

Patient Safety Incident Response Framework 2020

An introductory framework for implementation by
nationally appointed early adopters

March 2020



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Foreword

The NHS has systems to support the reporting of safety incidents and from these reports it learns how to make healthcare safer. However, despite these efforts and the continuing advances in patient care, the inherent risks and complexity of healthcare mean an NHS entirely free of incidents is an unrealistic expectation.

Identifying incidents, recognising the needs of those affected, examining what happened to understand the causes and responding with action to mitigate risks remain essential to improving the safety of healthcare.¹

Creating systems that do this is a complex, challenging and continuous endeavour that requires the right skills, processes and – perhaps most importantly – behaviours.

We know that organisations are struggling to deliver good quality investigations that consistently support the reduction of risk. As a result, opportunities to reduce patient safety incidents can be missed.²

‘Bright spots’³ in the NHS and insight from other industries demonstrate that the challenges are not insurmountable and addressing them results in action that achieves measurable change and improvement; avoids further unintended harm; and maintains patient and public trust and confidence in the NHS.

This introductory Patient Safety Incident Response Framework responds to calls for a new approach to incident management, one which facilitates inquisitive examination of a wider range of patient safety incidents “in the spirit of reflection and learning” rather than as part of a “framework of accountability”.⁴ Informed by feedback and drawing on good practice from healthcare and other sectors, it supports a systematic, compassionate and proficient response to patient safety incidents; anchored in the principles of openness, fair accountability, learning and continuous improvement.

¹ Conway J, Federico F, Stewart K, Campbell MJ (2011) *Respectful management of serious clinical adverse events*, second edition. IHI Innovation Series white paper. Cambridge, MA: Institute for Healthcare Improvement. Available at www.IHI.org.

² See details of our engagement programme, [The future of patient safety investigation](#).

³ Dixon-Woods M, Baker R, Charles K, et al (2014) [Culture and behaviour in the English National Health Service: overview of lessons from a large multimethod study](#). *BMJ Qual Saf* 23: 106–15.

⁴ Vincent C, Amalberti R (2016) *Safer healthcare – strategies for the real world*. Springer.

Its release marks the start of transforming the way the NHS responds to things going wrong. Our approach refocuses systems, processes and behaviours on delivering a sustained reduction in risk, rather than simply applying a reactive, bureaucratic process that too often does not lead to change.

Changing embedded incident management processes will take time, particularly as the NHS is in the midst of intense organisational and system-wide transformation. We are taking a phased approach to implementing the new framework: first supporting several 'early adopter' systems of healthcare providers and commissioners to do so and then using their experiences to inform its wider implementation from this summer. We are publishing this introductory framework so that all parts of the NHS, patients, families and other stakeholders can engage with the proposals and help us learn how we best ensure our aim is met.

A handwritten signature in black ink that reads "D. L. Forsyth". The signature is written in a cursive, flowing style.

Donna Forsyth
Head of Patient Safety (Investigation)

Summary

The Patient Safety Incident Response Framework (PSIRF) guides the NHS on how to develop the cultures, systems and behaviours necessary to respond to patient safety incidents in a way that ensures we learn from them and improve.

The PSIRF document has three parts (Figure 1):

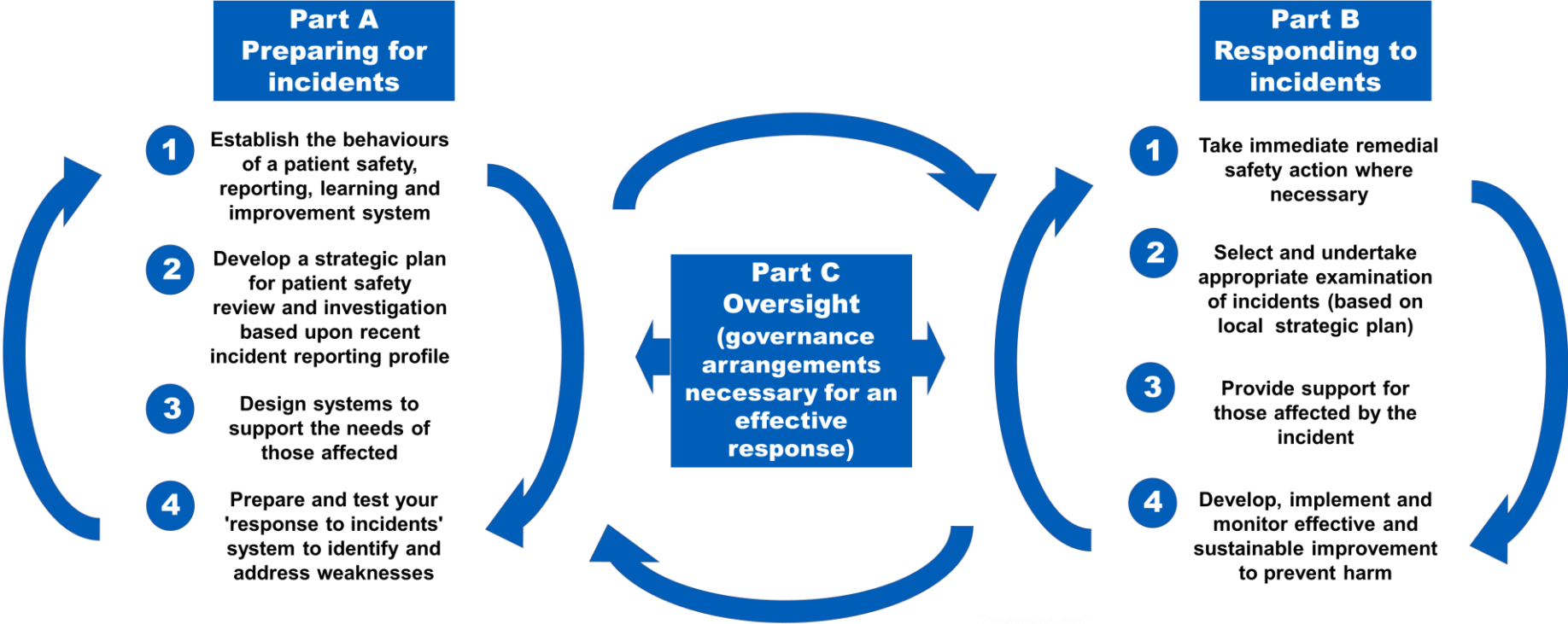
- **Part A: Preparing for incidents** describes four steps organisations should take so that staff know what to do and how to behave when an incident does occur.
- **Part B: Responding to incidents** describes four steps organisations should take in their response to each case.
- **Part C: Oversight** describes the governance arrangements (including key organisational roles and responsibilities) necessary for an effective response.

The PSIRF will replace the Serious Incident Framework (SIF), from which it differs in the following key aspects:

- **Broader scope:** the PSIRF moves away from reactive and hard-to-define thresholds for 'Serious Incident' investigation and towards a proactive approach to learning from incidents. It promotes a range of proportionate safety management responses.
- **Investigation approach:** safety investigation is now tightly defined. Quality of investigation is the priority with the selection of incidents for safety investigation based on opportunity for learning and need to cover the range of incident outcomes.
- **Experience for those affected:** expectations are clearly set for informing, engaging and supporting patients, families, carers and staff involved in patient safety incidents and investigations. In accordance with a just culture,⁵ staff involved in incidents are treated with equity and fairness.

⁵ "A culture in which people are not punished for actions, omissions or decisions commensurate with their experience and training, but where gross negligence, wilful violations and destructive acts are not tolerated." Eurocontrol (2019) [Just culture](#).

Figure 1: Overview of the Patient Safety Incident Response Framework



- **Investigator expertise, experience, time and authority:** the framework clarifies that investigations must be led by those trained and experienced in patient safety incident investigation (PSII), with the authority to act autonomously and with dedicated time and resource.
- **Investigation timeframe:** timeframes are more flexible and set in consultation with the patient and/or family. They should average three months and never exceed six.
- **Terminology:** ‘systems-based⁶ PSII’ replaces the term root cause analysis (RCA).
- **Governance and oversight:** this is strengthened, with commissioners and local system leaders assuring plans and co-ordinating investigations spanning multiple settings. Provider boards now sign off PSII quality and safety improvements.

Our purpose in making these changes and the new approach are described in this document, with the necessary practical detail given in the appendices.

Several early adopter systems are now working to implement this framework and, by learning from their experiences, we will develop supportive resources and further refine this framework ahead of its wider implementation across the NHS from 2021.

Note: Other than the early adopters, organisations are not expected to start implementing the requirements in this framework until **early 2021**. All NHS-funded organisations will likely be required to fully deliver the framework by **late 2021** (and depending on what we learn from the early adopters this timeline may shift).

⁶ Breaking down a complex arrangement into simple units to assist understanding of the complexity, interactive nature and interdependence of the various external and internal factors.

Key differences between the PSIRF and the Serious Incident Framework (2015)

Changes related to patient safety <i>incident management and investigation</i>	
A broader, risk-based approach to patient safety incidents	<ul style="list-style-type: none"> • Highlights the value of a range of incident management activities as part of a systems approach to safety. • Signposts guidance and support to help prepare and respond to patient safety incidents. • Moves away from reactive and hard-to-define thresholds for Serious Incidents and towards a proactive approach to learning from patient safety incidents. • Introduces local provider patient safety incident response plans (PSIRPs), agreed with commissioners. • Includes the option to use alternative, proportionate and effective responses to incidents (eg case note review; timeline mapping; after action review; audit), to better describe common review activities and address queries.
Just culture	<ul style="list-style-type: none"> • A system designed for safety and learning rather than performance management. • Emphasises a fair and equitable response to patient safety incidents. • Updates a 'memorandum of understanding' (MoU) between healthcare and the police for dealing with concerns around potential criminality.
Transparency, support and engagement for those affected by patient safety incidents	<ul style="list-style-type: none"> • Sets expectations for informing and supporting patients, families and carers involved in patient safety incidents. • Sets expectations for informing and supporting staff involved in patient safety incidents.
Governance and oversight	<ul style="list-style-type: none"> • Commissioners and local system leaders assure effective systems to prepare for and respond to patient safety incidents. • Provider boards or equivalent leadership groups build, test and manage safety systems to prepare for and respond to patient safety incidents.

Changes related to patient safety <i>incident management and investigation</i>	
A specialist approach to PSII for complex systems	<ul style="list-style-type: none"> • Promotes a systems approach to patient safety incident investigation (PSII). • Refers the reader to the technical detail required for effective PSII as a discreet specialism.
Purpose of patient safety incident investigation (PSII)	<ul style="list-style-type: none"> • Clarifies purpose; that is, to support system learning and continuous improvement in patient safety, rather than address individual concerns or performance management issues which are the remit of other types of investigation. • Insulates against other remits/scope creep that frustrate safety improvement, ie: <ul style="list-style-type: none"> – individual performance management (which requires HR review use of A just culture guide) – retrospective assessment of ‘avoidability’, predictability, liability – determining cause of death (requires coronial investigation). • Refers incidents that lie outside the scope of this work and require other types of investigation and decision-making, eg: <ul style="list-style-type: none"> – professional conduct/competence – referred to human resources – establishing liability/avoidability – referred to claims or legal teams – cause of death – referred to the coroner’s office – criminal – referred to the police.
Transparency, support and engagement for those involved in PSII	<ul style="list-style-type: none"> • Sets expectations for engaging patients, families and carers in PSII. • Sets expectations for engaging staff in PSII.
A strategic, risk-based approach to PSII	<ul style="list-style-type: none"> • Moves away from reactive and hard-to-define thresholds for Serious Incident investigation and towards a proactive approach to safety and learning investigations. • Selects incidents for PSII based on the opportunity for learning. • Selects PSII for learning to ensure the wide range of outcome severities is covered. • Introduces local provider patient safety incident response plans (PSIRPs), agreed with commissioners. • Highlights alternative, proportionate and effective responses to incidents (eg case note review, timeline mapping, ‘being open’ conversations, after action review, audit), to better describe common review activities and address queries. • Prioritises the quality of PSII to support improvement. • Supports more balanced allocation of resources to develop improvements and equity of care from PSII findings.

Changes related to patient safety *incident management and investigation*

	<ul style="list-style-type: none"> • Develops improvements based on findings from more than one similar completed incident investigation.
PSII timeframes	<ul style="list-style-type: none"> • More flexible and based on an investigation management plan. • Agreed wherever possible with patients, families and carers. • Finalised on average in 3 months and never taking longer than 6 months.
PSII expertise, experience, time and authority	<p>PSII to be led by those with:</p> <ul style="list-style-type: none"> • PSII training • experience of conducting quality PSII • authority to act autonomously • dedicated time and resource to conduct a good quality PSII.
PSII methodology	<ul style="list-style-type: none"> • ‘Systems-based PSII’ or a ‘systems approach to investigation’ replaces the term ‘root cause analysis’ (RCA). • PSII relates only to ‘comprehensive’ and ‘independent’ investigations. • Replaces previously termed ‘concise investigations’ with techniques such as audits and reviews. • Discontinues use of the ‘5 Whys’ technique as it is inadequate when used literally, in a linear fashion or as the sole analysis technique. • Promotes analysis techniques that facilitate a systems approach to identification of the interconnected contributory, human and causal factors. • Moves from over-reliance on documentation and statements to increased use of listening, interviews, discussion and observation. • Identifies system strengths as well as problems (together with their associated mitigating and contributory factors).
PSII standards and template	<ul style="list-style-type: none"> • New national PSII standards. • A new standard PSII report template.
Cross-setting and regionally commissioned PSII	<ul style="list-style-type: none"> • Better reflects the patient experience. • Clear roles and responsibilities for commissioners to co-ordinate PSII across multiple settings. • Clear roles and responsibilities for regional teams to support PSII of complex cross-system incidents where needed.
PSII governance and oversight	<ul style="list-style-type: none"> • Commissioners and local system leaders assure effective application of local PSIRPs and PSII standards. • Provider boards or equivalent leadership groups sign off PSII quality and safety improvements.

Introduction

Purpose and scope

The NHS must always be ready to respond to patient safety incidents. Where organisations establish effective systems, processes and behaviours to do this, recovery from the physical and emotional effects of an incident, learning and improvement are more likely.

The Patient Safety Incident Response Framework (PSIRF) provides the NHS with guidance on how to respond to patient safety incidents⁷ – with no distinction between incidents and ‘serious incidents’ – for the purpose of learning. As such it is relevant to all bodies involved in providing, commissioning, supporting, overseeing and regulating NHS-funded care. This includes services operating as part of a primary care network and other independent, non-NHS providers of NHS-funded care/services.

It uses the principles and practices endorsed by [The NHS Patient Safety Strategy](#) to support the creation of systems that are underpinned by a patient safety culture and can deliver sustainable safety improvements and equity of care.

A patient safety incident is investigated or reviewed under this framework to understand the circumstances that led to it, for the purpose of system learning and improvement, and **not**:

- to determine the cause of death (where applicable); that is for coroners
- to hold any individual or organisation to account; this includes judgements on avoidability, preventability, liability, predictability, etc.

In view of this, some incidents may require separate review and/or investigation beyond the scope of this framework, eg investigation by the coroner, police or human resources.

⁷ Defined as “unintended or unexpected incidents which could have or did lead to harm for one or more patients receiving healthcare”. <https://improvement.nhs.uk/resources/report-patient-safety-incident/>

Separate processes must be followed where there are legitimate concerns about individual and/or organisational accountability including: criminal or civil proceedings, disciplinary procedures, employment law and systems of service, and professional regulation. Where organisational or professional regulators need to be involved, they must be informed and their relevant protocols followed.

Why judgements about culpability do not fit with PSII's conducted for the purposes of learning in the NHS

A patient safety incident investigation (PSII) looks back at what happened and why, so that action can be taken **to help prevent or significantly reduce the likelihood of a similar incident in the future**. Drawing conclusions about whether an incident **could have** been prevented cannot sit alongside this process for a number of reasons:

- With the benefit of hindsight an incident will often look as if it could have been prevented. However, evidence suggests the contrary. In most cases those involved in an incident could not have foreseen that their actions could result in an adverse outcome.^{8,9}
- Determining preventability involves judging the degree of attribution. People or organisations that are the subject of such a judgement can feel blamed and become closed and fearful; they will be reluctant to help investigators understand the safety aspects of an incident. This can create a culture of concealment which limits the opportunity for learning and improvement.
- A PSII is conducted using the benefit of hindsight and careful analysis to identify the causal factors and steps that could be taken to help prevent future recurrence. If the investigator is also tasked with drawing conclusions about whether the outcome was foreseeable, avoidable or preventable **at the time of the incident**, the two statements can appear contradictory and invite challenge around objectivity. Identifying the problems, why they occurred and actions to help prevent them in the future must be sole the focus of a PSII.

