSIB as it works through its independent investigation).

Maternity patient safety incidents not referred to HSIB

Besides the incident types referred to HSIB, there will be various other known incident types, areas of risk or safety concerns within maternity services, as well as the potential for new and under-recognised issues to emerge. Organisations with maternity services should include in their patient safety incident response plans how they intend to respond to the different types of non-HSIB referred maternity patient safety incidents and, as with all other services, use the guidance and processes outlined in the PSIRF and its supporting documents to do so. Planning and implementation of PSIRF must involve maternity governance teams, clinicians and maternity safety champions, and engagement with wider supervisory teams and organisations.

Organisations should select an appropriate learning response method for incidents that occur based on their patient safety incident response plan. The response should be conducted in line with relevant standards and guidance.

As with all patient safety incident responses undertaken under the PSIRF, the focus is on examining and understanding how to reduce the risk of future incidents. There is no role for assigning blame, liability, criminality, or judgement of avoidability. A response

under PSIRF does not form part of any HR, fitness to practice, clinical negligence, or other non-PSIRF-related process. Where those wider issues are raised, they must be managed through separate processes.

Reporting maternity patient safety incidents

Please note that a single notification portal is being established to co-ordinate reporting requirements for cases meeting the 'Each Baby Counts' and maternal death criteria and reduce the duplication outlined below.

Reporting to HSIB

- Patient safety incidents that meet the 'Each Baby Counts' and maternal deaths criteria and require referral to HSIB are a 'current national priority requiring referral to others for investigation'. This means they must be reported to HSIB.
- The local patient safety incident response plan should include details on this arrangement.

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 (LFPSE) service:

- All maternity patient safety incidents, including those reported to HSIB, should be reported to NRLS via the trust's local risk management system.
- All patient safety incidents that meet the 'Each Baby Counts' and maternal deaths criteria and require referral to HSIB must also be reported to StEIS.
- Once the HSIB investigation report is finalised and handed back to the organisation, the organisation can complete the uploading of investigation findings to StEIS for sharing and learning purposes, ahead of closure of the incident.
- Any other maternity incidents subject to a PSII but not reported to HSIB should be reported to StEIS.

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.

- All patient safety incidents, regardless of whether they are referred to HSIB or whether they are subject to an investigation, should be reported to LFPSE once available.

- Organisations can record on LFPSE the method they are using to respond to an incident locally or if they are referring the incident to HSIB for investigation.

Reporting to NHS Resolution's Early Notification Scheme

- Organisations should report to NHS Resolution's Early Notification Scheme all term births where the baby is diagnosed with potentially severe brain injury in the first seven days of life that has been accepted by HSIB/Maternity and Newborn Safety Investigations (MNSI) for investigation. NHS Resolution will then review those babies who have an abnormal MRI scan and there is evidence of changes in relation to intrapartum hypoxic ischaemic encephalopathy (HIE).

Reporting to the MBRRACE-UK (Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK) scheme and the Perinatal Mortality Review Tool (PMRT)

- Organisations should report relevant safety events to MBRRACE-UK and the PMRT as set out in their respective reporting requirements.

Responsibility for Duty of Candour for maternity incidents referred to HSIB

The requirements to comply with Duty of Candour regulations remain unchanged for all maternity incidents: that is, all organisations must inform the parents/family/carers of any notifiable patient safety incident and follow all the requirements of the Duty of Candour regardless of who the incident has been reported to or how it is being responded to.

HSIB will provide ongoing communication and involvement of the parents/family/carers in safety investigations, in collaboration with the organisation, and encourage joint discussions at agreed points in the investigation.

Contact us:
patientsafety.enquiries@nhs.net

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

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