NHS
Cornwall and
Isles of Scilly

Patient safety incident response policy

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NHS Cornwall and Isles of Scilly Integrated Care Board

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1. Introduction

This policy describes and defines the responsibility of NHS Cornwall and Isles of Scilly Integrated Care Board, known thereafter as ICB, when providing oversight to organisations who have transitioned as 'early adopters' to the introductory patient safety incident response framework (PSIRF) and for organisations to whom the serious incident framework (SIF) continues to apply.

In March 2020, NHS England (NHSE) published the PSIRF. The PSIRF is a key part of the patient safety strategy (NHSE 2019) and supports the NHS to improve its understanding of safety by drawing insight and learning from patient safety incidents.

The PSIRF replaces the serious incident framework (2015) and makes no distinction between 'patient safety incidents' and 'serious incidents.' 'Serious Incidents' and their associated thresholds no longer exist under PSIRF. PSIRF promotes a proportionate approach to responding to patient safety incidents by ensuring resources allocated to learning are balanced with those needed to deliver improvement.

Cornwall Partnership NHS Foundation Trust (CFT) and the Royal Cornwall Hospital NHS Trust (RCHT) are early adopter provider organisations of the PSIRF, all other organisations nationally (excluding primary care) are expected to adopt PSIRF in 2022 as part of the NHS standard contract.

Primary care services and independent providers of NHS funded care should continue to use the SIF until additional national guidance is released for these organisations.

This policy document will be reviewed when the further national PSIRF guidance is published and thereafter annually.

2. Purpose

This document sets out the general principles and processes for the management patient safety incidents (PSI's) and serious incidents (SI's) occurring within services commissioned by the ICB.

This revised policy is based on the introductory version of the PSIRF 2020 for which RCHT and CFT have early adopter status. The document is also informed by the national serious incident framework published by NHS England in March 2015[1], which is relevant to NHS funded care in the primary care and independent sectors.

Adherence to this policy will support provider organisations and the Cornwall system to transition from the SIF to PSIRF.

This policy will define the responsibilities of the ICB as commissioners in the development and monitoring of the individual organisations patient safety incident

response plan, and the responsibilities of the commissioner for those organisations who continue to report serious incidents under the SIF.

This policy should be read in conjunction with the following guidance:

- Serious incident framework – NHS England (March 2015)
- Revised never events policy and framework and never events list (2018)
- The patient safety incident response framework 2020 NHS England (2020)
- The patient safety strategy NHS England (2019)

3. PSIRF

The PSIRF sets out the NHS's approach to developing and maintaining effective systems and processes for responding to patient safety incidents for the purpose of learning and improving patient safety.

Patient safety incidents are unintended or unexpected events (including omissions), in healthcare that could have or did cause harm to one or more patients.
PSIRF fundamentally shifts how the NHS responds to patient safety incidents for learning and improvement. Unlike the SIF, PSIRF is not an investigation framework to determine the cause of death or to hold any individual or organisation to account. PSIRF advocates a co-ordinated and data-driven approach to patient safety incident response that prioritises compassionate engagement with those affected by patient safety incidents. PSIRF embeds patient safety incident response within a wider system of improvement and prompts a significant cultural shift towards systematic patient safety management.

'Early adopter' provider organisations are required to develop a thorough understanding of their patient safety incident profile, ongoing safety actions (in response to recommendations from investigations) and established improvement programmes. To achieve this each organisation must collect and triangulate information from a wide variety of sources and collate via a wide stakeholder engagement exercise. The output of this patient safety incident response planning exercise is used to inform the selection of a proportionate response when something goes wrong. This may include a response to generate safety actions for improvement where this does not already exist, or to ensure that a safety improvement plan is put in place where learning from patient safety incident response has already been identified.

The PSIRF approach is flexible and adapts as organisations learn and improve to ensure organisations can explore patient safety incidents relevant to their context and the populations they serve.

The principles and practices endorsed by PSIRF are aligned with the NHS patient safety strategy and wider initiatives under the strategy including the introduction of patient safety specialists (PSS), the development of a national patient safety syllabus, development of the involving patients in patient safety framework and the introduction of

the learn from patient safety events service (the successor to the national reporting and learning system (NRLS)).