⁸ Turner BA, Pidgeon N (1997) *Man-made disasters*, second revised edition. Oxford: Butterworth-Heinemann Ltd.

⁹ Toft B, Reynolds S (2005) *Learning from disasters: a management approach*, extended third edition. Palgrave Macmillan.

Alignment with existing duties and regulations

This framework supports:

- NHS leaders to “govern effectively and in doing so build patient, public and stakeholder confidence that their health and healthcare is in safe hands”¹⁰
- the principles of good clinical governance, which all providers of NHS-funded care and individual professionals are required to uphold as part of their Care Quality Commission (CQC) registration requirements and professional duty
- assessment of and response to the key lines of enquiry in CQC’s inspection regime, particularly those relating to the safe and well-led domains.

Implementation of the framework

Until an organisation formally moves over to the PSIRF, we will expect it to continue to abide by the [2015 Serious Incident Framework](#) and all its relevant reporting and incident investigation and management requirements.

National and regional teams are now working with several early adopters to implement the new framework. We will draw on their experience to develop resources to support the new framework’s adoption across the NHS.

We are releasing this introductory framework so organisations can familiarise themselves with the new concepts, start to consider the new approaches and tell us about any challenges or uncertainties they may have with its implementation. Local systems and organisations will be encouraged to move across to the new framework from **early 2021**, and all parts of the NHS in England will be expected to be using it in full by **late 2021** (and depending on what we learn from the early adopters, this timeline may shift).

From **April 2020**, all NHS-funded providers and commissioners must identify an appropriate executive lead (Appendix 2 gives details of the role) to support and oversee preparations for delivery of the PSIRF by late 2021.

¹⁰ Conway J, Federico F, Stewart K, Campbell MJ (2011) Respectful management of serious clinical adverse events, second edition. IHI Innovation Series white paper. Cambridge, MA: Institute for Healthcare Improvement. Available at www.IHI.org.

Part A: Preparing to respond to patient safety incidents

Step 1: Establish the behaviours of an effective and compassionate patient safety reporting, learning and improvement system

The required behaviours should reflect three main principles:

- openness and transparency
- a just culture
- continuous learning and improvement.

The actions that support their development in a patient safety reporting, learning and improvement system are summarised in Table 1 below.

Openness and transparency

Recording and sharing incident-related information

Executive leaders and managers at all levels must enable and encourage all staff (including temporary staff, those working as part of shared services agreements and agency/third-party contractors) to record and share information about:

- hazards, risks and/or incidents (including those that do not result in harm) in their work environments
- good practice and actions taken to avoid incidents, so that this practice can be explored and used to prevent incidents elsewhere.

Patients, families, carers and the public should also be encouraged and told how to record and share information about patient safety incidents.

Organisations must have systems that capture patient safety incidents, risks or concerns raised through different reporting routes, including complaints. Patient safety incidents must be addressed through the same incident response pathway, regardless of how they were first raised or reported (a ‘no wrong door’ approach¹¹). Those managing complaints and those managing patient safety incidents must work closely together to align their approaches in response to patient safety incidents given the sizeable overlap in these valuable sources of learning.

One indicator of a well-led trust is effective ‘speaking up’ arrangements. These must be set up and supported by senior leaders. NHS Improvement has published guidance on the expectations of boards in relation to [Freedom to Speak Up](#).

People need to know that the time they take to record and share information is valued, and **never** feel that they were wrong to report a patient safety risk or incident. Appropriate feedback loops may range from acknowledgement and thanks to detailed conversations about opportunities for improving care.

Organisations need procedures to fulfil external reporting and notification requirements. For high profile or complex incidents, they should engage with oversight and regulatory bodies as soon as possible to facilitate a joined-up and informed response across the system.

They also need mechanisms to share information with the national patient safety team. Currently this is done through reporting to the National Reporting and Learning System (NRLS) and, where a patient safety investigation is undertaken, the Strategic Executive Information System (StEIS). Work is underway to replace these systems with a [unified reporting system](#) that supports appropriate incident management processes. Until the new unified reporting system is in place, organisations should continue to use the NRLS and StEIS.

Engaging with patients, families and carers affected by incidents

Behaviours that demonstrate openness and transparency are fundamental when engaging with those affected by an incident. Too often it is not the incident (or its severity) that damages people’s trust in the NHS but the way the organisation

¹¹ Health Service Executive (2018) [Incident management framework](#).

responds. Apologising and being open about what happened can help patients and their families overcome the emotional and physical effects of incidents.¹²

‘Being open’ principles (see Appendix 1) and associated practices must be incorporated in policies and procedures, as well as in ongoing staff training. Organisations must be able to demonstrate they uphold the [Duty of Candour](#) for all ‘notifiable incidents’ (that is, those resulting in moderate or severe harm or death).

All healthcare professionals also have a professional responsibility to be honest with patients when things go wrong.

Organisations should seek feedback from patients, families and carers to determine how well they are upholding the principles of openness and transparency. This feedback can come from conversations with staff supporting those affected or be retrospectively sought after an organisation concludes its response to an incident.

Organisations must respect confidentiality and protect data but not allow these concerns to unnecessarily undermine openness and transparency. Their Caldicott Guardian and/or data protection officer can advise on concerns about accessing and/or sharing information.

A just culture

As made clear in The NHS Patient Safety Strategy, a systems approach to improving the safety of healthcare should be adopted. Most incidents are caused by weaknesses in systems which lead to conditions that make it difficult for individuals to do the right thing. Policies must clearly articulate a systems approach to the analysis and management of patient safety incidents and ensure these are updated by staff trained in patient safety and systems thinking.

Organisations must consider how they guard against:

- **bias:** staff involved in similar actions or decisions leading to a patient safety incident should be treated in the same way, irrespective of whether the patient was or was not harmed (outcome bias) and their grade or professional group
- **risk of discrimination,** by ensuring that:

¹² Crane M (2001) What to say if you made a mistake. *Med Econ* 78: 26–8, 33–6.

- those involved in making decisions about referring staff for disciplinary professional regulation or individual training and reflection are trained in equality and diversity and the risks of unconscious bias
- the protected characteristics of staff referred to other bodies, particularly professional regulators, are recorded so that this data can be analysed and any patterns reviewed and addressed
- procedures are consistently reviewed, and steps taken to understand and resolve inequality and potential unfair treatment.

The General Medical Council's (GMC) recommendations in [Making sure doctors are treated fairly](#) include that employers develop strategies and initiatives to mitigate the risk of disproportionality in discipline and referral processes; to maintain positive working environments; to develop cohesive team working; and to meet the needs of diverse staff.

[A just culture guide](#) is useful when assessing concerns about individuals to ensure they are treated consistently, constructively and fairly. Such assessments must be:

- used only when there is reason to believe the deliberately malicious, negligent or incompetent actions or decisions of an individual contributed to an incident, and **not** routinely whenever an incident is reported or a PSII is conducted¹³
- managed completely separately from any activity to examine an incident for the purposes of learning and improvement
- led by a colleague of appropriate seniority and with relevant human resources, individual management review or fitness to practise investigation training.

Inappropriate blame is extremely damaging to individuals and an organisation's safety and culture. Staff should never be automatically suspended or their duties restricted or changed unless that is required to support their wellbeing or to protect patients, irrespective of whether they have been involved in other patient safety incidents. These actions should only be taken after a skilled assessment

¹³ A new memorandum of understanding' (MoU) sets out how health and care organisations, police and regulatory, investigatory and prosecuting bodies in England will work together in cases where criminal activity in a health or care setting is suspected to have led to a person's death or life-changing harm. On publication, a link to this resource will be available on [the patient safety incident investigation webpage](#).

demonstrates they are necessary to protect staff or patients. Involvement in more than one patient safety incident does not mean an individual is at fault.

It is also unsafe to keep the focus on individuals in a non-punitive way, such as by recommending individual training and self-reflection without evidence showing that an individual's behaviour or inadequate training was the reason behind any problems.

Those overseeing PSIs must ensure that recommendations drive a systems approach to improvement by:

- appropriately training staff in investigation or review of patient safety incidents for learning and giving them enough time to conduct a meaningful PSI or review of system safety
- the board and leaders throughout the organisation constructively challenging the strength and feasibility of recommendations to improve underlying system issues.

Systems to support and facilitate the involvement of staff affected by patient safety incidents must also be established (see Part A, step 3).

Continuous learning and improvement

The findings from incident reviews, PSIs or other related activities must be translated into effective and sustainable action that reduces the risk to patients. For this to happen, organisations must be able to apply knowledge of the science of patient safety and improvement to identify:

- where improvements are needed
- what changes need to be made
- how changes will be implemented
- how to determine if those changes have the desired impact (and if they do not, how they could be adapted).

Organisations may find the [quality, service improvement and redesign \(QSIR\) programme](#) helpful for this purpose. Longer term work is also underway nationally to develop an NHS-wide [patient safety syllabus](#) that will support training and education in patient safety science.

A balance is needed between activity examining incidents and that implementing improvements/solutions. The ultimate test of success is to ask: **Have changes been made which led to measurable and sustainable reduction in recurrence of repeat incidents?**

All NHS organisations – including providers, commissioners, sustainability and transformation partnerships (STP)/integrated care systems (ICSs)/integrated care partnerships (ICPs), and oversight bodies – must have plans to support the continuous development of their improvement skills, practices and behaviours. Their leaders also need to identify, measure and develop behaviours that help generate an organisational culture conducive to learning and improvement. The [Developing People Improving Care programme](#) gives access to an evidence-based national framework to guide improvement skill building, leadership development and talent management for people in NHS-funded roles.

Table 1: Actions to support the effective behaviours of a patient safety reporting, learning and improvement system

Principles and behaviours	Actions
<p>Openness and transparency:</p> <p>Recording and sharing</p>	<ul style="list-style-type: none"> • Ensure mechanisms are in place to allow staff, patients and the public to record patient safety-related issues/concerns/incidents. • Integrate reporting systems (eg patient safety incidents, complaints, and freedom to speak up reports) to triangulate information and ensure risks are identified and responded to in the most effective way, regardless of how they were first raised or reported. • Provide proportionate feedback to support reporting. • Find out how people feel they are treated when they raise concerns (use data from the NHS patient and staff surveys to understand reporting cultures). • Develop strategies to overcome issues that could undermine reporting. • Ensure Freedom to Speak Up expectations are met. • Encourage staff to identify, record and share information about good practice and/or actions to prevent incidents so this practice can be explored and potentially adopted elsewhere. • Ensure processes are in place to report incidents to regulators and other stakeholders as required.

Principles and behaviours	Actions
	<ul style="list-style-type: none"> • Ensure systems are in place to share records with the national patient safety team to allow insight, improvement and equity of care can be considered at a national level.
Engaging with affected patients, families and carers	<ul style="list-style-type: none"> • Ensure there is a clear understanding of ‘being open’ principles and associated practices and that staff are supported to uphold their professional duty of candour. • Ensure there is a clear understanding of and procedures to support the Duty of Candour (relevant for all notifiable patient safety incidents). • Ensure requirements are implemented, periodically evaluated for compliance and, and improved where required. • Ensure General Data Protection Regulation (GDPR) and information governance policies and procedures are developed to provide clarity, confidence and enable openness and transparency (see Part C). • Ensure systems are designed to support those affected by patient safety incidents. • Seek feedback from patients, families and carers about the organisation’s response to incidents (through liaison staff and/or written feedback following an incident) and ensure good practice is sustained and poor practice addressed.
A just culture	<ul style="list-style-type: none"> • Ensure risk management, patient safety, clinical and HR/organisational development teams and professional midwifery advocates work closely to ensure staff are not unfairly exposed to punitive disciplinary action by: <ul style="list-style-type: none"> – correcting policies that inhibit or undermine a just culture (eg those that automatically invoke disciplinary procedures pending a patient safety incident investigation or after a person has been involved in more than one incident) – ensuring concerns about an individual are managed as a separate process, by appropriately trained staff with due regard for Black, Asian and Minority Ethnic (BAME) groups that have traditionally faced disproportionate disciplinary actions, and assessed using recognised tools such as A just culture guide. • Ensure systems support the needs of those affected by patient safety incidents and those involved in PSIs (see Part B). • Seek feedback from staff about their treatment when involved in incidents (through liaison staff and/or written feedback following an incident). • Develop strategies to overcome issues that undermine a just culture. • Ensure recommendations made following analysis of patient safety incidents do not inappropriately focus on training and self-reflection for individuals.

Principles and behaviours	Actions
Continuous learning and improvement	<ul style="list-style-type: none"> • Ensure plans are developed to support continuous development of improvement capability and capacity. • Ensure systems are in place to identify, measure and develop characteristics of organisational culture conducive to learning and improvement. • Ensure a balance between activity to examine incidents and to implement improvements/solutions. • Ensure recommendations for change are constructively challenged. • Ensure that any improvement effort develops measures to determine whether change has led to demonstrable improvement – supports review and adaption of actions wherever the desired outcome is not being achieved.

Step 2: Develop a patient safety incident response plan

This framework requires providers of NHS-funded care to develop a patient safety incident response plan (PSIRP), in line with the [national PSIRP template](#). The aim of this is to support a strategic, risk management approach to balancing the activity and range of incident responses with those of safety improvement.

PSIRPs must describe the local strategic and operational arrangements for a proportionate and co-ordinated response to patient safety incidents. It should describe:

- the local situational analysis in relation to patient safety incidents
- the approach to the different types of patient safety incidents that normally arise
- selection of incidents for patient safety investigation or review, based on national and local priorities
- roles and responsibilities (see Appendix 2)
- incident reporting arrangements (see Appendix 6)
- procedures to support patients, families and carers affected by patient safety incidents (see Appendix 1)
- procedures to support staff affected by patient safety incidents (see Appendix 3)
- mechanisms to develop and support improvements following incidents (Part A, Continuous improvement and Part B, step 4)

- evaluating and monitoring outcomes following PSIs and reviews (Part 2, step 4 and Part C)
- complaints and appeals.

Responding to incidents

An organisation’s PSIRP should set out its approach to the different types of patient safety incident identified from the local situational analysis, acknowledging that this will include ‘do not investigate’ or ‘no response required’.

An organisation must have systems to ensure the approach and tools it uses in its response to a patient safety incident achieve useful learning/insight and outline the circumstances where they are indicated – in its PSIRP. Table 2 lists available approaches and tools.

Table 2: Responses to patient safety incidents

Technique	Method	Objective
Patient safety incident reporting (PSI)	Recording and notification	To notify all relevant people and bodies (locally, regionally and nationally) of a patient safety incident/ risk/concern (details are given in Appendix 6).
Patient safety incident investigation (PSII)	Systematic process which includes systems-based analysis	To identify what happened, where, when, how, to whom and why . To design recommendations/ improvements which address the underlying interconnected, system-based contributory and causal factors of patient safety incidents.
Alternative responses to PSII		
Immediate safety actions	Incident recovery	To take urgent measures to address serious and imminent: <ul style="list-style-type: none"> • discomfort, injury, or threat to life • damage to equipment or the environment.
‘Being open’ conversations	Open disclosure	To provide the opportunity for a verbal discussion with the affected patient, family or carer about the incident (what happened) and to respond to any concerns.
<u>Case record/note review</u>	Clinical documentation review	To determine whether there were any problems with the care provided to a patient by a particular service (To routinely identify the prevalence of issues; or when bereaved families/carers or staff raise concerns about care).

Technique	Method	Objective
Hot debrief	Debriefing	To conduct a post-incident review as a team by discussing and answering a series of questions.
Safety huddle	Briefing	A short multidisciplinary briefing, held at a set time and place and informed by visual feedback of data, to: <ul style="list-style-type: none"> • improve situational awareness of safety concerns • focus on the patients most at risk • share understanding of the day's focus and priorities • agree actions • enhance teamwork through communication and collaborative problem-solving • celebrate success in reducing harm.
After-action review	Team review	A structured, facilitated discussion on an incident or event to identify a group's strengths, weaknesses and areas for improvement by understanding the expectations and perspectives of all those involved and capturing learning to share more widely.
LeDeR (Learning Disabilities Mortality Review)	Specialist review	To review the care of a person with a learning disability (recommended alongside a case note review).
Perinatal mortality review tool	Specialist review	Systematic, multidisciplinary, high quality audit and review to determine the circumstances and care leading up to and surrounding each stillbirth and neonatal death, and the deaths of babies in the post-neonatal period having received neonatal care.
Mortality review	Specialist review	A systematic review of a series of case records using a structured or semi-structured methodology to identify any problems in care and draw learning or conclusions that inform action needed to improve care, within a setting or for a specific patient group, particularly in relation to deceased patients.
Transaction audit	Audit	To check a trail of activity through a department, etc, from input to output.
Process audit	Audit	To determine whether the activities, resources and behaviours that lead to results are being managed efficiently and effectively, as expected/intended.
Outcome audit	Audit	To systematically determine the outcome of an intervention and whether this was as expected/intended.

