Shared Insights

The Patient Safety Incident Response Framework (PSIRF)

Lauren Mosley Head of Patient Safety Implementation, NHS England

Tracey Herlihey, Head of Patient Safety Incident Response Policy, NHS England

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brownejacobson LLP

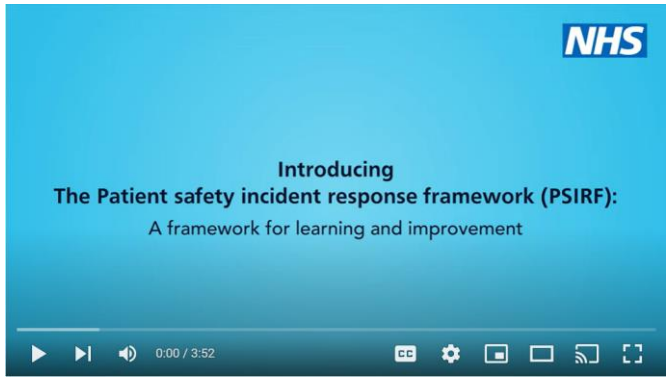
Introduction

We were delighted to be joined by NHS England's Lauren Mosley and Tracey Herlihey, the architects of PSIRF, which is due to be implemented by autumn 2023.

Lauren explained that PSIRF replaces the Serious Incident Framework 2015. Described by NHS England as a movement, the new Framework encompasses safety culture, quality improvement and supporting behavioural change across the NHS. It will continue to change and evolve.

The framework published in August 2022 reflected learning from early adopters and independent evaluation.

This video produced by NHS England will tell you more:



Key points

- PSIRF is NOT an investigation framework
- Serious incidents no longer feature
- Sets out new approach to achieve effective learning and improvement following patient safety incidents
- Embeds patient safety incident response within a wider system of improvement
- Supports a significant shift in safety culture
- Prompts a move away from a reactive and bureaucratic approach to safety to a more proactive approach
- Testing and revision has been a formal part of the development cycle

Amelia Newbold
Risk Management Lead
amelia.newbold@brownejacobson.com
+44 (0)115 908 4856

Nicola Evans
Partner
nicola.evans@brownejacobson.com
+44 (0)330 045 2962

Damian Whitlam
Partner
damian.whitlam@brownejacobson.com
+44 (0)330 045 2332

Patient Safety Incident Response Framework

Lauren Mosley
Head of Patient Safety Implementation, NHS England

Tracey Herlihey, Head of Patient Safety Incident Response Policy, NHS England

What does PSIRF include?

1. Compassionate engagement and involvement of those affected by patient safety incidents – patients/families/carers/ staff. It does not affect Duty of Candour. NHS England have created separate guidance to support compassionate engagement of those affected. The aim is to drive a very human and open process.
2. Application of a range of system-based approaches to learning from patient safety incidents – Patient Safety Incident Investigation (PSII) and RCA are not interchangeable terms, learning responses offer "a window on the system" rather than the identification of cause(s) relating to a specific incident. There are a range of responses in addition to PSII, e.g. case review, MDT, Swarm Huddle or After Action Review.
3. Considered and proportionate responses to patient safety incidents – see more on planning below
4. Supportive oversight focused on strengthening the effectiveness of patient safety incident response system functioning and improvement – changes relationship and ways of working/allocating resources.

Safety Incident Response planning

- Under PSIRF organisations are asked to work with stakeholders to develop a Patient safety incident response policy and plan (all incidents are considered).
- The plan is what will guide an organisation's response to patient safety incidents. Except for events which nationally require a specific type of response (e.g. never events) it is locally derived.
- It incorporates both proactive and reactive elements i.e. an organisation agrees how it will respond (or not respond) to incidents/issues which are known to them. However, the organisation must also have a process for the identification and response to incidents that highlight new/unknown issues.
- Plans are dynamic documents which should be kept under review. A full review is required every 4 years.

Patient Safety Incident Response Framework

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What does this mean for Coroners?