3.1 Who does PSIRF apply to?

Currently, the PSIRF applies only to those organisations who have early adopter status (RCHT and CFT). When launched across England (anticipated spring 2022) the PSIRF will be a contractual requirement under the NHS standard contract and as such is mandatory for services provided under that contract including acute, ambulance, mental health, and community healthcare providers. This will include specialities within organisations such as maternity services and all specialised services.

3.2 Secondary care providers that are not NHS trusts

Secondary care organisations that provide NHS funded care under the NHS standard contract which are not NHS trusts or foundation trusts (for example independent provider organisations) will also be required to adopt this framework for all aspects of NHS funded care and may apply this approach to their other services for consistency. These organisations may not need to undertake the full analysis required for patient safety incident response planning (for example due to limitations on data availability), however processes such as stakeholder engagement in preparing plans are still required.

3.3 Primary care and PSIRF

Primary care services will continue to report patient safety incidents in line with the SIF (see section 10) until further national guidance is published regarding PSIRF and primary care. This guidance will be amended when further national guidance is received.

4. PSIRF organisational roles and responsibilities

(See appendix 1 for further details)

4.1 NHSE national team

NHSE national team will oversee the activity of regional teams to support effective response to patient safety incidents, providing strategic direction and leadership while monitoring effectiveness of PSIRF.

4.2 NHSE regional team

The NHSE regional teams will support ICB PSIRF leads with the learning system within NHSE. To support co-ordination of system wide responses to patient safety incidents

while identifying incidents that may require centrally co-ordinated and independent patient safety incident investigation.

4.3 Integrated care board

Roles, responsibilities and accountability:

- 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 or enable co-ordination of cross system review or 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 or services that have demonstrably improved care and or reduced risk.
- Annually review provider organisations' progress against investigation or review plans.

Specific roles and responsibilities include:

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 Health NHS Trust, where a regulator or oversight organisation has concerns regarding the safety of NHS commissioned services, additional information and assurance will be sought from the provider. If this involves the commissioning of an independent investigation or review, this will be additional to those in the provider's PSIRP.

PSIR guidance which sets out other requirements the PSIRP should include:

- 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 PSIIs and reviews (part 2, step 4 and part c)
- complaints and appeals

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:

All commissioning systems (and or sustainability and transformation plans (STP), integrated care systems (ICS) or integrated care partnerships (ICP)) must develop their capacity and capability, where these are insufficient, for coordinating cross system investigation and have systems to recognise incidents that extend beyond local boundaries and may require coordination at a regional level.

Information sharing to support patient safety investigations:

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:

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

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.

4.4 Providers of NHS funded care

Providers who have transitioned to PSIRF must ensure organisations meet national patient safety incident response standards with PSIRF central to governance arrangements, while receiving assurance of learning response outputs. Providers must ensure that standards for the legal duty of candour are adhered to for patient safety incident investigations and reviews.

4.5 Local maternity and neonatal system (LMNS)

The LMNSs and other local support networks play a crucial role in supporting improvement and facilitating review of patient safety incident responses. ICBs should ensure that provider organisations demonstrate their commitment to engaging with LMNSs and other local support networks as key stakeholders within their patient safety incident response plan. In addition, providers organisations should use their LMNS and support networks to facilitate review of incident responses between peers. This will support organisations to learn from each other's incident response approaches and reduce the risk of organisations becoming isolated and help to bring a level of standardisation regarding how incidents are reviewed.

4.6 Care Quality Commission (CQC)

The CQC's assessment of a provider's leadership and safety considers an organisation's ability to respond effectively to patient safety incidents, including consideration of whether change and improvement follow its response to patient safety incidents. CQC teams will apply the PSIRF and associated patient safety incident response standards as part of their assessment of the strength of an organisation's systems and processes for preparing for and responding to patient safety incidents.

4.7 Healthcare safety investigation branch (HSIB)

HSIB investigations identify the contributory factors that have led to harm or have the potential to cause harm to patients. HSIB recommendations aim to improve healthcare systems and processes to reduce risk and improve safety. HSIB aims to improve patient

safety through effective and independent investigations that do not apportion blame or liability.