Technique	Method	Objective
<u>Clinical audit</u>	Outcome audit	A quality improvement cycle involving measurement of the effectiveness of healthcare against agreed and proven standards for high quality, with the aim of then acting to bring practice into line with these standards to improve the quality of care and health outcomes.
<u>Risk assessment</u>	Proactive hazard identification and risk analysis	To determine the likelihood and severity of identified hazards, and apply sensible measures to control those risks (eg clinical, safety, business). See: <u>Healthcare Risk Assessment Made Easy</u> .

Planning which incidents will require PSII

There is no nationally agreed or recommended annual minimum or maximum number of PSII each organisation should undertake. Instead, this framework directs organisational effort at identifying areas of most significant risk and implementing systems to prevent incidents or reduce their likelihood. Organisations need to have this purpose uppermost when selecting which incidents to investigate (see below). There is no remit in this framework to apportion blame or determine liability, preventability or cause of death. There are, however, a few incident categories for which a PSII is nationally mandated.

Table 3 summarises guidance on nationally mandated incident categories requiring PSII and on identifying local priorities for PSII.

PSIRPs should set out how an organisation's systems ensure these incidents are identified and are then investigated according to the [national PSII standards](#), and include the requirement to report them to [StEIS](#) (and then its successor when this becomes available). Unless the investigation is led by another body (eg the Healthcare Safety Investigation Branch, HSIB), the provider is responsible for ensuring these standards are upheld.

Table 3: Overview¹⁴ of indications for PSII

Indications	
<p>Nationally-defined priorities to be referred for PSII or review by another body or team¹⁵</p>	<p>Maternity and neonatal incidents which meet the ‘Each Baby Counts’ and maternal deaths criteria detailed in Appendix 4. These must be referred to HSIB for a HSIB-led PSII.</p>
	<p>Mental health-related homicides by persons receiving mental health services – or within six months of their discharge. These must be referred to the relevant NHS England and NHS Improvement regional independent investigation team who commission mental health homicide investigations.</p>
	<p>Child deaths (see Appendix 6) need to be referred to the local Child Death Overview Panel. A PSII may also be indicated where there is reason to believe that one or more patient safety incidents/ problems in care could have contributed to the death.</p>
	<p>Deaths of persons with learning disabilities (see Appendix 6) need to be referred to the local LeDeR reviewer. If a trust wishes to complete its own internal mortality review, the LeDeR initial review process is recommended; documentation is available.¹⁶</p>
	<p>Safeguarding incidents need to be referred to the local safeguarding lead.</p>
	<p>Incidents in screening programmes need to be referred to the local Screening Quality Assurance Team.</p>
	<p>Deaths of patients in custody, in prison or on probation where healthcare was/is NHS funded and delivered through an NHS contract. These are reviewed by the Prisons and Probation Ombudsman (PPO; see Appendix 6) who will work with NHS England and NHS Improvement to commission an independent clinical review of the healthcare the person received in custody before their death.</p>
<p>Nationally-defined incidents requiring local PSII</p>	<p>Incidents meeting the Never Events criteria 2018.</p>
	<p>Incidents meeting the ‘Learning from Deaths’ criteria’ ie: a death clinically assessed as more likely than not due to problems in care. (This clinical assessment will have been conducted as part of a local LfD plan, or following concerns about care or service delivery. It will be conducted by a clinical specialist not involved in the patient’s care, using a recognised method of case record/case note review). Note: this is not a legal term and is not the same as ‘cause of death’ or ‘avoidable mortality’, which have specific meanings in law and public health respectively and are outside the scope of a PSII. Further examples of deaths where a PSII must take place are set out below.</p>

¹⁴ Full details are also listed in the [national patient safety incident response plan \(PSIRP\) template](#)

¹⁵ This list will be reviewed at least every three years and updated as new national risks emerge

¹⁶ <http://www.bristol.ac.uk/sps/leder/>

	<p>Deaths of persons with mental illness whose care required case record review as per the Royal College of Psychiatrists' mortality review guidance¹⁷ and which have been determined by case record review to be more likely than not due to problems in care.</p>
	<p>Deaths of persons with learning disabilities where there is reason to believe that one or more patient safety incidents/problems in care could have contributed to the death. In these circumstances a PSII must be conducted in addition to the LeDeR review.</p>
	<p>Deaths of patients in custody, in prison or on probation where there is reason to believe that one or more patient safety incidents/problems in healthcare provided by the NHS could have contributed to the death.</p>
	<p>Suicide, self-harm or assault resulting in the death or long-term severe injury of a person in state care or detained under the Mental Health Act.</p>
<p>Locally-defined incidents requiring local PSII</p>	<p>Emergent incidents which justify a heightened level of response because the consequences for patients, families and carers, staff or organisations are so significant and the potential for learning is so great.</p>
	<p>Locally predefined incidents, prioritised based on all of the following criteria:</p> <ul style="list-style-type: none"> • actual and potential impact of incident • likelihood of recurrence • potential for learning.

To support local improvement, organisational leaders also must determine which categories of incident are priorities locally and require a PSII. They should do this by reviewing past incident data (from the last three to five years where available) to identify those incidents representing the most significant risks. This list must be set out in the PSIRP, reviewed every two years and adapted as new risks emerge or diminish locally.

The case study below shows how an organisation can determine its local priorities for patient safety investigation. It is for illustrative purposes only. National and regional patient safety leads will work with early adopters during 2020 to test approaches in the PSIRF. Insights and advice from this will be shared with the wider system.

¹⁷ Royal College of Psychiatrists *Using the care review tool for mortality reviews in mental health trusts. Guidance for reviews.* <https://www.rcpsych.ac.uk/improving-care/campaigning-for-better-mental-health-policy/care-review-tool-for-mental-health-trusts>

Case study

An acute trust's patient safety team reviewed its patient safety incident reporting data over the last three years alongside patient safety concerns highlighted through complaints, mortality review processes, coroners' inquests, litigation claims, infection prevention and control-related audits, and other relevant clinical audits completed over the previous 12 months.

Based on frequency of occurrence, severity and cost, its review highlighted three high risks: inpatient falls, wrong route medication errors in children and missed diagnosis of spinal cord compression. The team scrutinised the incident reports to get a detailed understanding of the issues and to identify specific areas of greatest risk. The review of falls data, for example, revealed that falls were most common during the early hours of the morning on the elderly wards.

The trust (with input and agreement from their commissioners) then agreed, as part of the patient safety incident response plan, that five full PSIIIs in each of these areas (15 in total) would be undertaken over a 12-month period. These would be conducted by six trained patient safety investigators (two for each high-risk area). Working in pairs, one investigator would take the lead investigator role and the other a supporting role, with support from the patient safety team, clinical leads and the communications team as required.

The trust also undertook a case note review and duty of candour/being open discussions for all other incidents associated with the high-risk areas, where the incident outcome was moderate harm and above, and for which a PSII was not conducted.

It was agreed that no more than two PSIIIs would be undertaken by the same team at the same time. The frequency of incidents associated with inpatient falls and wrong route medication errors in children meant that investigators had to be selective about which incidents they investigated and when. Investigators worked to complete each PSII within 10 weeks.

Organisations must also initiate a PSII for incidents which signify an unexpected level of risk and/or potential for learning and improvement but fall outside the predetermined national and local priorities. These will be determined on a case-by-

case basis by key members of the patient safety team or equivalent responsible for reviewing patient safety incident reports and initiating relevant action through PSII leads. This process must not become a bureaucratic and burdensome panel assessment of each incident report. Instead, staff trained and experienced in patient safety should be empowered to determine the most appropriate action based on the available evidence, including that from clinical and patient/family/carer input.

The selection of incidents for local patient safety incident investigation should be based on the:

- actual and potential impact of the incident's outcome (harm to people, service quality, public confidence, products, funds, etc)
- likelihood of recurrence (including scale, scope and spread)
- potential for new learning and improvement in terms of:
 - knowledge and understanding of the deep-seated underlying factors
 - opportunity to influence efficiency and effectiveness
 - opportunity to influence wider system improvement.

Organisations should base their annual budget for PSII on their anticipated level of investigation activity but build flexibility into this because some demand-led/reactive activity will continue. However, their PSIRPs must base and describe the planned PSII activity on past incident reporting data. Organisations should agree their PSIRP with their lead commissioner and monitor it annually.

Where an incident is of a relatively well understood type – because previous incidents of this type have been thoroughly investigated and national or local improvement plans targeted at causal factors are being implemented and monitored for effectiveness – resources are better directed at improvement rather than repeat investigation.

Where the systems-based, interconnected contributory and causal factors of an incident are still not well understood, a PSII may be needed to fully understand why it occurred. The findings inform system improvements to prevent or continuously and measurably reduce repeat patient safety risks and incidents.

Supporting cross-system patient safety incident investigation

Incidents often stem from weaknesses at the interface between different systems: between departments (within the same organisation), between services (within the

same organisation or across different organisations) and between agencies (eg health and social care).

Providers and commissioners (including those working as part of a STP, ICS or ICP and regional teams need to recognise and establish the infrastructure to support the investigation of such incidents, as outlined in Appendix 5. This responsibility should be reflected in an organisation's PSIRP.

Commissioners and then ICSs, ICPs or STPs as they develop are responsible for co-ordinating investigations that would benefit from a multi-organisation or multi-agency PSII and report these as appropriate (see Appendix 6).

We expect organisations to work together to establish and undertake such investigations, but where issues arise they will be supported by NHS England and NHS Improvement regional teams who are accountable for ensuring cross-system PSII involving multiple organisations are delivered as required. Appendix 5 gives more detail on these investigations.

Independent patient safety incident investigations and public inquiries

This framework aims to reduce the need to commission independent PSII and public inquiries outside predetermined criteria by promoting quality local PSII that are more open, inclusive and effective.

Where an incident falls outside the predefined criteria for independent patient safety incident investigation set out in the [national PSIRP template](#), organisations, systems (ICSs/ICPs/STPs) or NHS England and NHS Improvement may still decide to commission one if this is considered necessary. Its remit should be systems learning and improvement.

NHS England and NHS Improvement Regional Independent Investigation Teams (RIITs) will commission an independent investigation, for incidents meeting one or more of the following criteria:

- an organisation is too small to provide objective investigation and analysis
- an organisation is perceived to be too close to the incident to be objective
- for a multi-agency incident, no single provider is the clear lead for an investigation

- the incident(s) represent significant learning potential for the wider system (regional or national).

Independent (and in-house) patient safety investigations commissioned by NHS England and NHS Improvement, ICSs, ICPs or STPs must adhere to the patient safety incident investigation standards. Investigation reports must be signed off by a formally constituted group as part of their board's governance process.

This guidance reaffirms that mental health-related homicides will need to be considered for an independent investigation, but an independent investigation will only be commissioned by NHS England and NHS Improvement if one or more of the above criteria is met.

Incidents that require independent public inquiry or other national inquiry will be identified and managed separately, usually by the Department of Health and Social Care.

Interface with other types of review and/or investigation

Certain types of incident trigger specific responses described in other guidance or legislation, eg where a person dies in prison or an incident affects patients participating in a national screening programme (see Appendix 6 for details of such incidents and their management).

Mechanisms to support reviews and/or investigations led by external agencies such as the police, coroners, Health and Safety Executive, HSIB or local authority are outside the scope of this framework, but organisations must consider how they will contribute where required. As such, the PSIRP should set out how these wider reviews and mechanisms interface with the trust-led safety incident response.

National standards for local systems-based patient safety incident investigation in NHS-funded care

The national PSII standards must be followed. Compliance with these standards, such as the need for appropriately trained and resourced investigators, must not be compromised. If an organisation cannot currently meet the standards, it must have plans to develop capacity and capability to meet them.

An overview of the national PSII standards is given in Table 4, with the [detailed standards](#) published separately.

The guiding principles underpinning these standards support PSII to be:

- strategic
- preventative
- collaborative
- fair and just
- expert/credible
- people focused.

Table 4: An overview of the national patient safety incident investigation standards

1.0 STRATEGIC

- 1.1 Board-level oversight and governance
- 1.2 Proactive planning of each PSII
- 1.3 Focus on quality over quantity
- 1.4 Timely and responsive
- 1.5 Objective
- 1.6 Resourced
- 1.7 Monitored

2.0 PREVENTATIVE

- 2.1 Identify and act on deep-seated contributory or causal factors to prevent or measurably and sustainably reduce recurrence
- 2.2 Maintain a patient safety remit (not seeking to identify avoidability; blame; competence; cause of death)

3.0 COLLABORATIVE

- 3.1 Support cross-system PSII (cross-pathway/boundary issues)
- 3.2 Enable information sharing and action across systems
- 3.3 Facilitate development of improvement plans based on more than one similar PSII

4.0 FAIR AND JUST

- 4.1 Fair and just
- 4.2 Open, honest and transparent

5.0 PEOPLE FOCUSED

- 5.1 Patients, families and carers are active and supported participants
- 5.2 Staff are active and supported participants

6.0 EXPERT/CREDIBLE

- 6.1 Systematic, systems-based and systemic
- 6.2 Trustworthy
- 6.3 Credible and adept

Timescales for patient safety incident investigations

PSIIs must start as soon as possible after the incident is identified, and usually be completed within **one to three months**. The PSII timeframe should be agreed with the patient/family/carer in each case as part of the terms of reference for the PSII, provided the patient/family/carer are willing and able to be involved in that decision. In exceptional circumstances a longer timeframe may be needed for completion of the PSII. In this case, any extension to timescales should also be agreed with the patient/family/carer.

No local PSII should take longer than **six months** because the time needed to conduct a thorough investigation has to be balanced against the impact of lengthy timescales on those involved in the incident, and the risk that a delay in reporting findings may adversely affect safety or require further checks to ensure the recommended actions remain relevant. (Where external bodies cannot provide information within six months, a local PSII should be finalised using the information available and may be revisited at a later date, should new information indicate the need for further investigative activity.)

Patient safety partners

[The NHS Patient Safety Strategy](#) promotes the involvement of patients, families and carers as partners both in their own care and in the wider delivery and oversight of healthcare. Such involvement is of specific value in the development of PSIRPs and PSII oversight committees.

Step 3: Design systems to support the needs of those affected

PSIRPs should set out how the needs of those affected by patient safety incidents – patients, families, carers and staff – are met. Those affected should be able to say:

- we were treated with respect
- we were supported appropriately
- we were given meaningful, truthful and clear answers and information in response to all our queries and concerns
- where our expectations were not met or we were not satisfied, we were given a meaningful, truthful and clear explanation for why this was not possible

- our questions or challenges to the organisation never inhibited its efforts to engage with us.

Patients, families and carers

Identifying and responding to the clinical needs of patients affected by an incident is the priority. Organisations' PSIRPs should make this clear and include plans to ensure that patients receive appropriate clinical care in the immediate aftermath of an incident and on an ongoing basis, including during any PSII or alternative review of the incident.

It may not always be obvious who has been affected by an incident, especially when the incident is identified sometime after it happened, as can be the case, for example with some screening incidents. A co-ordinated effort should be planned to determine who may have been affected, their potential exposure to harm and how to contact them; to include contacting the clinical practitioner or team best placed to inform this inquiry.

An apology and open disclosure are mandatory for all incidents resulting in moderate or more severe harm; this applies to everyone affected by an incident, including patients who harm others, their families and carers. Organisations must have systems to uphold the [Duty of Candour](#). Professionals also have an individual duty of candour and organisations should encourage, train and support their staff to apologise to and be open with patients or those close to them when something has gone wrong. Appendix 1 gives further detail and the [General Medical Council](#) and [Nursing and Midwifery Council](#) provide guidance.

PSIRPs should set out how the process of open disclosure will be initiated and led by a person trained in 'duty of candour' and 'being open', and able to establish a relationship with those affected, identify what support is needed,¹⁸ facilitate access to or signpost that support, and set expectations about the response to the incident. In some cases, particularly incidents that caused moderate or more severe harm, this information should be disclosed by a named contact (see Appendix 2).

Conversations to facilitate open disclosure and support for those affected should start as soon as practical, but with their exact timing and format guided by those affected. Those who choose to engage sometime after an incident can still provide

¹⁸ This may include practical, emotional (bereavement support/counselling), religious and spiritual support, and access to information, advice and advocacy support.

an additional, important perspective to an ongoing PSII and must receive the support required from the point at which they become engaged in the process.

