Patient Safety Incident Response Framework (PSIRF)

NHS England has committed to the introduction of the Patient Safety incident Response Framework (PSIRF). PSIRF will replace the previous serious incident report (SIR) framework, which is being phased out.

Contents

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patient safety and **justice**

AvMA is the charity for patient safety and justice. We provide specialist advice and support to people when things go wrong in healthcare and campaign to improve patient safety and justice.

For advice and information visit
www.avma.org.uk

Or call our helpline
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What is PSIRF?

PSIRF is the way anyone who provides services under an NHS contract is expected to respond to patient safety incidents.

It is important to know that the investigation and subsequent report are prepared for the purpose of learning and improving. The investigation is not prepared for the purpose of identifying whether the care provided was of an acceptable standard.

PSIRF sets out how certain NHS organisations should respond to a patient safety incident for learning and improvement. There are four phases to a PSIRF investigation:

(i) Planning

(ii) Information gathering

(iii) Synthesis

(iv) Interpreting and improving

When will PSIRF be introduced?

PSIRF should be used whenever a patient safety incident is investigated, however it is important to note that not all patient safety incidents will be investigated under PSIRF. The PSIRF investigation process was to have been put in place by Autumn 2023, however at the time of writing this leaflet (February 2024) it appears that some NHS providers are still in the process of adopting PSIRF.

Where the patient safety incident meets the definition of a notifiable patient safety incident, it should be dealt with by following the Duty of Candour – see below for more information.

Who does PSIRF apply to?

Anyone who provides services under an NHS Standard Contract must adopt PSIRF. That includes providers of acute care, ambulance services, mental health, and community healthcare providers.

PSIRF also applies to maternity and specialised services, although when it comes to maternity investigations other investigation processes such as Maternity Newborn Serious Investigations (MNSI) may be used instead of PSIRF. See our leaflet on MNSI: www.avma.org.uk/wp-content/uploads/MNSI-birth-investigations.pdf

It should be noted that MNSI only investigates certain types of maternity incidents, details of the type of incident can be found here:

https://www.mnsi.org.uk/our-investigations/what-we-investigate/

If a maternity incident does not meet the MNSI investigation criteria then the PSIRF may apply.

Primary care providers can adopt PSIRF if they wish to, but they are **not** required to. A primary care provider is a service which provides the first point of contact in the healthcare system, sometimes referred to as the "front door" of the NHS. GP services, community pharmacy, dental and optometry (eye health) services are typical examples of a primary care service.

The Duty of Candour

Regardless of whether a patient safety incident occurs which is to be investigated under PSIRF or any other investigation such as MNSI, providing the patient safety incident is considered a **"Notifiable safety incident"** then

THE DUTY OF CANDOUR MUST ALWAYS BE FOLLOWED.

Commonly asked questions on Duty of Candour:

Q: Who does the duty of candour apply to?

A: It applies to every health and social care provider regulated by the Care Quality Commission (CQC)

Q: What is the duty?

A: To be open and transparent with the patient (or their family/loved ones) when a notifiable safety incident has occurred. Reasonable support should be provided, and a written record of the incident should be sent to the patient including an apology. The written record is often referred to as a Duty of Candour letter – see below for more details.

Q: What is a notifiable safety incident?

A: It is any UNINTENDED or UNEXPECTED incident which in the health care professional's opinion **could** or **appears to have** resulted in the service users: (i) Death (ii) Severe or moderate harm (iii) Prolonged psychological harm

Q: When does the duty apply?

A: The duty to be open and transparent applies as soon as practicable after the healthcare provider becomes aware that a **Notifiable Safety Incident** has occurred. See above for definition of a notifiable safety incident.

Q: What information should be included in a duty of candour letter?

A: A duty of candour letter is the written notification provided by or on behalf of the healthcare professional treating the patient about the notifiable patient safety incident which occurred.

The letter should contain or be followed up with correspondence which:

- Provides a true written account of all the facts known to the health service body at the time they notify the patient in writing.
- Explains what further enquiries into the incident are considered to be appropriate.
- Includes an apology
- Provides details of any enquiries to be undertaken
- Provides the results of any further enquiries into the incident.

Please see our leaflet on the duty of candour for more information:

https://www.avma.org.uk/wp-content/uploads/Duty-of-candour.pdf

The Serious Incident Reporting (SIR) Process:

Under the previous Serious Incident Report (SIR) process an investigation would be carried out when a recognisable trigger occurred. The triggers were that there had been:

- An unexpected or avoidable death.
- An unexpected or avoidable injury resulting in serious harm.
- A never event.
- An allegation of abuse.