4.8 Patient safety partners

In line with the NHS patient safety strategy, NHS is committed to the recruitment of patient safety partners and anticipates that these posts will be recruited to by September 2022. Patient safety partners play an important role on oversight committees where patient safety incidents or concerns regarding patient safety are discussed. More information is provided in the framework for involving patients in patient safety.

4.9 Safeguarding

Everyone has the right to live their lives free from abuse, neglect, violence and exploitation. Some people, because of their circumstances, may not be able to exercise this right and are unable to protect themselves from abuse and neglect. The ICB has a duty to take appropriate steps to support and protect babies, children, young people and adults who may be at risk of abuse or neglect. As part of a response to any patient safety incident, it is expected that any safeguarding concerns will be identified and that the appropriate response will be provided in line with:

- The providers own safeguarding policies and procedures
- ICB safeguarding policies and procedures
- Cornwall and Isles of Scilly adult safeguarding boards adult safeguarding policy
- Cornwall and Isles of Scilly Safeguarding Children Partnership procedures

When any patient incident raises concern about abuse or neglect arising from the actions of paid staff, the employing organisation will follow their own policy and procedure for responding to any allegations made against staff. This must include consideration of whether to refer to the local authority designated officer for children. For adults the organisation will consider whether to refer to the local authority designated officer responsible for overseeing allegations made against people in position of trust, as per the Cornwall and Isles of Scilly policy.

The ICB will ensure we are able to discharge our duties to respond to safeguarding concerns that arise from a patient safety incident by providing leadership or designated professional oversight of all relevant patient safety incidents and attendance at the Cornwall systems patient safety meeting. The lead and designated professionals will also provide information and advice on responding to concerns about abuse or neglect.

5. Patient safety incident response

The ICB is aligned to the development and maintenance of an effective patient safety incident response system across Cornwall which integrates 4 key aims:

5.1 Compassionate engagement and involvement of those affected by patient safety incidents including patients, families, carers and staff

The ICB will ensure that those affected by patient safety incidents have the opportunity to participate in patient safety investigations to understand what has happened and answer any questions they have in relation to the incident and to be signposted to support as required. The ICB will ensure that PSIR plans and policies for provider organisations seek to work with those affected by patient safety incidents and to involve them meaningfully in the investigation process.

The ICB promotes and embraces a just culture to ensure that staff are treated fairly and appropriately following patient safety incidents. When providing system oversight for patient safety reviews and investigations the ICB will ensure that engagement from staff has been sought and used to inform each investigation.

When considering organisations PSIR plans the ICB will ensure that organisations have systems and structures in place to enable managers and wider staff to:

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

5.2 Application of a range of system-based approaches to learning from patient safety incidents:

PSIRF promotes a range of system based approaches for learning from patient safety incidents, rather than methods that assume simplistic, linear identification of a single cause.

Several national system based learning response tools and guides have been developed and will be launched nationally in Spring 2022 to encourage a systems based approach which explores contributory factors in relation to patient safety incidents to inform improvement. The ICB staff and provider organisations are encouraged to apply national tools or similar system based equivalents.

The ICB will ensure that PSIR plans detail the provision of education and training for staff to ensure that they have the specific knowledge and experience required to lead patient safety incident investigations or reviews. The ICB will also ensure that those involved in the oversight of PSIRF have the knowledge and skills required to undertake this role effectively.

5.3 Considered and proportionate responses to patient safety incidents:

The ICB recognises that organisations have finite resources available for patient safety incident response. PSIRF supports organisations to use their incident response resources to maximise improvement rather than repeatedly responding to patient safety incidents based on subjective thresholds and definitions of harm where limited new learning is possible.

If an organisation and the ICB is satisfied that improvement work is ongoing to address known contributory factors in relation to an identified patient safety incident and that safety actions are being monitored, it is acceptable to not undertake a detailed investigation into an incident other than engaging with those affected and recording that it occurred.

5.4 Supportive oversight focused on strengthening response system functioning and improvement:

The ICB will work collaboratively, with a common understanding of the aims of the PSIRF framework, to provide an effective governance structure around the Cornwall system response to patient safety incidents. The ICB will facilitate collaboration at both place and local system level to support provider PSIR plans to be strong and effective.