Patients, families and carers involved in incidents must be given, or told where they can find, a copy of the local PSIRP and this PSIRF. If the incident is to be investigated, they must be informed about that process and given a copy of the [national PSII standards](#) setting out the expectations for supporting and involving people in PSIIIs.

Where an incident is not selected for patient safety investigation, the organisation should still share any information that may help the patient and/or their family and carers, eg the incident report, the incident timeline/chronology (or other documentation to describe what happened) and any information about how the organisation has responded to the incident in question or to similar incidents (including any improvement work underway).

The needs of those affected by patient safety incidents should guide the level and type of information shared with them, and the guidance in Part A, step 1 above on openness and transparency followed when designing systems to respond to their needs. The 'being open' principles (see Appendix 1) and [Learning from Deaths: Guidance for trusts on working with bereaved families and carers](#) (including the information leaflet) are useful resources on how to support those affected by incidents, including how to apologise and disclose information in an open, timely, compassionate and effective manner.

Staff

Organisations must “never lose sight of the staff at the sharp end of the error”¹⁹ and plan accordingly.

The establishment of a just culture ensures staff are treated fairly and appropriately following patient safety incidents (as described in Part A, step 1 above). For staff to be appropriately supported, all organisations must have systems and structures that ensure managers and wider staff:

- are confident about which incidents are being investigated and why
- understand the potential impact of patient safety incidents on staff

¹⁹ Canadian Patient Safety Institute (2012) [Canadian Incident Analysis Framework](#).

- can recognise and help to manage the signs and symptoms of stress (including those associated with post-traumatic stress disorder) in themselves and colleagues
- have access to support following patient safety incidents.

Staff should never be left feeling isolated and uninformed about what will happen following a patient safety incident. They must be given or know how to find a copy of their local PSIRP and this PSIRF and, if a PSII is planned, a copy of the national PSII standards. Where there is to be a PSII, staff should be fully informed in person and in writing about what will happen. Staff should also have the opportunity to contribute to other responses that enable learning from the incident.

Organisations must establish procedures to identify all staff who may have been affected by a patient safety incident and to provide access to the support they need. In some cases, line managers and peers can provide enough support, but in complex cases (often where moderate or more severe harm has occurred) an appropriate named contact may need to be appointed to ensure staff, including trainees on rotation, can access relevant help and support. Appendix 3 lists the national sources of support for healthcare professionals, including those affected by a patient safety incident, and organisations should supplement this with local sources.

Step 4: Prepare, test and review the patient safety incident response system to identify and address weaknesses

For organisations to respond appropriately to patient safety incidents, they must have procedures, overseen by staff trained and skilled in patient safety, to support good practice at every stage of the incident management process.

Organisations should use both prospective and retrospective approaches to prepare, test, review and ultimately improve their ‘response to incidents system’ (see Table 5).

Table 5: Example activities to improve incident responses

Activity	Description	Application
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Tutorials	Teaching staff about the procedures to use when responding to an incident.	Preparing/informing staff.
Table-top scenario testing	Using examples of incidents to consider how the organisation would or should have responded. This applies principles similar to those for major incident/emergency preparedness planning.	Prospectively to consider how incidents might be managed before they occur (this can help prepare an organisation for high profile incidents). Organisations can review/reflect on their response to past incidents and consider how it could have been better.
Strategic review of features underpinning an organisation's response to incidents systems	Questions asked/intelligence sought to understand the effectiveness of the system, processes and behaviours (see the questions leaders should ask below).	Reviewing effectiveness of the system, processes and behaviours to identify strengths/weaknesses

Questions leaders should ask to support review

- How many of our staff report incidents?^{a,b}
- Do staff think the procedures for reporting incidents are fair and effective?^a
- Do staff feel confident and secure when they raise concerns?^a
- Does our board agree what the highest risk/priority areas are?^{c,d,e}
- Have the highest risk/priority areas across services and/or organisational boundaries been identified?^{d,e}
- Are those affected (patients/families/carers and staff) appropriately supported?^f
- Are those affected (patients/families/carers and staff) appropriately involved?^{f,g,h}
(sources: feedback from those affected by patient safety incidents)
- Are staff appropriately trained in relevant disciplines?ⁱ
- Are identified remedial actions completed?^{e,j}
- Are repeat incidents measurably and sustainably reduced once actions are completed?^e

Data sources: a, NHS staff survey; b, National Reporting and Learning Explorer Tool; c, relevant board meetings; d, organisational strategies for improvement; e, reports on quality improvement activity; f, feedback from those affected by patient safety incidents and staff

running support services; g, intelligence from patient advice and liaison services and/or complaints; h, [Perinatal mortality review tool](#); i, training records for individuals/access to training; j, observation audits.

An organisation should test its preparedness to respond to patient safety incidents using scenarios (similar to how it tests its major incident/emergency response plan). Does it have the systems and processes to respond appropriately? An example scenario is provided below but organisations can use their own past incidents.

The questions are included as prompts to test key aspects of the patient safety incident response process. There are no set or definitive answers to these. Organisations should refer to this PSIRF and the national PSII standards to inform their answers, as well as considering the operational detail in their systems and their ability to respond appropriately.

Example scenario²⁰

You heard at this morning's CEO leadership huddle that a 40-year-old father of five died in the surgical ICU last night, hours after receiving medication intended for another patient. Everyone is upset and questions are flying around the hospital.

- What would you expect to happen in the first hour, the first 24 hours and the first week? Who would be responsible for those actions?
- How would the needs of those affected (including the patient, their family and carers, and staff) be supported? Who would be responsible for delivering that support? Are they appropriately trained and supported?
- How would you expect this incident to be examined/analysed?
- Who would lead this type of examination?
- Would they have had appropriate training?
- How would they be supported?
- What mechanisms would be used to ensure that the examination of the incident leads to meaningful insight and improvement in your organisation?

²⁰ Taken from: Institute for Healthcare Improvement [Respectful management of serious clinical events](#).

- Who would be responsible for ensuring actions are monitored and reviewed?
- What efforts would be made to share insight from the incident occurring in your organisation with others?

All test and review activities must evaluate the system's processes, not individuals. Everyone involved in testing should be invited to contribute to a debriefing session which can inform the review of a system's effectiveness.

Activities should involve multidisciplinary teams and colleagues from other organisations wherever possible to support the sharing of good practice and the development of relationships between organisations, teams and individuals who may need to work together to respond to incidents in the future. Data from any of these sources must be used in the spirit of improvement (that is, with curiosity and open inquiry) and not to provide assurance or reassurance in relation to safety performance.

Testing systems in commissioning and oversight bodies

While providers are typically best placed to respond to patient safety incidents, commissioning and oversight bodies also have a role; whether that be in their capacity to oversee the implementation of effective systems and processes to support the response to patient safety incidents in providers, or to facilitate cross-system working by supporting review/PSII across services in their local areas.

They should therefore prepare, test and review their procedures in a similar way to providers to ensure that they too are prepared to fulfil core responsibilities in responding to patient safety incidents.

Involving other commissioners and providers helps share good practice and establish jointly agreed procedures wherever possible.

Example

Local maternity systems, co-terminous with STP footprints, have specific responsibility for improving the safety of maternity care by investigating and learning

from incidents and sharing this learning through their local maternity systems (LMSs). Local learning systems provide quality improvement support to LMSs to facilitate improvements from shared learning as part of the Maternity and Neonatal Safety Improvement Programme.

Part B: Responding to patient safety incidents

The appropriate response to a patient safety incident depends on its scale and nature. The steps below summarise the activities that are most often required but, in reality, they may be undertaken simultaneously or in a different order appropriate to the specific circumstances. Inevitably more detailed incident management plans will be required to support the response to some individual incidents; those leading that response will need to use their initiative to shape the most effective and proportionate plan.

Development of the appropriate skills, experience and behaviours in the staff who lead, manage and facilitate the response to patient safety incidents is critical.

Step 1: Identify those affected, take immediate remedial action and establish ongoing support

As soon as a patient safety incident is identified the following actions should follow:

- identification of all patients who have been harmed and arrangement of their ongoing clinical care
- immediate remedial action to reduce the imminent risk of any further harm to the patient or others
- identification of others who may have been affected by the incident, including families, other patients and staff
- acknowledgment of the incident and apology to those affected – the [professional duty of candour](#) provides information to support this. Obligations relevant to the [Duty of Candour](#) must be upheld where required
- identification of a suitable named contact to support those affected
- depending on the nature of the incident, several organisations may need to contact those affected, with the need to do so clearly explained to them. The partner agencies should agree a co-ordinated approach and which of them should take the lead in discussions with those affected, where appropriate

- if the incident affected a large population or has the potential to undermine public confidence, a clear communication and media management plan will be needed, enacted by teams with relevant skills and experience. A spokesperson may need to be assigned (usually the chief executive supported by communication and media management teams)
- identification and ongoing review of the equitable support needs of those affected – responsibility for this must be clearly assigned.

Step 2: Notify others, record information and secure evidence

Notifying others and recording and sharing relevant information are crucial to an effective and co-ordinated response to patient safety incidents. The following must happen as soon as possible:

- Staff who identified the incident should also inform their line managers so they can:
 - ensure clinical staff involved in or responsible for the patient’s care are given relevant information
 - inform other care providers who need to know about the incident, particularly of any implications for care and how they can support patients and families emotionally and practically as required
 - liaise with other healthcare providers and commissioners where a cross-system response may be required.
- Management teams should ensure internal and external notification and recording procedures are followed. Communication channels may also need to be established between providers and relevant regulatory and/or oversight bodies to ensure a co-ordinated response to the incident.
- A clear record of what happened should be documented in the patient’s clinical record and the organisation’s local risk management system. (This should be a factual account based on what is known at the time. Records should then be updated as required.)
- Information (such as staff accounts of what happened) and physical evidence (such as equipment, pictures of the area, etc) likely to be useful in any subsequent review or PSII should be obtained and stored securely.

- Incidents subject to a PSII (selected as per the organisation’s patient safety incident response plan; PSIRP) should be reported to StEIS (and its successor when this becomes available).

Reporting to the National Reporting and Learning System (NRLS)

Organisations should continue to report patient safety incidents to the NRLS. Further guidance will be issued when this is replaced by the new Patient Safety Incident Management System (PSIMS).

Note: For NHS trusts, statutory notification requirements are typically met by reporting incidents to the NRLS. One notable exception is the death of a patient detained under the Mental Health Act, which must be reported directly to CQC. [CQC’s notification guidance](#) outlines how each type of notification needs to be made. See also Appendix 6 of this document.

Reporting patient safety incidents to the Strategic Executive Information System (StEIS)

Under the PSIRF, the ‘StEIS’ reporting platform will change from a system enabling commissioners to monitor the process and progress relating to individual patient safety investigations, to a reporting and monitoring system for providers.

Commissioners should change to using StEIS to conduct a single annual review of progress against each local provider’s PSIRP. In line with this change:

- incidents previously defined as Serious Incidents will no longer be reported to StEIS and providers will instead use StEIS to log and monitor all patient safety incidents identified as requiring a PSII (in line with national and locally identified priorities in their local PSIRPs)
- management and monitoring of individual PSIIIs should immediately become the responsibility of providers.

Step 3: Examine incidents appropriately (based on the local PSIRP)

Once immediate steps have been taken to care for those affected by an incident, the organisation must ensure the incident has been reported and, following its PSIRP, determine whether a PSII or alternative review is required (Figure 2 below shows an example process).

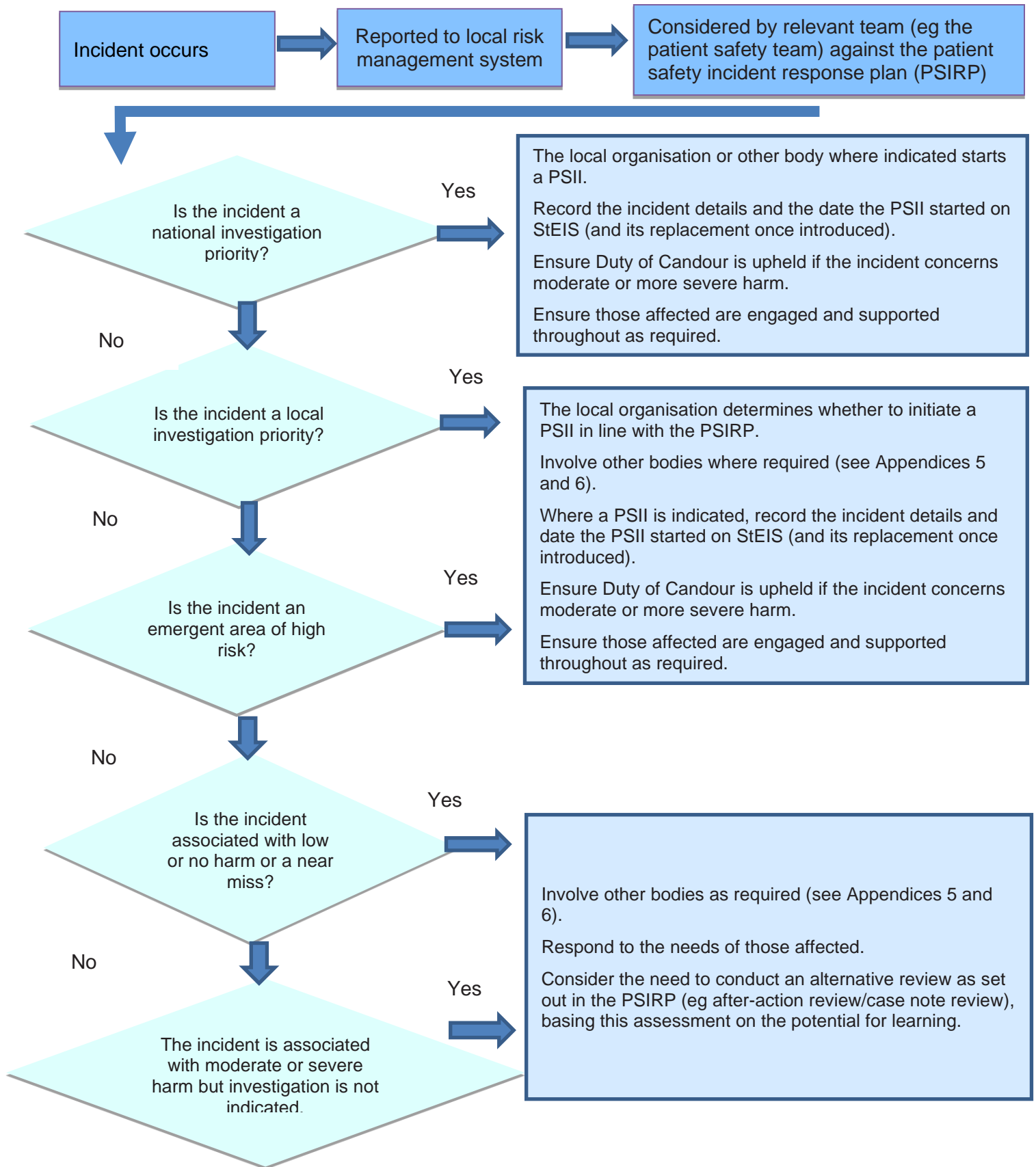
Where a PSII is to be conducted, the [national PSII standards](#) must be followed.

Typically the information available at the initial reporting stage will be insufficient for a full understanding of what happened and, more importantly, **why**. More information will need to be gathered. Table 2 in Part A above lists the tools and approaches that can be used to extract different types of information and learning following patient safety incidents. The quality of this learning will depend on the time, effort, skills and experience of those using the tools/approaches. The learning and what it helps to achieve should be shared with others.

Step 4: Share safety insight, implement improvements/solutions to prevent harm and monitor impact

Sharing the knowledge gained from activities associated with patient safety incident management – the ‘lessons learned’ – of itself may not achieve the desired outcome: that is, a lower risk of the same incident happening again or its prevention. Step 4 highlights the importance of being clear about what has been learned and how ‘lessons’ in the form of proposed improvements/solutions should be tested to see if they achieve the intended change and improvement.

Figure 2: Example process for determining if an incident should be investigated



Share safety insight

There are multiple opportunities through the incident management process to extract and share information, and this information can be used in different ways to support safety improvement. Information can be used at a team, department, organisation or system level to identify the most commonly reported incident types and insight about the nature of these incidents; triangulation with information from other sources (eg complaints, claims and coroner inquests) can provide further insight into the level of risk and potential opportunity for improvement.

Organisations must ensure they have systems to explore incident reporting data 'with curiosity' and to use the intelligence it provides to identify the areas in most need of improvement. PSIRF early adopter sites will explore how to do this well.