- In some cases there will still be an investigation report called a PSII report but this will be different from an SI Report (new template and new methods).
- Not all deaths reviewed by a Coroner will be subject to a full PSII.
- Under the new Framework, the learning response within the NHS should not be expected to make judgments about cause of death.
- If a PSII is undertaken regarding a death that will be reviewed by a coroner, the coroner will receive the PSII report.
- If a different learning response is undertaken, the output from the response will be shared with the Coroner.
- Where there is no specific report generated by the healthcare provider, they will undertake necessary work to respond to Coroner questions (and can consider/reconsider if an investigation or other learning response method would be beneficial).
- The remit of learning response methods is focused on system learning and improvement (and does not cover judgments about cause of death).
- Collection of statements is not required for any learning response method. A system based method using interviews, observations, cognitive walk throughs etc is used for information gathering.
- NHS England have held some regional webinars and have met with the Chief Coroner to discuss the changes being made. Early adopters have engaged with their local coroners during the implementation of PSIRF.

What does this mean for litigation?

- The remit of learning response methods is focused on system learning and improvement (they do not apportion blame or determine culpability or preventability).
- Statements no longer recommended as part of a PSII or learning response.
- Statements should be collected outside the learning response process.
- If a PSII or other learning response has been undertaken this will be shared as part of the litigation process.
- Staff will require support through the litigation (and or coronial process) separate to the learning response process.
- Training “lot” under development to support PSIRF, for PSIR, oversight and patient/ family and staffing engagement. Training all related to learning responses rather than legal responses.
- Exploring an additional lot to support training needed for other investigative processes e.g. claims and inquest.

Resources

There is loads more information on the website- (click here) including the framework, guidance and templates.

If you are not already a member of NHS Patient Safety Futures Forum, Lauren and Tracey recommend becoming a member, by emailing NHSps-manager@future.nhs.uk

What does PSIRF mean for Trusts when dealing with Coroners?

Nicola Evans,
Partner
Browne Jacobson LLP

Key points for Trusts to consider

The message is that early engagement by Trusts with their local coroner is key before the deadline for implementation in Autumn 2023. At a local level, this would usually be led by the Trust's legal team, who often have an agreed process in place for regular meetings and discussions with their local Coroners to discuss working arrangements. Regional NHS England colleagues are also considering how they can support this engagement alongside ICBs so that there is collective conversation and comms with Coroners.

Heads of Legal have an important role in supporting your Trust to develop the Patient Safety Incident Response Plan (PSIRP) – inquests and claims data will be crucial to develop an understanding of the patient safety incident profile and identifying where the areas of most concern are so that incident investigation can be targeted in the most appropriate way.

Turning to how we manage inquests, PSIRF is a total change in how the Trust will look at learning and there is no doubt that the implementation of PSIRF will impact on the presentation of organisational learning evidence at inquest.

For Coroners, their Statutory Duty under Regulation 28 remains the same – i.e. they have a duty to issue a PFD Report where their investigation gives rise to a concern that circumstances exist which create a risk of future deaths. The Chief Coroner, when speaking at our recent Health and Care Conference, was clear that nothing about the introduction of PSIRF alters the Coroner's statutory duty and therefore the onus is on the NHS organisation to ensure that evidence is presented at inquest to assure the Coroner that the duty to issue a PFD Report is not triggered.

Historically we have placed heavy reliance on SI reports to provide this assurance, because these reports set out the facts of the case, identify shortcomings in care and usually provide some findings which are relevant on causation.

The SI also has an Action Plan which we can use as the basis of our organisational learning report to the Coroner. So the SI Report fed several masters and it was very useful to us at inquest. Coroners usually ask for a copy of the SI Report and often a witness will speak to the report and it will be relied upon to assure the Coroner that a PFD is not required.

Under PSIRF we won't have the SI Report any more.

Under PSIRF, as outlined by Lauren above, not all deaths reviewed by a Coroner will receive a full patient safety incident investigation (PSII). Some will and if a PSII has been undertaken in relation to the death then this report will be disclosed to the Coroner. However, as Lauren explained, the PSII reports will look very different from an SI and will focus on exploring outcomes within complex systems; characterised by multiple interactions between various components, both human and technological, not root causes. Crucially, it will not cover cause of death or causation.