6. PSIRF process

6.1 The appointment of an ICB PSS lead

The ICB will appoint an appropriate PSS who will work collaboratively with the provider services across the system to develop, maintain and review each provider's patient safety incident response policy and plan.

The ICB PSS lead will work as an integral collaborator with system providers to:

- review the application of the national PSIRF standards
- establish roles, responsibilities, and structures for oversight within the system
- establish mechanisms for escalation of incidents and risks that may require support or action at system or regional level

The ICB when considering PSIR plans must ensure that it is clearly stated how the organisation intends to deliver an effective response to patient safety incidents. The response methods the organisation intends to use to respond to patient safety incidents for the purpose of learning and improvement must also be detailed.

The designated ICB PSS will work collaboratively with provider services across the system as they develop and review their PSIR plans to:

- understand the patient safety improvement profile of provider organisations
- support the selection of appropriate response methods for anticipated patient safety incidents based on an understanding of potential for new learning and ongoing safety improvement work
- support provider organisations to work in collaboration to identify themes and trends across the wider system to inform learning

6.2 Agreement of provider patient safety incident response policies and plans

The ICB is required to approve and sign off the incident response policies and plans for provider organisations in their system. Approval of an organisation's policy and plan demonstrates the ICB acknowledgement that the documents have been developed according to PSIRF guidance and meet (or demonstrate a plan to meet) PSIRF standards.

The ICB PSS and quality leads will collaborate with provider organisations to assess whether the systems and processes put in place to respond to patient safety incidents have achieved demonstrable improvement.

A national framework for understanding the effectiveness of learning response systems in place in achieving improvement and appropriate data to seek out, is due to be published in summer 2022.

Considerations for ICB oversight includes ensuring:

- patient safety response teams are being trained or resourced appropriately and in line with standards
- responses to patient safety incidents are timely (for example completed within the expected or planned timeframe)
- the experience of those affected is sought and is positive or improving (for example via verbal feedback, interviews, review of complaints data, survey response)
- incident response output is high quality (for example blame is avoided, contextual factors prioritised)
- areas for improvement and safety actions identified are system based
- evidence that insight from incident response is being used to inform improvement (locally, ICS, and nationally as appropriate)
- safety improvement plans are being strategically developed (for example is their strategic alignment with other areas of the business or quality improvement strategy?)
- clear plan for criteria of incidents requiring patient safety incident investigation (PSII) including nationally defined incidents and local priorities (see appendix 2)

6.3 ICB responsibility when PSIR plans are challenged

Where a provider's systems and processes for responding to patient safety incidents are challenged the ICB will provide support for safety improvement. This may be through seeking support from colleagues in regional teams, by sharing expertise or by linking with other organisations whose systems and processes are more developed.

6.4 ICB support for co-ordination of cross system PSIIs

There is frequently more than 1 organisation involved in the care and service delivery in which a patient safety incident has taken place, all providers must have a process in place to recognise incidents that require a cross system learning response.

The organisation that identifies the incident is responsible for recognising the need to alert other providers, commissioners, and partner organisations via their respective risk management or governance teams. A lead organisation should be identified to coordinate the investigation, this should be agreed by all organisations involved.

The ICB quality team will facilitate discussion as to the most appropriate organisation to take responsibility for co-ordinating the investigation process. Where no 1 provider organisation is best placed to assume responsibility for co-ordinating an investigation, the commissioner may lead this process (NHSE, 2015). If the incident involves 3 or more organisations, the ICB will consider coordinating the investigation process.

The incident should be reported onto STEIS by the lead organisation until the learn from patient safety events (LFPSE) system is launched nationally. All providers are expected to respond and participate in joint SI or PSII investigations when requested.

Responses should be managed as locally as possible to facilitate the involvement of those affected by the incident and those responsible for delivery of the service where the incident occurred. However, where a PSII involving multiple providers and or services across a care pathway is too complex or costly to be managed by a single provider the ICB will support the co-ordination of a cross system PSII.

The ICB will seek the views of local system partners to ensure that learning responses are co-ordinated at the most appropriate level of the system. Where there is insufficient capacity and or capability, providers should engage early with the ICB who will support the co-ordination of a cross system learning response.