Implementing improvements/solutions to prevent harm and monitor impact

Once a PSII has been finalised, recommendations can be formulated and actions developed to reduce the risk of an incident happening again by addressing the key underlying causal factors. This is where the improvement journey starts.

People with relevant skills, experience and time to design and support technical aspects of improvement efforts are required, led by those skilled in supporting these efforts.

Measurement is fundamental to any improvement programme. Without it, organisations may invest time and effort implementing changes that have little or no impact or, in the worst case, increase the risk of further harm. From the start those responsible for implementing improvements/solutions must establish procedures to monitor actions and determine whether they are having the desired effect. Both outcome and process measures should be used to interpret the impact of actions and to inform how actions should be adapted if they fail to have the desired effect.²¹

Organisational escalation processes must be developed to manage situations where resources are insufficient to robustly implement actions or influence improvement, eg where an investment in technology or a widespread/systemic change may be the better option.

²¹ Canadian Patient Safety Institute (2012) [Canadian Incident Analysis Framework](#).

The ultimate test of continuous learning and improvement in response to patient safety incidents is to ask: Have changes been made and have they led to measurable and sustainable risk reduction? A positive answer must be substantiated with evidence.

Example

Providers of maternity and neonatal services should draw on the role of the safety champion at midwifery, neonatal, obstetric and trust board level to ensure insights and learning are resulting in measurable change locally. The local maternity system (LMS) should support rapid sharing of insights and learning for safety and improvement over a wider geographical footprint.

Part C: Governance arrangements

Patient safety incident data

Governance ensures systems are working as intended and action is taken where they are not. Data is critical for this and appropriate data needs to be used for each purpose.

Governance arrangements that include inappropriate measures of incident management performance, such as those focusing on aspects of process (eg timeframes for completion of patient safety incident investigations; PSIs) rather than the fundamental purpose of reducing risk and improving outcomes for patients, can drive inappropriate behaviours. Importantly, data on incident reporting rates should only be used in governance to identify worryingly low levels of reporting. This data is not an appropriate measure of the actual level of harm in a system because incident reporting is a behavioural activity influenced by both actual incidents and people's perceptions, beliefs and concerns. For example, when it is used for performance monitoring, people's concern about being held to account for problems with the systems they work in and which are outside their control can reduce reporting activity.

As reinforced in [The NHS Patient Safety Strategy](#), all organisations must ensure they:

- have eliminated inappropriate incident reporting and incident management performance measures from all dashboards and performance frameworks (see Table 6)
- monitor their reporting culture and people's confidence in their reporting and response procedures as part of their overarching governance systems.

The other data sources listed in Table 6 (together with those highlighted in Part B) do support/guide improvement in safety reporting cultures and PSI more specifically.

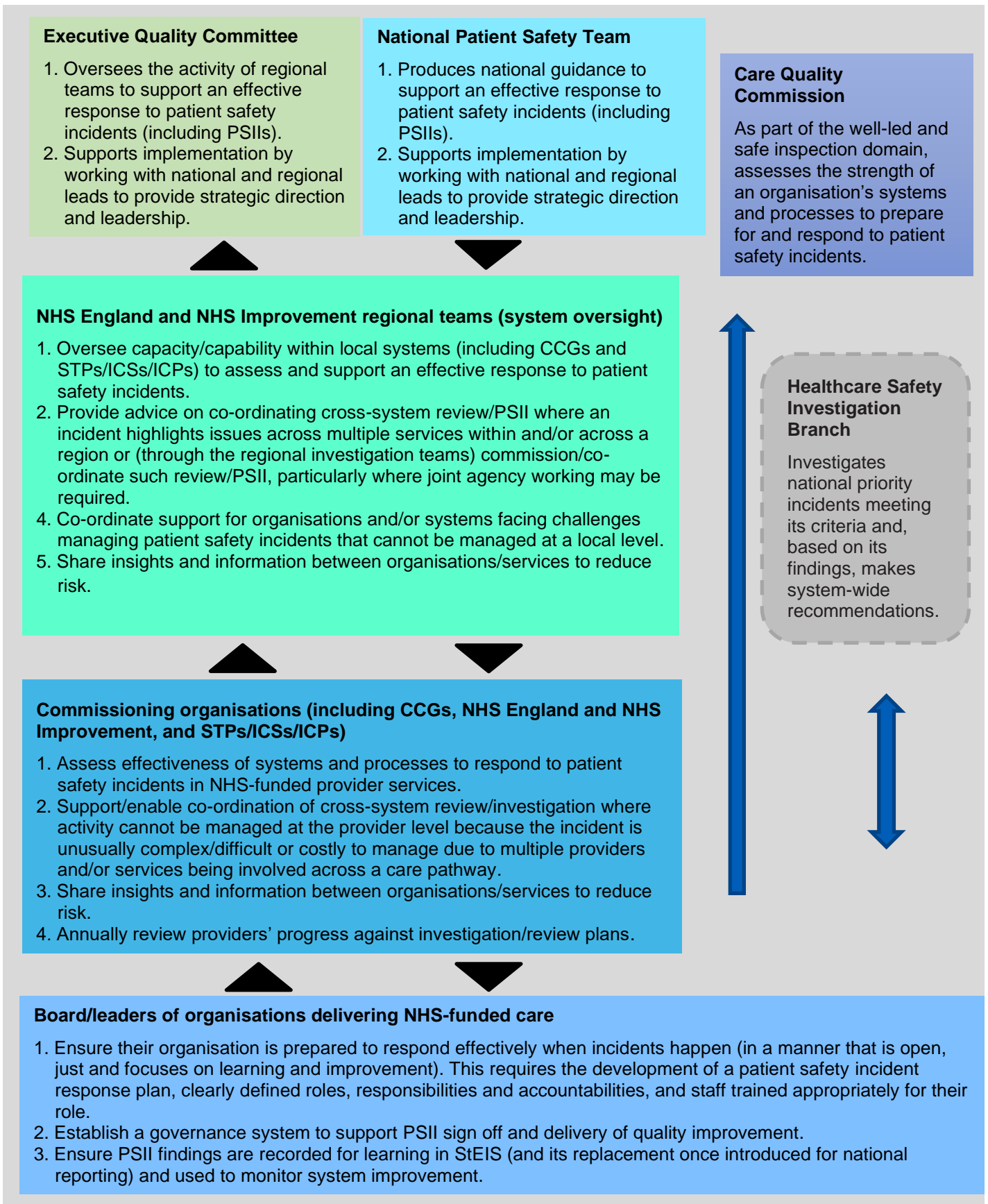
Table 6: Inappropriate use of data from incidents

Performance measures that must be abandoned	Data sources that provide intelligence about systems and processes for incident management
Incident measures – number of: <ul style="list-style-type: none"> • incidents • incidents defined as avoidable/unavoidable • Serious Incidents 	NHS staff survey data (specifically questions about number of staff reporting, confidence in reporting, perception that processes are fair and that information is valued and acted on). The findings from safety climate and/or culture surveys.
Investigation measures – number of: <ul style="list-style-type: none"> • ‘Serious Incident investigations’ (compared to other organisations) • investigations finalised within 60 working days 	Feedback from staff involved/affected. Feedback from patients and families. Pre and post-assessment of risk. Statistically significant increase or decrease in specific measures associated with the risk/incidents identified.

Organisational responsibilities

Healthcare organisations involved at all levels in providing NHS-funded care need to work collaboratively, with a common understanding of the aims of this framework, to provide an effective governance structure around the NHS response to patient safety incidents. Figure 3 below gives an overview of the organisational responsibilities.

Figure 3: Organisational responsibilities for an effective governance structure



Providers of NHS-funded care

The trust board, or partners or management team in the case of primary care, holds the primary responsibility and accountability for effective incident management in their organisation. Those in positions of accountability – through an assigned and appropriately trained lead – must ensure their organisation has the necessary systems, tools, policies and procedures (underpinned by appropriate behaviours of openness and transparency, a just culture and continuous learning and improvement) to prepare for and respond to patient safety incidents as described in Parts A and B. Governance includes identifying roles, accountabilities and responsibilities of staff to support an effective organisational response to incidents, and devising training and professional development plans for staff according to their roles.

Monitoring and annual review of the patient safety incident response plan (PSIRP) must form part of the overarching quality governance arrangements and be supported by clear financial planning to ensure appropriate resources are allocated to Patient Safety Incident Response Framework (PSIRF) activities, particularly PSII and safety improvement.

Providers should agree their PSIRPs with their lead commissioners and publish a summary document on their websites, followed by annual reports of PSII activity and improvement plans. Publication should align with related information about Learning from Deaths where applicable.

Leaders must be able to demonstrate how the organisation:

- ensures those affected by patient safety incidents (including patients, families and staff) are effectively:
 - supported
 - involved in the response to incidents
- ensures staff involved in patient safety incident response and PSII roles are properly trained
- monitors (on an annual basis) the balance of resources going into patient safety incident response and PSII versus improvement
- evaluates (on an annual basis) whether actions in response to patient safety incidents have measurably and sustainably reduced risk.

Patient safety incident investigation

This framework places the responsibility for the sign-off of locally-led (that is, provider-led) PSII with the board(s)/leaders of the organisation(s) involved. This means that someone who meets the training requirements for PSII and oversight should be responsible for reviewing a PSII report in line with the [national PSII standards](#) and signing it off as finalised, all overseen by an executive who meets the training requirements for PSII and investigation oversight.

Organisations must have processes to ensure actions recommended by PSII reports are monitored and reviewed, to check they are delivering the required changes and improvement, as well as mechanisms to support cross-system PSII (see Appendix 5).

Sensitive and confidential information in patient safety incident investigation reports

Records will need to be shared when commissioning and undertaking PSII. Commissioners should assist in this process where information is being transferred between organisations; it must be done in line with information governance structures²² and relevant guidance, regulation and legislation.²³

Only in the specific circumstances detailed in the guidance for access to health records are healthcare staff entitled to receive details about deceased persons and copies of their medical records. Health professionals must maintain their confidentiality obligations to a person after their death.

The investigation report must be written sensitively with the patient, family and carers in mind at all times. They should be invited to engage in any patient safety investigation and offered the opportunity to talk through the draft report with a member of staff so that, if necessary, the language used can be explained and/or altered before the report is finalised.

Although independent PSII are normally written for publication, local PSII reports will not be routinely published.

²² Information governance structures support investigations which involve all affected individuals and families – see National Patient Safety Agency (2009) [Being open framework](#) and [National guidance for NHS trusts engaging with bereaved families](#).

²³ See [Guidance for access to health records requests](#).

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

The right to privacy for both individual and family life, provided under Article 8 of the European Convention on Human Rights (ECHR)²⁴ must be considered.

Independent PSII reports will be shared with stakeholders, including the affected individuals and families, and are normally written for publication. The impact a published independent investigation report can have on those affected must be considered with care, especially when individuals may be identifiable.

Where a patient, or the family of a deceased patient, does not consent to publication, the rights of those involved must be balanced against the wider public interest when deciding whether to publish. If by identifying an issue or circumstances publication may prevent a similar incident, the wider public interest could well outweigh the rights of individuals and their desire for privacy to be maintained.

A contemporaneous written record must be made and retained of the factors considered in the decision to publish sensitive material, both those in favour and against, together with the final decision taken and the reasons for it. This is crucial as families, patients and the public may challenge these decisions.

Further guidance can be obtained from the Department of Health's [Guidance for access to health records requests](#) and the Access to Health Records Act 1990.

Training

As part of The NHS Patient Safety Strategy, work is underway to develop and deliver NHS-wide patient safety training. However, organisations should not delay work to ensure their staff are skilled for the roles in PSII while this takes shape. They can draw on current [tools and guidance](#).

²⁴ <https://www.legislation.gov.uk/ukpga/1990/23/contents>

Patient safety incident investigation training for lead investigators. In line with previous guidance detailed in the [Serious Incident Framework frequently asked questions](#), lead investigators should:

- have attended a theory and practical PSII training course which:
 - follows and promotes this PSIRF or its predecessor, the Serious Incident Framework
 - runs for a minimum of two days
 - follows and endorses current NHS PSII guidance
 - teaches recognised good practice approach(es) to systems-based PSII
 - includes modules on human factors, just culture and Duty of Candour
 - covers effective improvement/solution generation and implementation
 - promotes the use of NHS PSII tools and templates
- have conducted a full PSII within 12 months of training
- consider completing advanced training within three years of the initial two-day course to advance their skills in the above and in complex safety investigations spanning different care or organisational boundaries; engaging patients and staff in PSII; incident analysis; improvement science;²⁵ and PSII reports.

Patient safety incident investigation training for those overseeing, supervising or reviewing PSII. Those overseeing, supervising or reviewing PSII should have:

- attended a theory and practical PSII training course which:
 - follows and promotes this PSIRF or its predecessor, the Serious Incident Framework
 - follows and endorses current NHS PSII guidance
 - runs for a minimum of two-days
 - teaches recognised, good practice approach(es) to systems-based PSII
 - includes modules on human factors, just culture, Duty of Candour and ‘being open’
 - covers effective improvement/solution generation and implementation

²⁵ Improvement science is about finding out how to improve and make changes in the most effective way. It is about systematically examining the methods and factors that best work to facilitate quality improvement. Health Foundation (2011)
<https://www.health.org.uk/publications/improvement-science>

- promotes the use of NHS PSII tools and templates
- attended a one-day PSII oversight course
- attended training in coaching, feedback and delivery of learning
- conducted a full PSII within 12 months of training
- considered completing advanced training within three years of the initial two-day course to advance their skills in the above, complex PSII spanning different care or organisational boundaries; engaging patients and staff in investigations; incident analysis; improvement science and PSII reports.

Training for those teaching PSII skills. Patient safety incident investigation trainers must have:

- completed formal, structured theory and practical PSII training (in addition to conference attendances) that is centred on recognised, good practice in systems-based PSII. This should cover: just culture; human factors; engaging staff, patients and families; improvement science and complex investigations spanning different organisations, settings and stakeholder boundaries
- completed formal, structured training (in addition to basic investigation training and conference attendances) that provides additional and advanced skills in: human factors; Duty of Candour, 'being open'; patient and family liaison cognitive interviewing; a range of systems-based PSII analysis techniques; quality improvement
- completed formal training in coaching, feedback and delivery of learning
- completed update or advanced training within the last three years on core investigation-related subjects.

An NHS suppliers' PSII training framework will be developed to assist with identifying training suppliers. On publication, a link to this resource will be available on [the patient safety incident investigation webpage](#).

Medical examiner system

The national medical examiner system is being introduced across England and Wales during 2019/20.²⁶ This will first encompass deaths in acute care and is planned to be rolled out to cover all deaths by the end of 2020/21.

²⁶ For more details see: <https://improvement.nhs.uk/resources/establishing-medical-examiner-system-nhs/>

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

- improve the quality and accuracy of the Medical Certificate Cause of Death
- ensure timely and accurate notifications to the coroner
- listen to the bereaved, increasing transparency and offering them the opportunity to raise concerns.

Medical examiners will bring concerns about the care provided to patients who have died to the attention of both the trust mortality lead and the trust lead for the PSIRP. These leads will then ensure the death is considered for review and/or a PSII in line with the trust's Learning from Deaths policy and PSIRP. Where evidence, however identified, suggests the 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.

Commissioning organisations

New commissioning models

Where STPs and/or ICSs/ICPs within STPs are assuming both provider and commissioning roles, effective governance and accountability systems must be established to fulfil the relevant responsibilities of provider and commissioning organisations in responding to patient safety incidents.

Specific structures and procedures must be developed locally to fit with local arrangements and service architecture.

Multiple commissioners often contract services from the same provider; this can lead to confusion for the provider if each commissioner establishes separate reporting routes and sets different expectations. Commissioning organisations have a responsibility to work together to develop governance structures which support a co-ordinated approach to the oversight of patient safety incident management in all the services they commission.