It is unlikely that the PSII on its own will be enough for an inquest where causative criticism is anticipated and in those cases you will need to give careful thought to your evidence on causation and PFD matters – you may need to prepare a separate Position Statement or organisational learning report. There are PSIRF outputs which may also help e.g. improvement plans. PSIIs can also still capture immediate actions where appropriate and suggested areas for improvement which will feed into improvement planning cycles. Legal teams will need to think about how all of this is presented to the Coroner.

What does PSIRF mean for Trusts when dealing with Coroners?

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As we have said, not all deaths reviewed by a Coroner will receive a full patient safety incident investigation (PSII). In some cases there will be a different learning response such as a case review, MDT, Swarm Huddle or an After Action Review. The output from that response will need to be shared with the Coroner. However – you will need to think about the best way to capture the detail at the time. How will these Case Reviews, Swarm Huddles and After Action reviews be documented contemporaneously? What quality assurance process will Trusts have in place to to ensure the documents are accurate? Where will that documentation be stored?

You will also need to think about how to present this output to the Coroner - some early adopters have agreed reporting templates/methods. Again, the remit of these other learning response methods is focused on system learning and improvement and they do not cover judgments about cause of death and causation, so you will still need to think about whether you need a separate report or Position Statement for the Coroner.

Trusts need to think about disclosure of any documentation that is generated during this process. The Chief Coroner has recently issued Guidance no 44 to Coroners dealing with disclosure obligations and suggesting wording that Coroners could use when ordering IPs to provide disclosure –

I direct that: (i) By [date] all Interested Persons, having conducted reasonable and proportionate searches, must assure the Court in writing that all potentially relevant documents identified by their searches have been disclosed to me; and (ii) By [date] all Interested Persons must indicate with precision and in writing any suggested shortcomings in disclosure made to them (within the scope of the Inquest).

Collection of statements is not required for any PSIRF learning response method. So if you typically share statements obtained through the Serious Incident process with the Coroner as factual evidence you need to revisit that too.

Under the PSIRF Framework, there should be no expectation for staff to write statements or reflections of any kind for a learning response. A system based method using interviews, observations, cognitive walk throughs etc is used for information gathering. Trusts should take steps to ensure that staff have adequate time to prepare for interviews etc and that they have had access to the relevant documents and time to read them in advance of any interview, cognitive walk through etc.

Trusts should take steps to ensure that staff understand that any documents created as part of the different responses to an incident are not protected by legal privilege. This means that if these documents are requested by the Coroner during the inquest process then it is likely that they will be disclosed to him/her and there might be focus on them in the Court.

Statements for the Coroners should be written specifically for them. Trusts should of course have a process to support staff with statement writing and questioning at inquest.

These are conversations you need to start having within your organisation and with your local Coroner now if you haven't already – so you can explain the differences and agree an approach to provide the Coroner with the information they need over the next 12 months so you are ready for implementation in Autumn 2023.

Key practical takeaways

- Engage with your local Coroner now if you have not already done so.
- Think about how you will manage disclosure obligations.
- Think about procedures around how and where you are going to store documents generated.
- Consider how you are going to present learning responses.
- Once PSIRF implemented, in individual cases think about whether a position statement or organisational learning report is required for an inquest. NB Improvement plans may also provide useful information

Disclosure in claims

Damian Whitlam,
Partner
Browne Jacobson LLP

Disclosure in claims

The search, disclosure and inspection of documents is a challenging and technical process and continues to need to be treated with care. In a claim, there are a number of rules all operating symbiotically at the same time. The rules of privilege and disclosure do not change as a result of the introduction of PSIRF. Part 31 of the Civil Procedure Rules and the case law that protects certain documents under legal advice and litigation privilege still apply. It is important to look at each case and document bearing in mind this framework, which NHS legal teams will be familiar with. However, if in doubt, then do seek legal advice. Once a document is disclosed to a third party, privilege is waived.

There are two issues to bear in mind in deciding if a document is disclosable.