The ICB PSS will liaise with relevant providers (and other ICBs or ICS if appropriate) to agree how the PSII will be led and managed and how actions will be monitored.

The ICB will also ensure that providers have systems in place to support a co-ordinated and measured, systems based response to high profile or complex incidents such as mental health homicides (MHH) (appendix 2) which includes how to support the needs of those affected during the investigation. Provider organisations and the ICB will work together to establish and undertake cross system PSIIs. NHSE regional teams are available to provide support if challenges arise (see NHSE responsibilities; appendix 1).

6.5 PSII or SI Interface with other types of review and or investigation

Certain types of incident trigger specific responses described in other legislation (for example where a person dies in prison or an incident that affects patients participating in a national screening programme). The ICB is committed to contributing to and supporting system partners to engage in external PSII's or investigations led by agencies such as the police, coroners, Health and Safety Executive, HSIB (see appendix 2).

The ICB acknowledges that there are occasions where the PSIRF or SIF processes will coincide with other procedures, such as a domestic homicide review, mental health homicide, child rapid review or child safeguarding practice review, child death review or a safeguarding adult review (SAR), a safeguarding adult enquiry or another externally led investigation. In such circumstances, co-operation and collaborative working between partner agencies is essential for minimising duplication, uncertainty and or confusion relating to the investigation process. Ideally, only 1 investigation should be undertaken (by a team comprising representatives of relevant agencies) to meet the needs or requirements of all parties. However, in practice this can be difficult to achieve as investigations may have different aims or purposes which may inhibit joint investigations. The undertaking of a parallel processes may also be required by law. Where this is the case the ICB will make every effort to ensure duplication of effort is minimised. In such cases, a strategy discussion to agree how the interfaces between reviews will be managed.

In the event of criminal proceedings, wherever possible, patient safety investigations or serious incident investigations should continue alongside criminal proceedings to maximise patient safety learning. Any immediate actions required to keep people safe should not be delayed if a delay would mean people experiencing significant and avoidable harm. It is important that any patient safety enquiries do not prejudice any investigations undertaken by agencies who have powers of prosecution. This includes but is not limited to the police, CQC, Office for Standards in Education (Ofsted) and the Medication and Healthcare Products Regulation Agency (MHRA). If there is a possibility that any agency may be undertaking a process of criminal investigation the ICB safeguarding team must be contacted for advice.

A request must be sent to any involved agencies to request a strategy meeting to coordinate all investigations. This meeting should clarify and agree which agency has primacy in relation to the investigation. It should also clarify if the patient safety investigation should be put on hold or continued and under what parameters. If a decision is made to suspend progress, arrangements to review this position must also be agreed. It is recognised that the timing of the reviews are not within the control of NHS organisations. However, the NHS has a duty of care to future patients and should therefore not unduly delay any necessary action pending the outcome of separate reviews. This principle should always be applied to any decisions regarding parallel processes. The SI report may be utilised to form the basis of other reports. In these cases, a conversation needs to be had as soon as possible between the provider's

head of governance, provider's risk manager, ICB lead safeguarding designate who is the head of nursing. and patient safety specialist to ensure all parties are clear regarding terms of reference and the approach being taken.

7. Management of mental health homicide (MHH) investigation

See appendix 3.

Homicides committed by those in receipt of mental health care have devastating consequences for the family of the victim(s), patients and their families and a profound impact for all parties involved. These incidents are a defined nationally as a priority to be investigated as a PSII (see appendix 2). These incidents often require complex, multi-agency collaboration and engagement involving internal and external stakeholder across geographical and organisational boundaries. The ICB will support the provider organisation if required to engage external organisations and provide investigation support where we required for example terms of reference setting, multi-agency meeting.

If an MHH investigation is considered by all stakeholders to be complex, then an external investigation maybe commissioned in consultation with the NHSE regional team.

Following completion of any local PSII, the report will be shared with NHSE regional team who will consider if a further external investigation is needed.

As with the PSIRF core values the victim's family, the alleged perpetrator and their family will be offered the opportunity to participate in each stage of the investigation to inform system learning.