Commissioners will support the implementation of good practice by appointing an appropriately trained patient safety lead(s) – see Training section above, and ensuring systems are established to do the following:

1. **Assess effectiveness of systems and processes to respond to patient safety incidents in the provider services they commission.** This means seeking information from providers through regular communication structures and/or assurance systems to determine whether there is:
 - Evidence of behaviours, through governance and leadership, that appropriately underpin the patient safety reporting, learning and improvement system. Quantitative and qualitative information needs to demonstrate:
 - openness and transparency, eg from recognised indicators of reporting culture and feedback from patients, families and carers affected by patient safety incidents
 - a just culture, eg from staff feedback; efforts to remove policies/procedures that undermine a just culture; demonstration of fair and consistent treatment of staff; separation of patient safety/learning investigations and accountability reviews/fitness to practise investigations; application of recognised tools (such as [A just culture guide](#))
 - continuous learning and improvement, eg from developing skills/capability among staff and improvement strategies; attention to monitoring and evaluation of actions taken in response to patient safety incidents.
 - Focus on establishing, improving and/or maintaining effective systems for responding to incidents including: establishing roles, responsibilities, accountability and applicable training provision; development of a PSIRP; establishing support systems for those affected; and testing the strength of all systems. Commissioners should work with providers to agree the PSIRP before a summary is published on the provider’s website.
 - Focus on delivering an effective response to patient safety incidents as and when they occur, eg appropriate immediate action; notification/involvement of others; facilitation of ongoing support; strategic approach to the selection of incident analysis tools (and compliance with the national PSII standards as required); systems to support monitoring and evaluation of actions taken in response to patient safety incidents to ensure changes deliver demonstrable improvement.

2. **Support co-ordination of cross-system PSIIIs.** All commissioners should assign leads to support this where required (that is, where a PSII involving multiple providers and/or services across a care pathway is too complex or costly

to be managed by the provider). This lead must liaise with other commissioners and providers to agree how the PSII will be led and managed and how the implemented actions will be monitored. Appendix 5 gives details about co-ordinating cross-system PSIIIs.

Commissioners should also ensure that providers have systems to support a co-ordinated and measured response to high profile or complex incidents, and one that focuses on supporting the needs of those affected and taking meaningful action in response to the incident's causes.

3. **Provide support for PSIRF-related improvement** where weaknesses in a provider's systems and processes for responding to patient safety incidents are identified. This may be through seeking support from colleagues in other areas or regional teams; sharing expertise by linking with other organisations whose systems, processes and behaviours are more developed; involvement with Academic Healthcare Science Networks
4. **Share insights and information across organisations/services to reduce risk.** Commissioners should seek to identify and work with organisations that have demonstrably improved/reduced risk and share the changes they have made with others.

NHS England and NHS Improvement regional teams (system oversight)

NHS England and NHS Improvement regional teams will support the NHS to understand patient safety risks and enable improvement. They will do this by:

- supporting the establishment of systems and processes for providers to locally respond to patient safety incidents
- reviewing the availability of relevant skills and capacity to deliver the framework for responding to patient safety incidents (the PSRIF from 2021)
- reviewing the availability of relevant skills and capacity to deliver the PSIRF
- sharing insights and information between organisations/services to reduce risk
- supporting co-ordination of local cross-system reviews and PSIIIs where required.

Regional teams will help co-ordinate cross-system PSIIIs, primarily by working with commissioners (and/or STPs/ICSSs/ICPs) to ensure they have the relevant systems

to support these investigations at a local level, and supporting co-ordinated and measured responses – both to take meaningful action against an incident’s causes and to meet the needs of those affected – to high profile or complex incidents. On occasion, regional teams will directly co-ordinate more complex, multi-organisation PSIIIs where these cannot be managed at a local system level. Appendix 5 gives details about co-ordinating cross-system PSIIIs.

Related to this, the Regional Independent Investigation Teams (RIITs) will help identify those incidents highlighting system-based, cross-system issues that may require a centrally co-ordinated and independent PSII, such as a mental health-related homicide.

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 or a spate of high-profile patient safety incidents, regional teams will work with relevant teams/individuals to determine how best to resolve identified problems.

Specialised commissioning

NHS England and NHS Improvement commission around 146 services directly through specialised commissioning arrangements and are responsible for ensuring the providers of these services apply this framework.

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, focusing on whether change and improvement follow its response to patient safety incidents. Inspection teams will apply this PSIRF when assessing the strength of an organisation’s systems and processes for preparing for and responding to patient safety incidents, as well as nationally agreed quality metrics. Incident data will not be inappropriately used as a measure of safety performance.

CQC will expect to be informed (via the regional relationship lead) of high profile and complex incidents, as part of the co-ordinated response. CQC will focus on ensuring that the provider can support the needs of those affected and take meaningful action in response to an incident’s causes.

Where it specifically considers PSII, CQC's review will be conducted by an appropriately trained inspection lead²⁷ against the [national PSII standards](#).

Healthcare Safety Investigation Branch

The Healthcare Safety Investigation Branch (HSIB) independently investigates around 30 patient safety concerns in NHS-funded care across England a year; these investigations do not apportion blame or liability.

HSIB decides what to investigate based on the scale of risk and harm, the impact on the individuals involved and on public confidence in the healthcare system, as well as the potential for learning that could prevent future harm.

Its investigation reports identify opportunities for relevant organisations with the power to make safety recommendations and observations.

HSIB also conducts about 1,000 local independent maternity safety investigations to identify common themes and influence systemic change as part of a national action plan to make maternity care safer.

For information about current HSIB priority areas and incidents that must be reported to it for a national independently-led investigation, refer to its [website](#) and Appendix 4.

Coroners

In their work with coroners, organisations should:

- Ensure that they comply with the new Notification of Deaths regulations which came into effect on 1 October 2019. These 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”.
- Ensure that they provide coroners with any requested documents, such as PSII reports or relevant supporting materials where these exist. Further, if they become aware that a coroner is holding an inquest into someone’s death, they should advise the coroner of the existence of any relevant documents they hold, even if these are not specifically requested.

²⁷ That is, an inspector who has received a minimum of two days’ patient safety investigation training.

- Make early contact with the coroner in the above circumstances to advise 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 continues to consider the potential impact of any shared investigative supporting materials entering the public domain.

Note: Coroners do not have powers to require an NHS organisation to undertake an investigation. However, where they request a PSII report and this does not exist because a PSII has not been done and is not due to be done, the organisation should, in discussion with the coroner, give serious consideration to undertaking a PSII or review. In many instances a 'case note review' may meet this requirement.

Appendix 1: Supporting patients, families and carers

Principles of the being open framework²⁸

'Being open' incorporates 10 principles that healthcare staff should follow when communicating with patients, their families and carers following a patient safety incident in which the patient was harmed. 'Being open' supports a culture of openness, honesty and transparency.

1. Acknowledgement

All patient safety incidents should be acknowledged and reported as soon as they are identified. Where a patient, their family or carers inform healthcare staff that something has gone wrong, they must be taken seriously from the outset, and treated with compassion and understanding by all staff.

2. Truthfulness, timeliness and clarity of communication

A nominated appropriate person should give patients, families and carers clear, unambiguous information in a truthful and open manner. This information should not come from different staff, and must not conflict, be unnecessarily complex or use medical jargon that a lay person may not understand.

What happened should be explained step by step as soon as possible after the incident, based solely on what is known at the time and without making causal or outcome predictions. Staff should explain that new information may emerge from a patient safety incident investigation (PSII), and that patients, families and carers will be kept up to date on progress with the investigation process until the full findings are available.

Patients, families and carers should be given a single point of contact for any questions or requests they may have.

²⁸ Adapted from National Patient Safety Agency (2009) [Being open framework](#).

3. Apology

Patients, families and carers should receive a meaningful apology as soon as possible – one that is a sincere expression of sorrow and regret for the harm resulting from a patient safety incident. Delay is likely to increase patient, family and carer anxiety, anger or frustration and no reason justifies it. Patient and public focus groups report that patients who do not quickly receive an apology are more likely to seek medicolegal advice.

A verbal face-to-face apology is essential as soon as staff become aware of an incident. A written apology must follow clearly stating the organisation is sorry for the suffering and distress resulting from the incident.

Organisations should agree the words to be used and decide who is most suited to give the verbal and written apologies; by considering seniority, relationship to the patient, and experience and expertise in the type of patient safety incident. These staff must be made available.

4. Recognising patient and carer expectations

Patients, their families and carers can reasonably expect to be fully informed of the issues surrounding their patient safety incident, and its consequences, in a face-to-face meeting with representatives from the organisation. They should be treated sympathetically and with equity, respect and consideration. Support should be provided for patients, families and carers across different protected characteristics and include tailored support such as an independent patient advocate or a translator.

Where appropriate, they should be told about the Patient Advice and Liaison Service (PALS) and other support organisations like Cruse Bereavement Care and Action against Medical Accidents (AvMA).

5. Professional support

Organisations must create an environment in which all staff (including those independently contracted) are encouraged to report patient safety incidents.

Staff should be supported throughout the PSII process because they too may have been traumatised by their involvement. They should not unfairly face disciplinary action, increased medicolegal risk or any threat to their registration. We advise

organisations to follow the [A just culture guide](#) when concerns about individuals are raised. These concerns must be managed completely separately from the PSII.

The Practitioner Performance Advice Service via NHS Resolution (see Appendix 6) can advise on handling such concerns and whether assessment of the individual's practice would be helpful. Where the organisation has reason to believe a member of staff has committed a punitive or criminal act, it should take steps to preserve its position and immediately advise that person so they can independently seek legal advice and/or representation, and support from relevant professional bodies.

6. Risk management and systems improvement

Every organisation should integrate 'being open' principles in local strategies, policies and procedures associated with responding to patient safety incidents. This contributes to an integrated approach to reducing risk and improving patient safety following a patient safety incident.

7. Multidisciplinary responsibility

Any local policy on openness should apply to all staff who play key roles in the patient's care. That most healthcare is provided by multidisciplinary teams should be reflected in communications with patients, families and carers when things go wrong – to ensure that 'being open' is consistent with the philosophy that incidents usually result from system failures and rarely the actions of an individual.

For 'being open' principles to be followed consistently across disciplines, senior clinical, nursing and managerial opinion leaders must support them and model behaviours by participating in PSII and clinical risk management.

8. Clinical governance

The clinical governance of PSII's needs to support 'being open'. Findings should be disseminated to staff so that they can learn from patient safety incidents. A system of accountability through the chief executive to the board is needed to ensure changes are implemented and their effectiveness reviewed. Practice-based risk systems should be established in primary care.

Organisations need programmes to continuously learn from patients' experiences of 'being open' and audits to monitor the implementation and effects of practice changes following a patient safety incident.

9. Confidentiality

Policies and procedures for 'being open' should fully consider and respect patient, family, carer and staff privacy and confidentiality. The details of a patient safety incident are confidential: communications with parties outside the clinical team should be on a strictly need-to-know basis and, where practicable, records should be anonymised. Patients, families and carers must be told how information about them will be used in any PSII process.

Advice on confidentiality and data protection must be sought from the relevant Caldicott Guardian and/or data protection officer as required to ensure the culture of openness and transparency is lawfully upheld.

10. Continuity of care

After an incident a patient can expect to continue to receive all usual treatment and to be treated with dignity, respect and compassion. If they express a wish to be transferred to another team, this should be arranged where practicable.

Sources of support

- [National guidance for NHS trusts engaging with bereaved families](#)
- [Learning from deaths – information for families](#) explains what happens after a bereavement (including when a death is looked into by a coroner) and how families and carers should comment on care received.
- [Mental health homicide support materials](#) for staff and families. This information has been developed by the London Region Independent Investigation Team in collaboration with the Metropolitan Police. It is recommended that following a mental health homicide or attempted homicide the principles of the Duty of Candour are extended beyond the family and carers of the person who died, to the family of the perpetrator and others who died, and to other surviving victims and their families.
- [Patient Advice and Liaison Services \(PALS\)](#) offers patients, families and carers confidential advice, support and information on health-related matters. As well as informally helping to resolve issues, PALS can guide people on filing a formal complaint and advise on accessing advocacy services.
- **NHS complaints.** Everyone has the right to make a complaint about any aspect of NHS care, treatment or service. The [NHS website](#) gives guidance on how to

do this and details of local advocacy providers. The independent [NHS Complaints Advocacy Service](#) will provide someone to help navigate the NHS complaints system, attend meetings and review information given during the complaints process. [Local Healthwatch](#) also provides information about making a complaint, including sample letters.

- [Parliamentary and Health Service Ombudsman](#) makes the final decisions on complaints patients, families and carers deem not to have been resolved fairly by the NHS in England, government departments and other public organisations.
- [Citizens Advice Bureau](#) provides UK citizens with information about healthcare rights, including how to make a complaint about care received.

Appendix 2: Roles and responsibilities

Roles, responsibilities and accountability need to be clear to ensure an appropriate response to patient safety incidents.

Trust boards (including board quality sub committees)

- Ensure that the patient safety incident response framework (PSIRF) is implemented from board to ward.
- Ensure that wider strategy development and implementation is aligned with the principles and requirements of the PSIRF.
- Take responsibility for leading the development of a just, open and learning culture within the organisation – and for role modelling the behaviours required to achieve this.

Chief executive

- Overall responsibility for ensuring the organisation has processes that support an appropriate response to patient safety incidents (including contribution to cross-system/multi-agency reviews and/or patient safety incident investigations (PSIIs) where required).
- Overall responsibility for ensuring the development of a patient safety reporting, learning and improvement system.
- Ensures that systems and processes are adequately resourced: funding, management time, equipment and training.
- Appoints executive lead for supporting and overseeing implementation of the PSIRF.
- Approves publication and ongoing review of the organisation's patient safety incident response plan (PSIRP).
- Ensures that the PSIRF, patient safety incident reporting data, patient safety incident investigation data, findings, improvement plans and progress are discussed at the board's quality subcommittee.

- Ensures that the organisation complies with internal and external reporting/notification requirements.
- Acts as spokesperson in complex/high profile cases where the media/public is engaged.

Governors (where applicable)

- Hold the board and non-executive directors to account for:
 - ensuring implementation of the PSIRF from board to ward
 - developing a just, open and learning culture within the organisation – and for role modelling the leadership behaviours required to achieve this

Executive lead for supporting and overseeing implementation of the PSIRF

Note: This may be the person with overarching responsibility for quality or more specifically patient safety. They must be a member of the board or executive team and equipped (through training²⁹ and professional development) with up-to-date safety skills, knowledge and experience, including conduct of patient safety review and investigation; knowledge of and appropriate responses to human factors; application of ‘being open’ and Duty of Candour principles; systems thinking/systems-based design; and quality improvement practices (including leadership for improvement).

- Ensures that the organisation has processes that support an appropriate response to patient safety incidents (including contribution to cross-system/multi-agency reviews and/or investigation where required).
- Ensures that processes for preparing for and responding to patient safety incidents are reviewed as part of the overarching governance arrangements.
- Ensures that the executive and non-executive team can access relevant information about the organisation’s preparation for and response to patient safety incidents, including the impact of changes following incidents.
- Oversees development and review of the organisation’s PSIRP.

²⁹ Training is available in specific skills to effectively respond to patient safety incidents, particularly PSII skills. An NHS-wide patient safety curriculum and training is being developed (as part of The NHS Patient Safety Strategy) and will include all relevant aspects of incident response. However, local systems should not delay work to ensure their staff are appropriately skilled while this national training takes shape.

- Agrees sufficient resources to support the delivery of the PSIRP (including support for those affected, such as named contacts for staff, patients, families and carers where required).
- Ensures that the Duty of Candour is upheld.
- Ensures that the organisation complies with the [national PSII standards](#).
- Establishes procedures for agreeing patient safety investigation reports in line with the [national PSII standards](#).
- Develops professional development plans to ensure that staff have the training, skills and experience relevant to their roles in patient safety incident management.
- Provides leadership, advice and support in complex/high profile cases.
- Liaises with external bodies/supports the chief executive as a spokesperson for the organisation as required.

Patient safety team/committee (or relevant alternative)

- Ensures that PSIIIs are undertaken for all incidents that require this level of response (as directed by the organisation's PSIRP).
- Develops and maintains local risk management systems and relevant incident reporting systems (including StEIS and its replacement once introduced) to support the recording and sharing of patient safety incidents and monitoring of incident response processes.
- Supports the development and review of the organisation's PSIRP.
- Ensures the organisation has procedures that support the management of patient safety incidents in line with the organisation's PSIRP (including convening review and PSII teams as required and appointing trained named contacts to support those affected).
- Establishes procedures to monitor/review PSII progress and the delivery of improvements.
- Works with the executive lead to address identified weaknesses/areas for improvement in the organisation's response to patient safety incidents, including gaps in resource including skills/training.
- Supports and advises staff involved in the patient safety incident response.

Patient safety incident investigators

Patient safety incident investigators must have been trained over a minimum of two days in systems-based PSII.³⁰

- Ensure that they undertake PSII in line with the national PSII standards.
- Ensure that they are competent to undertake the PSII assigned to them and if not, request it is reassigned.
- Undertake PSII and PSII-related duties in line with latest national guidance and training.

Named contacts for patients, families and carers

- Identify those affected by patient safety incidents and their support needs.
- Provide them with timely and accessible information and advice.
- Facilitate their access to relevant support services.
- Obtain information from review/PSII teams to help set expectations.
- Work with the patient safety team and other services to prepare and inform the development of different support services.
- Support staff training in openness and transparency.