Any patient safety incident which could be categorised as one of the above gave rise to a serious incident investigation. The Serious Incident Reporting process sets out when and how to investigate a patient safety incident, PSIRF takes a different approach.

Have Serious Incident Reports (SIR) ceased?

Depending on when your incident occurred a SIR may still be underway. If the patient safety incident occurred after autumn 2023 then the investigation is likely to fall under the Patient Safety Investigation Reporting Framework (PSIRF). All providers of NHS Healthcare are expected to have adopted the PSIRF approach to patient safety by autumn 2023, in practice some NHS practices will be quicker than others to introduce and apply PSIRF.

If the NHS provider has not yet introduced PSIRF, then they will be using the old Serious Incident Reporting (SIR) model of investigation. The SIR is being phased out, so increasingly the patient safety investigation will be carried out according to PSIRF.

What is the difference between a SIR investigation and PSIRF?

PSIRF differs from SIR in that it is much more flexible. PSIRF investigations do not occur because a particular incident triggers the need for an investigation, rather the investigation is introduced because it is required to establish learning and improvement. This means, that not every patient safety incident will be subject to an investigation under PSIRF. If a trust believes it know what went wrong and why the incident occured it may not investigate further.

What triggers PSIRF?

The Patient Safety Incident Response Framework (PSIRF) is triggered by a patient safety incident.

The PSIRF expects that where a patient safety incident has occurred, this will be explained to the patient and/or family, a description of the incident should be clearly set out. Where an investigation is to take place under PSIRF, the terms of reference should be discussed and shared with you. Please see below for more information on the terms of reference.

What is the PSIRF definition of a patient safety incident?

Patient safety incidents are ***any unintended or unexpected events (including omissions) in healthcare that could have, or did, lead to harm for one or more patients***. Examples of patient safety incidents include never events, and deaths thought to be due to problems in care – this is not a comprehensive list. Each patient safety incident will be considered against the facts and circumstances of the case.

It is important to note that PSIRF uses the above definition of a patient safety incident whereas the Duty of Candour applies in cases where a "notifiable safety incident has occurred". Please see above for paragraph on "The duty of candour".

Why has PSIRF been introduced?

The PSIRF has been designed to enable organisations to use their incident response resources for improvements, *"rather than repeatedly responding to patient safety incidents based on subjective thresholds and definitions of harm".*

PSIRF enables NHS trusts and others to take a *"proportionate approach to responding to patient safety incidents"* but, what does this mean in practice and for ordinary members of the public who are concerned that a patient safety incident has occurred? There is no one easy answer to this question, under PSIRF each NHS trust is responsible for their own patient safety response process, including what to investigate and how. Please see the paragraph below entitled "When is a PSIRF Investigation carried out?"

What can I expect from PSIRF?

The framework aims to prioritise ***compassionate engagement and involvement*** of those affected by patient safety incidents, that principle applies to NHS staff as well as the person or patient to whom the incident occurred, their family, close relations, partners, siblings, children, guardians, carers and anyone else with a direct and close relationship to the patient.

PSIRF recognises:

1. **Needs:** That people who have been affected by a patient safety incident may have a range of needs, including clinical needs as a result of the incident and these must be met where possible.

2. **Engagement:** This enables the NHS understanding of what happened and potentially how to prevent a similar incident in the future. Engagement describes everything an organisation does to communicate with and involve people affected by a patient safety incident in a learning response.

3. **Support:** Compassionate engagement and involvement include providing practical advice. Support in this context requires staff to consider if the person affected and their family have the correct support mechanisms available to them. If they do not, they should be referred or signposted to appropriate agencies or groups.

Support: Is assistance or comfort, which aims to assist people in coping with a variety of issues according to their individual needs. Support is broadly interpreted and may mean physical and/or psychological support and/or information and advice or advocacy needs. Support can be provided in a variety of ways, for example:

- By the healthcare provider
- By the persons own family, friends, or networks,
- By independent organisations
- By individuals specialising in different forms of support

Compounded harm: The framework is committed to preventing the harm being compounded through the investigation process. Compounded harm is not defined but includes things like additional harm caused by erosion of trust in the organisation and a feeling that the duty of care has been removed.

The core principles of PSIRF

There are nine core principles which are flexibly applied, they are flexible because the extent to which they apply will vary according to the different needs of the individuals affected. The core principles are:

1. **Apologies** are meaningful.

2. **Approach is individualised** – the approach should be adapted to reflect an individual's changing needs whether practical, physical or emotional

3. **Timing is sensitive.** This means you can expect the level of engagement to reflect the needs of the person affected.