1. For a party to have a right to inspect a document in the course of a claim, it must be a document that is relevant to an issue in the case. If PSIRF is looking at addressing systems issues that feed into ongoing patient safety, there may be occasions where it will be relevant. It is important to make sure you examine the allegations that are extant in a specific individual claim and whether the document addresses an issue that is relevant to a specific matter in issue in that claim. The rules of disclosure and inspection do not allow what is commonly referred to in litigation as “fishing expeditions”.
2. The search for documents must be proportionate. It is prudent to ensure that all documents collected in the course of an investigation are saved securely and are available to the Trust’s legal team. This can avoid issues where a patient’s representatives seek very wide searches of a Trust’s systems looking for documents they suspect exist but can’t be found. Satellite litigation around the extent of the search of disclosure and inspection can be costly and cause delay for both patients and Trusts.

Beware that as soon as a document is disclosed, privilege is waived. So during disclosure it is important to remember to ask the question as to whether the specific document in question is relevant to the matters in issue in that specific claim you are dealing with. If it is, it is then also advised that a Trust approach the patient’s representatives and agrees that the disclosed version will be a redacted version of the document.

During the general discussion which followed, some concern was expressed about the disclosability of documents generated as part of a PSIRF learning response inhibiting staff and colleagues from speaking up.

Feedback from an early adopter Trust

How we can help

The experience of an early adopter Trust

A representative from an early adopter mental health Trust spoke about their experience of PSIRF which they have found very useful for more focused learning and development in key areas.

Redaction of documents referring to third parties when providing disclosure to the coroner

This Trust tend to disclose everything and then also disclose a redacted version of the document with anything irrelevant to the Coroner's enquiry removed, and then present both documents to the Court and let the Coroner decide which information is relevant.

Liaison with the Coroner

In terms of liaison with the local Coroner, the phrase this early adopter Trust use is that "our investigations are into causation to learning and improvements rather than causation to death".

The early adopter Trust has also been presenting the Coroner with a lesson-learning statements in most cases.

How we can help

Our specialist team can provide advice and support to help with the transition to PSIRF and ensure that PSII reports are prepared and written to a high standard.

Areas we can help you with include:

- Deep dives of claims/inquests to assist with identifying your risk profile.
- Support and training in relation to drafting PSIIs (or Serious Incident reports during the transition to PSIRF) to ensure that they are clear and effectively communicate findings which are based on the evidence and linked to appropriate areas for improvement and developing safety actions https://www.england.nhs.uk/wp-content/uploads/2022/08/B1465-Safety-action-development-v1.1.pdf
- The documentation and storage of records produced in respect of responses other than PSII.
- Supporting you to support your staff through the inquest and litigation process.
- Training on other areas relevant to PSIRF including statement writing and duty of candour.

Contact us

Lorna Hardman
Partner

Nottingham
lorna.hardman@brownejacobson.com
+44 (0)115 976 6228

Simon Tait
Partner

Nottingham
simon.tait@brownejacobson.com
+44 (0)115 976 6559

Damian Whitlam
Partner

Nottingham
damian.whitlam@brownejacobson.com
+44 (0)330 045 2332

Amelia Newbold
Risk Management Lead

Nottingham
amelia.newbold@brownejacobson.com
+44 (0)115 908 4856

Nicola Evans
Partner

Birmingham
nicola.evans@brownejacobson.com
+44 (0)330 045 2962

Rachael Morris
Partner

Birmingham
rachael.morris@brownejacobson.com
+44 (0)121 237 3962

Contact us

Birmingham

Browne Jacobson LLP
15th Floor
103 Colmore Row
Birmingham B3 3AG

+44 (0)370 270 6000

Exeter

Browne Jacobson LLP
1st Floor
The Mount
72 Paris Street
Exeter EX1 2JY

+44 (0)370 270 6000

London

Browne Jacobson LLP
15th Floor
6 Bevis Marks
London EC3A 7BA

+44 (0)370 270 6000

Manchester

Browne Jacobson LLP
3rd Floor
No.1 Spinningfields
1 Hardman Square
Spinningfields
Manchester M3 3EB

+44 (0)370 270 6000

Nottingham

Browne Jacobson LLP
Mowbray House
Castle Meadow Road
Nottingham NG2 1BJ

+44 (0)370 270 6000

Dublin

Browne Jacobson Ireland LLP
Viscount House
6-7 Fitzwilliam Square East
Dublin 2
D02 Y447

+353 (0)1 574 3910

@brownejacobson

Browne Jacobson LLP

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