All named contacts for patients, families and carers following patient safety incidents:

- must have received relevant training in communication of patient safety incidents
- should have experience of and been trained in 'being open' and Duty of Candour
- must have sufficient time to undertake this role; that is, they should be staff dedicated to this role or with dedicated time for this role
- need to be closely linked to PSII teams and individuals.

When appointing staff to this role their characteristics should also be considered.

They should:

- be able to establish a relationship with those affected (and become known to and trusted by the patient, their family and carers)

³⁰ [National PSII standards.](#)

- be able to offer a meaningful apology, reassurance and feedback to patients, their families and carers
- have a good grasp of the facts relevant to the incident but be sufficiently removed from the incident itself
- be senior enough or have sufficient experience of and expertise in the type of patient safety incident to be credible to the patient, their family and carers, and colleagues
- have excellent interpersonal skills, including being able to communicate with the patient, their family and carers in a way they can understand, without excessive use of medical jargon
- have a good understanding of how the incident will be responded to and ensure realistic expectations are set
- be able to liaise with several different individuals and be prepared to help those affected navigate complex systems/processes
- actively listen to patient, family and carer queries/concerns and engage with other staff to ensure these are responded to openly and honestly
- be knowledgeable about and provide access to different types of support (including independent advocacy services as required)
- be able to maintain a medium to long-term relationship with the patient, their family and carers where possible, and to provide continued support and information
- be culturally aware and informed about the specific needs of the patient, their family and carers.³¹

For continuity and consistency of communication, a co-contact should be assigned to support the lead contact and to act as lead contact during times when the first named contact is absent.

Junior staff or those in training must not be appointed as lead named contacts unless accompanied to all meetings with patients, families and carers and supported by a senior team member.

Named contacts for staff

- Facilitate private and confidential conversations with staff affected by a patient safety incident.

³¹ Canadian Patient Safety Institute (2012) [Canadian Incident Analysis Framework](#).

- Work with line managers to provide advice and support to these staff.
- Facilitate their access to additional support services as required.
- Liaise between these staff and review/PSII teams as required.
- Support staff training in recognising the signs of stress and post-traumatic stress disorder in themselves and others and how to access help and support.
- Work with the patient safety team and other services to prepare/inform the development of different support services.

Department leads/managers

- Encourage the reporting of all patient safety incidents and ensure all staff in their department/division/area are competent in using the reporting systems and have time to record and share information.
- Ensure that incidents are reported and managed in line with internal and external requirements.
- Ensure that they and their staff periodically review the PSIRF and the organisation's PSIRP to check that expectations are clearly understood.
- Provide protected time for training in patient safety disciplines to support skill development across the wider staff group.
- Provide protected time for participation in reviews/PSIIs as required.
- Work with the patient safety team and others to ensure those affected by patient safety incidents have access to the support they need.
- Support development and delivery of actions in response to patient safety reviews/PSIIs that relate to their area of responsibility (including taking corrective action to achieve the desired outcomes).

All staff

- Understand their responsibilities in relation to the organisation's PSIRP and act accordingly.
- Know how to access help and support in relation to the patient safety incident response process.

Commissioners and commissioning organisations (including CCGs, NHS England and NHS Improvement, STPs, ICSs/ICPs)

- Ensure that they are familiar with this introductory framework as they begin to consider how their roles and responsibilities will evolve to meet its requirements.
-

- Assess effectiveness of systems and processes to respond to patient safety incidents in NHS-funded provider services as demonstrated by the behaviours of openness and transparency; the existence of a just culture; evidence of continuous learning and improvement.
- Support/enable co-ordination of cross-system review/investigation where activity cannot be managed at the provider level because the incident is unusually complex/difficult or costly to manage due to multiple providers and/or services being involved across a care pathway.
- Provide improvement support where weaknesses are identified in a provider's systems and processes for responding to patient safety incidents.
- Share insights and information between organisations/services that have demonstrably improved care and or reduced risk.
- Annually review provider organisations' progress against investigation/review plans.

Governance arrangements:

- From April 2020, all commissioners of NHS services must identify an appropriate executive lead from within their organisation to support and oversee preparations for delivery of the PSIRF by summer 2021.
- **Specific roles/responsibilities:**
 - **Patient safety incident response plans (PSIRPs):**
 - (1) Work with providers to agree PSIRPs before their publication on providers' websites. The designated lead commissioner for the provider should lead for this work and involve associate commissioners proportionate to their level of interest in the provider.
 - (2) With local system leaders, assure effective application of local PSIRPs and national patient safety investigation standards.
 - (3) Monitoring and annual review of the PSIRP must form part of the overarching quality governance arrangements and be supported by clear financial planning to ensure that appropriate resources are allocated to review, investigation and improvement activities.
 - (4) In line with recommendations from the Kirkup Review of Liverpool Community Hospital Trust,³² where a regulator or oversight organisation has concerns regarding the safety of NHS-commissioned services, additional information and assurance will be sought from the

³² Kirkup B (2018) *Report of the Liverpool Community Health Independent Review*. <https://www.england.nhs.uk/2018/02/independent-review-liverpool-community-health-nhs-trust-published/>

provider. If this involves the commissioning of an independent investigation or review, this will be additional to those in the provider's PSIRP.

– **Reporting patient safety incidents on StEIS:**

- (1) Under the PSIRF, the 'StEIS' reporting platform will change from a system enabling commissioners to monitor the process and progress relating to individual investigations, to a reporting and monitoring system for providers.
- (2) Commissioners should move to using StEIS to conduct a single, annual audit of progress against each local provider's PSIRP. In line with these changes:
 - Reporting incidents previously defined as 'Serious Incidents' to StEIS will stop and providers will instead use StEIS to log and monitor all patient safety incidents identified as requiring a patient safety investigation (in line with national and locally identified priorities in their local PSIRPs).
 - Management and monitoring of individual investigations should be picked up immediately by providers.

– **Supporting cross-system patient safety investigations:**

- (1) All commissioning systems (and/or STPs or ICSs/ICPs) must develop their capacity and capability, where these are insufficient, for co-ordinating cross-system investigation and have systems to recognise incidents that extend beyond local boundaries and may require co-ordination at a regional level.

– **Information sharing to support patient safety investigations:**

- (1) Records will need to be shared when commissioning and undertaking patient safety investigations, in line with information governance structures and relevant guidance, regulation and legislation. Commissioners should assist in this process.

– **Continuous learning and improvement:**

- (1) All NHS organisations including commissioners must have plans to support the continuous development of their improvement skills, practices and behaviours. Their leaders also need to identify, measure and develop behaviours that foster an organisational culture conducive to learning and improvement.

– **Testing processes in commissioning and oversight bodies**

- (1) While providers are typically best placed to respond to patient safety incidents, commissioning and oversight bodies also have a role. They should therefore prepare, test and review their procedures in a similar way to providers, to ensure that they too are prepared to respond to patient safety incidents.

Appendix 3: Support for staff following a patient safety incident

Mental Health First Aid (MHFA) – England

Provides:

- [workplace guidance](#) for employers and employees
- information on [mental health first aid training](#).

Caring for the caregivers

The Improvement Academy hosts the ['second victim support website'](#). The term 'second victim' is under review but refers to healthcare workers who are impacted by patient safety incidents. While patients and families will always be the first priority following safety incidents, the wellbeing of staff involved is often overlooked but can leave staff lacking confidence, unable to perform their job, requiring time off or leaving their profession.

There is existing evidence on the importance and effectiveness of support programmes for such staff and their potential to counter the negative impact outlined above to result in more positive impact for staff and patients alike.

'Being open'

The [Being open framework](#) (2009) includes guidance (p32) on supporting staff when things go wrong.

Freedom to Speak Up

If staff have a concern about the organisation failing to respond to a patient safety incident, or about the nature of its response, they can seek support from their organisation's [Freedom to Speak Up Guardian](#).

A just culture guide

[A just culture guide](#) is useful when assessing concerns about individuals to ensure they are treated consistently, constructively and fairly. This should have a particularly positive effect on staff groups who have traditionally faced disproportionate disciplinary actions, eg Black, Asian and Minority Ethnic (BAME) groups.

The ASSIST ME model

Managers and others can use the [ASSIST ME model](#) (produced by the Irish Health Service Executive) to guide appropriate conversations and to develop the necessary procedures to support staff following their involvement in patient safety incidents.

Local occupational health services

Occupational health services help keep employees healthy and safe while in work and manage any risks in the workplace that are likely to give rise to work-related ill health.

Occupational health teams keep people well at work – physically and mentally – and will be happy to talk to you about the services they can provide.

A-EQUIP midwifery supervision model

A-EQUIP is an acronym for ‘advocating for education and quality improvement’. The A-EQUIP model is made up of four distinct functions: normative, restorative, personal action for quality improvement, and education and development. It supports a continuous improvement process that builds personal and professional resilience, enhances quality of care, and supports preparedness for appraisal and professional revalidation. The ultimate aim of using the A-EQUIP model is that through staff empowerment and development, action to improve quality of care becomes an intrinsic part of everyone’s job, every day, in all parts of the system.

Midwives, the [Local Supervising Authority national taskforce](#) and the project’s Editorial Board developed the [A-EQUIP operational guidance](#) which has four parts:

- Part 1: Describes the impact of the legislative change on midwifery regulation and the changes to midwifery supervision.

- Part 2: Describes the A-EQUIP model and its benefit to midwives and users of maternity services
- Part 3: Has a clinical focus. Case studies show how the model can be used to support staff working in clinical and non-clinical roles, and its benefits to the multidisciplinary team
- Part 4: provides guidance for midwives and providers of maternity services, and describes key actions for maternity providers, clinical commissioning groups (CCGs) and higher education institutes (HEIs).

Appendix 4: Maternity incident investigations

Patient safety incidents requiring referral to HSIB for investigation

In November 2017, the Secretary of State for Health announced a new maternity safety strategy – and directed the Healthcare Safety Investigation Board (HSIB) to conduct independent safety investigations for cases meeting the ‘Each Baby Counts’ and maternal deaths criteria listed below. All cases meeting these criteria should be referred to HSIB through the web portal provided to all trusts.

Criteria for HSIB investigations

- **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).
- **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).

These investigations replace local patient safety incident investigations (PSIIs) and bring a standardised approach, without attributing blame or liability and making engagement with families an integral part to understand events from their perspective. They are conducted in collaboration with trusts and the staff involved to support wider system learning.

Reporting patient safety incidents meeting the ‘Each Baby Counts’ and maternal deaths criteria

Reporting to HSIB

The local patient safety incident response plan (PSIRP) should include details on this arrangement.

A single reporting portal is being established within maternity to co-ordinate reporting requirements for cases meeting the ‘Each Baby Counts’ criteria.³³

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

As with all other patient safety incidents, those referred to HSIB should be reported to NRLS and StEIS (and their replacements once introduced).

- Patient safety incidents which 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’. Reporting of all these incidents to StEIS should continue uninterrupted while work is underway to simplify reporting for providers.
- Once the HSIB investigation report is finalised and handed back to the provider, the provider can complete the uploading of investigation findings to StEIS for sharing and learning purposes, ahead of closure of the incident.

Responsibilities for incidents referred to HSIB under Duty of Candour³⁴

- The requirements for Duty of Candour **notification** remain unchanged for these incidents: that is, all providers must inform the patient/family/carers of the incident and of any subsequent plans for conducting a patient safety incident investigation (PSII).

³³ <https://www.rcog.org.uk/en/guidelines-research-services/audit-quality-improvement/each-baby-counts/information-for-trusts-health-boards/frequently-asked-questions/#q1>

³⁴ For further details see <https://www.hsib.org.uk/maternity/>

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

Maternity incidents requiring a local response

Specific maternity incident reporting systems must be adhered to and reflected in the PSIRP:

- Reporting patient safety incidents to NHS Resolution as part of the Early Notification Scheme
- reporting incidents meeting the 'Each Baby Counts' criteria to the Royal College of Obstetricians and Gynaecologists
- MBRRACE-UK (Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK) reporting requirements.

Other maternity-related incidents identified as a 'current local priority for patient safety incident investigation' or an 'emergent risk for which the potential for new learning is so great that it warrants a full investigation' should be investigated in line with national [standards for patient safety incident investigation](#).

A separate local patient safety incident investigation (PSII) would **not** normally be indicated for incidents that meet the above 'Each Baby Counts' criteria for an HSIB investigation

However, local providers should complete:

- Duty of Candour requirements (ahead of handover to HSIB for further involvement of patients/families in the investigation)
- reporting on StEIS (either as a Serious Incident under the Serious Incident Framework (SIF) (2015), or as an incident identified for investigation under the new Patient Safety Incident Response Framework; PSIRF)
- any immediate actions identified as necessary to avoid and/or mitigate further serious and imminent danger to patients, staff and the public
- the Perinatal Mortality Review Tool (in parallel with and with the assistance of HSIB as it works through its independent investigation).

Note: In relation to the 30 investigations that HSIB selects to conduct annually – which are distinct from those that meet the 'Each Baby Counts' criteria – HSIB

advises that it **would** expect a separate local patient safety investigation to be conducted wherever this is indicated under current SIF or new PSIRF arrangements.

Incidents that require an alternative response or review should follow the local organisation's PSIRP.

Appendix 5: Co-ordinating response to incidents spanning service, organisational and agency boundaries

Note: This guidance will be revised as the structure and functions of new integrated care systems (ICSs) and NHS England and NHS Improvement regional teams develop.

Patient safety incident investigations (PSIIs) 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 occurred. Organisations must use their judgement and seek the views of local partners to ensure that PSIIs are co-ordinated at the most appropriate level of the system. Table A6.1 below provides a guide to the most appropriate level based on how much cross-system working will be required.

Some incidents will trigger a specific type of multi-agency review and/or PSII, eg a serious case review, safeguarding adult review, domestic homicide review or mental health-related homicide PSII. Organisations should refer to the relevant guidance for these (see Appendix 6).

All **providers** must have a process to recognise incidents that require a cross-system PSII. Where they have sufficient capacity and capability, providers can co-ordinate and lead cross-system PSIIs through their internal PSII teams. Where they do not, providers must engage early with commissioning teams and/or relevant teams within the wider sustainability and transformation partnership (STP), ICS or local maternity system (LMS) who can support the co-ordination of a cross-system PSII within a local system.

Table A6.1: Level of co-ordination of PSII

PSII characteristics	Who should co-ordinate the PSII
One which can be managed by a local provider (with involvement as required of other providers, agencies and local commissioners).	Local healthcare provider.
One involving several organisations across a local health economy, co-ordination of which cannot be managed by a local provider.	Leads within relevant commissioning organisation, STPs or ICSs who are responsible for supporting the co-ordination of cross-system PSII.
One involving several organisations in different health economies within or across NHS England and NHS Improvement regional geographies.	Leads within relevant NHS England and NHS Improvement regional teams who are responsible for supporting the co-ordination of cross-system PSII.

All **commissioning systems** (and/or STPs or ICSs) must develop their capacity and capability, where these are insufficient, for co-ordinating cross-system PSII (to support the activities described below) and have systems to recognise incidents that extend beyond local boundaries and may require co-ordination at a regional level. They must engage early with relevant NHS England and NHS Improvement regional leads where a PSII involves several different organisations or agencies within and across health economies spanning regional boundaries, to support co-ordination.

NHS England and NHS Improvement regional teams must similarly develop their capacity and capability for supporting the co-ordination of PSII spanning multiple health economies. They need to support commissioning systems (and/or STPs or ICSs) in developing the relevant infrastructure to support cross-system PSII at a local level – because, as explained above, PSII need to be managed as locally as possible. Systems should be prepared, tested and reviewed using the approaches described in Part 1 of the framework.

NHS England and NHS Improvement Regional Independent Investigation Teams (RIITs) will also support the NHS infrastructure in cross-system PSII.

Those responsible for co-ordinating a cross-system PSII must:

- establish the facts of the incidents (and consider where parameters need to be set)

- identify which organisations/services need to be involved, establish key contacts and arrange joint meetings between partners/key contacts as required
- ensure that a co-ordinated approach to identifying and supporting the needs of those affected (patients, families, carers and staff), with a suitable named contact appointed to provide ongoing advice and support
- establish governance and reporting structures to:
 - monitor the PSII: the co-ordinator should report all PSIIIs on StEIS (and subsequently its successor) and monitor progress against the PSII plan; which must be developed by the lead investigator and agreed by relevant parties, including those affected, so that everyone is clear about the scope, purpose and timeframe for completion
 - ensure compliance with the [national PSII standards](#)
 - monitor delivery of actions and improvement following completion
- establish whether the organisations involved can resource an appropriately skilled PSII team
- where they cannot, commission the necessary level of investigative support from appropriate external suppliers (following advice from the relevant RIIT)
- support access to information (working with data protection officers and Caldicott Guardians as required)
- agree how the PSII will be resourced or funded
- ensure individual organisations are preparing staff and resources to facilitate their contribution to the PSII
- ensure that the PSII team once established develops an investigation plan and that this is shared with relevant partners and, through their named contact, those affected
- agree sign-off procedures
- share copies of the report with interested parties and those affected
- support ongoing collaboration to monitor and deliver the improvements that are required across services/organisations.