4. **Treatment of person raising concern:** Those affected are treated with respect and compassion.

5. **Guidance and clarity are provided on the investigation process.** This means explaining what a patient safety incident is, why the incident is being investigated or what the learning response entails. All communication should be clear, describe the process and its purpose and not assume any prior understanding.

6. **Those affected are heard:** this is about being listened to and providing the opportunity to share your experience

7. **Collaboration:** Approach to the investigation is collaborative and open

8. **Subjectivity is accepted:** This is about acknowledging that different people will experience the same incident in different ways, no one person's experience should be prioritised over anyone else's, and sources of information should be viewed as credible.

9. **Strive for equity:** recognising that an appropriate response for a family may be different to what an organisation or member of healthcare staff considers to be appropriate, the need to learn from an incident should be weighed against the needs of those affected by the incident.

When is a PSIRF investigation carried out?

PSIRF applies when a patient safety incident has occurred, however this does not mean that an investigation will automatically follow. An investigation is more likely to take place if it will provide learning and an opportunity for improving systems.

A PSIRF investigation is not guaranteed. It will depend on the nature of the incident and what is known about it. Not every patient safety incident will have an investigation, but the organisation must be able to say why it has decided to investigate or not.

There may be times when other investigation processes, such as when an inquest is being held where it might be more appropriate to see what is covered by the coroner's inquiry before carrying out a PSIRF investigation.

A patient safety incident *may* result in a PSIRF investigation. By contrast, a notifiable patient safety incident *must* result in the duty of candour being followed.

Whether a PSIRF investigation is carried out or not will depend on the particular circumstances of each patient safety incident. There is no one size fits all approach to whether a PSIRF investigation is required. The approach is adaptable. However, the organisation should:

(i) Be familiar with the facts of the incident. Where a family or staff member informs the organisation that something has gone wrong, they should be taken seriously.

(ii) Explain the patient safety incident in appropriate language.

(iii) Describe any immediate actions taken in response to the incident.

(iv) Describe how the organisation intends to respond, advise if a learning response is planned, whether improvement work is already underway and whether a review will be conducted to understand if further learning is required.

What you can expect if there is a PSIRF investigation

Where an investigation is to be carried out the organisation should:

- Notify you that this has been triggered.

- Ask you if you need any particular support.
- Explain and provide information about the process. You should be given an opportunity to ask any questions about the process.
- Give you the opportunity to set out your concerns and queries.
- Give you a copy of the Terms of reference: You should be given a draft copy of the terms of reference and be able to comment on it.
- Offer a suggested timetable for investigation and explain any likely delays.
- Make time to answer any questions or concerns you may have and ensure that everyone has an equal opportunity to engage in the process.
- Always apologise for the patient safety incident occurring at the earliest opportunity. Meaningful apologies should be provided where appropriate, they should not be contingent on the outcome of any investigation which may take place.
- Provide you with information on other redress such as a formal complaint.

About the PSIRF Terms of Reference

Where an investigation into a patient safety incident takes place, the nature and extent of the investigation should be clearly set out in writing and explained to the patient and/or their family. The terms of reference are important as they set out what the investigation will look at and identify the questions that need answering during the investigation.

The organisation should explain how the terms of reference were identified. You should have the opportunity to set out any questions not covered by the terms of reference which you think are relevant to the investigation.

How AvMA may be able to help

AvMA may be able to assist you with explaining the terms of reference and support you in identifying what issues the investigation should cover. We can also advise on the duty of candour and what is expected under the new PSIRF investigation system. If you would like assistance from us then please complete a New Client Form and one of our specialist workers will get back to you:

https://www.avma.org.uk/help-advice/new-client-form

www.avma.org.uk/donate

Be part of the movement for better patient safety and justice

Support AvMA's work today

You can help make healthcare safer and fairer for all

Our vision is a simple: **People who suffer avoidable medical harm get the support and the outcomes they need.** This vision is underpinned by four objectives, we believe, will transform trust in the NHS and healthcare generally and significantly cut the cost – financial and human – which is incurred annually in settling legal claims as well as dealing with the human costs associated with traumatic medical injuries and death. Our four key objectives are:

- To expand the range of communities we serve and so enabling more people experiencing avoidable harm to access services from us that meet their needs
- To empower more people to secure the outcomes they need following an incident of medical harm, whilst providing caring and compassionate support
- To eliminate compounded harm following avoidable medical harm
- To have the necessary diversity of sustainable resources and capacities to deliver

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£5/month could provide vital advice to patients and families via our helpline

£10/month could help train a volunteer helpline advisor

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