All involved organisations must have systems to enable the development and monitoring of actions that support their own and the collective response to the recommendations made.

Appendix 6: Incident types and associated guidance for required specific processes

This appendix outlines key reporting, review and/or patient safety incident investigation (PSII) processes that may be associated with certain incident types. It is not exhaustive and will be revised as required. All organisations and individuals are invited to help keep this document up to date by submitting comments/updates/queries to: patientsafety.enquiries@nhs.net, marked for the attention of the Patient Safety Incident Response Framework (PSIRF) team.

The processes below cannot enforce demands to alter the timeframe, methodology or scope of the patient safety review

and/or PSII. In most cases incidents triggering different types of review and/or PSII will be managed separately. However, all organisations undertaking separate investigations relating to the same incident must establish good working relationships to ensure appropriate information is shared and that the response is co-ordinated between agencies (where required) with careful consideration given to the needs of those affected. Where the purpose and terms of reference of processes are the same, organisations may choose to work together as part of a combined effort to avoid duplication.

Body/specific process	Incident types	Guidance notes
Care Quality Commission (CQC)	Health and Social Care Act (2012) notifications	<p>Health and Social Care Act (HSCA) notifications must be made by all services registered under the HSCA. These include all NHS trusts, independent healthcare providers, adult social care, primary dental care and independent ambulance providers. The way notifications are made depends on their nature and type of service.</p> <p>For NHS trusts, statutory notification requirements (with the exception of certain incidents, eg deaths of patients detained under the Mental Health Act) are typically met by reporting incidents to the National Reporting and Learning System (NRLS). CQC's notification guidance outlines how each type of notification needs to be made.</p> <p>CQC conducts inspections to assess compliance with fundamental standards and thematic reviews to support system learning – it does not investigate individual patient safety incidents.</p>
Child Death Overview Panel (CDOP)	Child deaths (see also serious case review guidance)	<p>CDOP conducts case reviews to help prevent child deaths. Organisations must ensure they make appropriate referrals.</p> <p>See Child death overview panels: contacts for contacts.</p> <p>See the guidance Working together to safeguard children.</p>
NHS Digital	Data security and protection-related incidents	<p>The incident reporting tool for data security and protection incidents (which replaces the IG SIRI reporting tool in the previous information governance toolkit) should be used to report all data security and protection incidents.</p> <p>The new incident reporting tool reflects the new reporting requirements of the General Data Protection Regulation (GDPR), and for relevant organisations the Networks and Information System (NIS) Regulations.</p>

Body/specific process	Incident types	Guidance notes
		<p>Reportable data security and protection incidents must be notified through the reporting tool. A tool is available to help organisations assess whether incidents should be reported.</p> <p>For immediate advice and guidance relating to a cyber security incident, please contact the NHS Digital Data Security Centre on 0300 303 5222.</p>
<p>NHS complaints procedures – including reporting to the Parliamentary and Health Service Ombudsman (PHSO)</p>	<p>Complaints (about any aspect of care provision or concerns about the quality or outcome of a PSII arising from any reported route)</p>	<p>All organisations must ensure they comply with relevant complaints legislation.</p> <p>All complaints from patients, families or carers which involve a patient safety incident (PSI) should be dealt with and responded to in the same way as a PSI reported by staff to a local risk management system or to the national reporting and learning system and its successor system.</p> <p>Parliament set up the PHSO to help individuals and the public. The PHSO’s powers are set out in law and the service is free to everyone. The service looks into complaints where an individual believes injustice or hardship has resulted from an organisation not acting properly or fairly, or giving a poor service and not putting things right.</p> <p>The PHSO also looks into concerns about the quality or outcome of a PSII where deemed appropriate.</p> <p>Organisations must ensure they provide patients/families/carers and the public with relevant information relating to the PHSO.</p>
<p>Controlled drugs officer</p>	<p>Controlled drug-related incidents</p>	<p>These incidents must be reported to the provider’s accountable officer.</p> <p>Reviews and investigations should be undertaken in line with local policy and procedures, which must uphold relevant obligations.</p>

Body/specific process	Incident types	Guidance notes
Coroner	Deaths where unnatural causes are suspected, and all deaths of detained patients	<p>The treating clinician or medical examiner must report these deaths to the coroner.</p> <p>Note: The coroner's inquest into how a person died is different from any review and/or PSII undertaken as part of the PSIRF (which do not seek to determine cause of death). Every effort must be made to share relevant information with the coroner to support their inquest, and this can include the patient safety incident, review or PSII report. However, the coronial process does not determine the timeframe, methodology or scope of the patient safety incident response or process.</p>
Domestic homicide reviews (DHRs) (overseen by the Community Safety Partnership; CSP)	<p>Death of a person aged 16 or over has, or appears to have, resulted from violence, abuse or neglect by:</p> <ul style="list-style-type: none"> • a relative or a person with whom they were having or had been in an intimate personal relationship; or • a member of the same household as them 	<p>DHRs are locally-led multi-agency reviews undertaken to prevent domestic violence homicide and improve service responses for all domestic violence victims and their children, through improved intra and inter-agency working.</p> <p>DHRs were introduced by Section 9 of the Domestic Violence, Crime and Victims Act 2004 (DVCA 2004) and came into force on 13 April 2011.</p> <p>The relevant police force will usually inform the local CSP of a domestic homicide. However, any professional or agency can refer a domestic homicide to the CSP, in writing, if they believe important lessons for inter-agency working can be learned.</p> <p>Overall responsibility for setting up a review panel and appointing its chair rests with the chair of the CSP. They must decide whether a DHR should take place within one month of the homicide coming to their attention.</p> <p>Advice about involvement in a DHR can be sought from the relevant NHS England and NHS Improvement Regional Independent Investigation Team (RIIT).</p> <p>Note: Where the victim is under 16, the serious case review process (which applies similar principles) will usually take precedence.</p>
Health Education England (HEE)	Incidents affecting trainees who may need support	Directors of education and quality (DEQ) in HEE and its local education and training boards are responsible for the quality of the education and training of medical, nursing,

Body/specific process	Incident types	Guidance notes
		<p>dental and allied health professional students and others, and training grade doctors. Local arrangements may be made to inform DEQs of safety incidents.</p> <p>In cases where the responsible DEQ can help provide support and subsequently help ensure the standards of training are appropriate, the provider should ensure they are informed of the incident as soon as possible.</p> <p>Information provided through the patient safety incident reporting route must not invite comment or judgement on the capability of trainees.</p>
Independent Office for Police Conduct	<p>Indications of misconduct by police officers and police staff</p> <p>Cases where police contact (direct and/or indirect) may have caused or contributed to a person's death or injury</p>	<p>Guidance is available.</p> <p>Advice can be sought from the relevant NHS England and NHS Improvement RIIT.</p>
Learning Disabilities Mortality Review (LeDeR) programme	Deaths of patients with learning disabilities	<p>The LeDeR programme supports local areas in England to review the deaths of people with learning disabilities (aged four years and over) using a standardised review process.</p> <p>All organisations must have processes to ensure deaths of patients with learning disabilities are reported and reviewed using the LeDeR methodology.</p> <p>See notification of such deaths.</p>
Learning from Deaths (LfD)	The National Quality Board recommends that all inpatient deaths in the following categories are reviewed:	The LfD framework introduced specific requirements for NHS acute, mental health and community trusts and foundation trusts, including the need to record deaths and to review certain deaths to support learning and improvement of NHS services.

Body/specific process	Incident types	Guidance notes
	<ul style="list-style-type: none"> • where the bereaved or staff raise significant concerns about the care • those with learning disabilities or severe mental illness • those in a specialty, diagnosis or treatment group where an ‘alarm’ has been raised (eg an elevated mortality rate, concerns from audit or CQC) • where the patient was not expected to die, eg in elective procedures • where learning will inform the provider’s quality improvement work <p>A sample of other deaths should be reviewed to clarify where learning and improvement are needed most. If possible, patients who die within 30 days of discharge from inpatient services should be considered in scope for potential review</p>	<p>The framework supports existing expectations to report all patient safety incidents to the NRLS to inform national learning or to other relevant agencies/bodies (such as the coroner) as required.</p> <p>The framework outlines which deaths should be reviewed using relevant case note review methodology to determine whether there were any problems in the care the patient who died received, to learn from what happened.</p> <p>Many of these deaths will be reviewed using the structured judgement review (SJR) method unless specific review methods must be followed (such as for the death of patients with learning disabilities, child death, stillbirth and maternal death).</p> <p>Note: If a case note review (using SJR or similar method) identifies that a death was more likely than not due to problems in care, then a PSII (in line with the national PSII standards) must be undertaken.</p>

Body/specific process	Incident types	Guidance notes
Professional regulators	Professional misconduct/fitness to practise/competency concerns	<p>If grounds for professional misconduct are suggested, the appropriate lead (eg the responsible officer/medical or nursing director) in the NHS provider must be alerted to ensure appropriate referral to the relevant professional regulator.</p> <p>There are nine professional regulators: General Chiropractic Council, General Dental Council, General Medical Council, General Optical Council, General Osteopathic Council, General Pharmaceutical Council, Health and Care Professions Council, Nursing and Midwifery Council, Pharmaceutical Society of Northern Ireland.</p> <p>Information relating to all statutory regulators and the process for managing professional misconduct can be found in the Statutory Regulators Directory.</p> <p>Concerns about individual practice must be managed completely separately from any patient safety review and/or PSII (as described in Part B of the PSIRF).</p>
Public Health England (PHE)	Incidents in national screening programmes	<p>NHS England and NHS Improvement screening and immunisation leads must ensure the Screening Quality Assurance Team is notified when incidents occur within screening programmes.</p> <p>The guidance for the management of incidents in national screening programmes must be followed.</p>
Public Health England (PHE)	Incidents potentially and/or adversely affecting the health of a wider population such as decontamination failures; outbreaks of healthcare-associated infections; release/widespread exposure to harmful chemicals or a source of radiation	<p>When such incidents occur the responsible NHS provider must contact the relevant PHE centre through their health protection team and involve PHE as part of the local incident control team.</p> <p>Registered medical practitioners in England and Wales have a statutory duty to notify their local authority or local health protection team of suspected cases of certain infectious diseases. All laboratories in England performing a primary diagnostic role must notify PHE when they confirm a notifiable organism. PHE collects these notifications and publishes analyses of local and national trends every week.</p> <p>See further information and requirements.</p>

Body/specific process	Incident types	Guidance notes
Prison and Probation Ombudsman (PPO)	Deaths of prisoners, young people in detention, approved premises' residents and immigration detainees due to any cause, including apparent suicides and natural causes (NB: Services required to be registered with CQC must also notify CQC of the death)	<p>The PPO works with NHS England and NHS Improvement to commission an independent clinical review of the healthcare the person received in custody before their death. For further information see:</p> <ul style="list-style-type: none"> • PPO independent investigations • Guidelines for the provision of Clinical Reviewers to support Health and Justice deaths in custody investigations • Guidelines for Health and Justice Clinical Reviewer
Perinatal Mortality Review Tool (PMRT)	All stillbirths and neonatal deaths, and the deaths of babies in the post-neonatal period having received neonatal care	<p>This standard review tool supports systematic, multidisciplinary, high quality review of relevant perinatal incidents.</p> <p>Staff need to be authorised to access the PMRT even if they are already registered to use the MBRRACE-UK system. For authorisation, complete and return the authorisation form by email to: mbrracele@npeu.ox.ac.uk, or by post to: MBRRACE-UK, Department of Health Sciences, University of Leicester, George Davies Centre, University Road, Leicester LE1 7RH.</p>
Health and Safety Executive	Work-related injuries/incidents	<p>Incidents may need to be reported under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR). The trigger point for RIDDOR reporting is over seven days' incapacitation (not counting the day on which the accident happened). See further information on reporting.</p> <p>Work-related incidents in which someone dies (or incidents where a person's injuries are so serious that medical opinion is they are likely to die) should be reported under RIDDOR and managed in accordance with the work-related deaths protocol. See further information.</p>

Body/specific process	Incident types	Guidance notes
Mental health-related homicide reviews	Incidents where someone dies as a result of actions by a patient who has been receiving mental healthcare	Incidents may be investigated by the NHS provider and/or the relevant NHS England and NHS Improvement RIIT. Advice must be sought from this team.
Medicines and Healthcare products Regulatory Agency (MHRA)	Incidents related to medicines and medical devices or to blood and blood components	Organisations should report suspected problems with a medicine or medical device to the MHRA using the Yellow Card Scheme as soon as possible. The UK Blood Safety and Quality Regulations 2005 and the EU Blood Safety Directive require serious adverse incidents and serious adverse reactions related to blood and blood components to be reported to the MHRA, the UK Competent Authority for blood safety. This information is vital to the reports compiled by the Serious Hazards of Transfusion (SHOT). See further details on reporting .
NHS Counter Fraud Authority (NHSCFA)	Fraud, violence, bribery, corruption, criminal damage, theft or other unlawful action such as market fixing	Organisations must ensure they have appropriate reporting procedures. See further information .
NHS Resolution	Clinical and non-clinical negligence claims Where organisations (and sometimes individuals) have concerns/queries about an individual's practice	NHS Resolution supports the management of clinical and non-clinical negligence claims. Note: All claims are managed outside the patient safety review and/or PSII process. Regular lines of communication should be established to support this process. Practitioner Performance Advice (formerly the National Clinical Assessment Service; NCAS) provides healthcare organisations with impartial advice about managing and resolving concerns about the practice of individuals. Note: NHS Resolution has links to the General Medical Council and other professional healthcare regulators to support the delivery of Healthcare Professional Alert Notices. For services in England, Northern Ireland and Wales: phone: 020 7811 2600 or email: advice@resolution.nhs.uk

Body/specific process	Incident types	Guidance notes
Police	<p>Evidence or suspicion that the actions leading to harm (including acts of omission) were reckless, grossly negligent or wilfully neglectful</p> <p>Evidence or suspicion that harm/adverse consequences were intended</p>	<p>A senior member of staff in the reporting organisation should refer these incidents to the police.</p>
Safeguarding adults reviews (SARs) under the Care Act (overseen by safeguarding adult boards)	<p>Deaths of adults from abuse or neglect, whether known or suspected, and where there is concern that partner agencies could have worked together more effectively to protect the adult</p>	<p>A SAR is a multi-agency review process which seeks to determine what relevant agencies and individuals could have done differently that could have prevented the harm or death, not to apportion blame but to promote effective learning and improvement to prevent future deaths or serious harm.</p> <p>Further information can be found in the Care and Support Statutory Guidance, Chapter 14.</p> <p>Advice can be sought from the relevant NHS England and NHS Improvement RIIT.</p>
Serious case reviews (SCRs) (overseen by the local safeguarding children's boards; LSCBs)	<p>Abuse or neglect of a child is known or suspected; and either:</p> <ul style="list-style-type: none"> (i) the child has died; or (ii) the child has been seriously harmed and there is cause for concern about how the authority, its board partners or other relevant persons worked together to safeguard the child 	<p>An SCR is a multi-agency review process which seeks to determine what relevant agencies and individuals could have done differently that could have prevented the harm or death, not to apportion blame but to promote effective learning and improvement to prevent future deaths or serious harm.</p> <p>Chapter 4 of Working Together to Safeguard Children (2013), published by the Department for Education, sets out the processes that LSCBs should follow when undertaking SCRs.</p> <p>Advice can be sought from the relevant NHS England and NHS Improvement RIIT.</p>

Body/specific process	Incident types	Guidance notes
NHS England and NHS Improvement zero suicide ambition	Inpatient suicides	In 2018, the Secretary of State announced a zero suicide ambition for mental health inpatients. To support this, NHS England and NHS Improvement national team has committed every mental health trust to develop a plan to implement the zero suicide ambition and report their inpatient suicides to local risk management systems and the NRLS. For these commitments see 2018 cross-government workplan on suicide prevention .
MBRRACE UK	UK Maternal mortality UK Maternal morbidity UK Perinatal mortality/morbidity	See further information .

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