8. Domestic homicide review

Please see the ICB domestic homicide review standard operating procedure.

9. Sharing and dissemination of learning across the system

The ICB have a responsibility to ensure that the insight and learning from patient safety incidents is shared and disseminated across the Cornwall system, to promote improvements in care and patient safety.

Learning within the Cornwall system will be shared with, but not limited to the following:

9.1 The Cornwall and Isles of Scilly system patient safety meeting

This system wide meeting, open to those leading on patient safety in all Cornwall organisations and is chaired by the ICB PSS. A priority of the meeting is to enable the opportunity for system partners to come together to identify and share learning and good practice from patient safety incident investigations and reviews.

The ICB recognises that an essential part of improving how organisations learn from patient safety incidents is external review which this meeting will facilitate. External review is important to help improve quality and to reduce siloed approaches to learning that can embed unintentional bias. It can also act as a means for anticipating future problems by reflecting on systems in place and anticipating risks. The Cornwall systems patient safety meeting will facilitate external review of patient safety investigations (after an incident has been signed off by an organisation's board or delegated executive lead). This will offer the opportunity for providers to review their own practice to ascertain 'could this happen here?'.

The Cornwall systems patient safety meeting will provide a forum to enable identification of themes and trends, and the opportunity for anticipating future problems or risks and to support actions to be taken in mitigation. This meeting will also deliver a platform to discuss the progression of multi -agency investigations, to provide support if required and to gain insight and shared learning across the system. Concerns regarding delivery of the PSIR plan will be raised at this meeting to enable the offer of cross system support.

The meeting will also provide the opportunity to share investigation tools and approaches and to highlight what went well or areas for potential learning.

9.2 Cornwall system learning events

The Cornwall PSS in conjunction with patient safety partners (PSP's) are committed to introducing a biannual learning event which will bring together multi-disciplinary partners and colleagues from across Cornwall. This will be an inclusive forum to enable discussion and shared learning from patient safety incidents to be highlighted at system level. The ICB will seek to identify and share areas of good practice in relation to patient safety incident response and investigations within this forum.

More information is provided in the framework for involving patients in patient safety.

10. Process for reporting patient PSII's on STEIS

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.

- Under PSIRF 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.

The following standing operating procedures (SOP) form part of this policy, defining the process undertaken by the quality team under the direction of the head of patient safety. These dictate the commissioning responsibilities for the organisations who must still implement the serious incident framework 2015 and do not have access to STEIS.

The following list of SOPs is not exhaustive and will updated as and when required by the quality team (see appendices):

1. PSIRF or SI notification onto STEIS (appendix 4).
2. Determining a provider without access to STEIS incident (appendix 5).
3. Reviewing final reports, all providers

11. Organisations who are not early adopters of PSIRF

Primary care and independent providers (who provide NHS care) Cornwall are required to comply with the SI framework (2015), until additional PSIRF guidance is launched nationally. The ICB, as a commissioner of these services, is accountable for quality assuring the robustness of SI investigations and the subsequent actions arising from lessons learnt. This involves gaining assurance from the provider organisation that incidents are properly identified and reported and then investigated to identify lessons learnt. Lessons should then be used to ensure that the risk of a similar incident happening again is minimised. It is a requirement of all registered organisations to report serious incidents to the CQC. This process in no way replaces this requirement.

11.1 serious incident definitions

In broad terms, serious incidents are events in health care where the potential for learning is considered significant, or the consequences to patients, families and carers, staff or organisations are so significant, that they warrant using additional resources to mount a comprehensive response. Serious incidents can extend beyond incidents which affect patients directly and include incidents which may indirectly impact patient safety or an organisation's ability to deliver ongoing healthcare.

In accordance with the SI framework (2015), there is no definitive list of events or incidents that constitute a SI and lists should not be created. Every incident must be considered on a case by case basis using the description below and reported to the ICB:

- acts and or omissions occurring as part of NHS funded healthcare (including in the community) that result in:

    - unexpected or avoidable death of 1 or more people. This includes suicide or self-inflicted death and homicide by a person in receipt of mental health care within the recent past
    - unexpected or avoidable injury to 1 or more people that has resulted in serious harm
    - unexpected or avoidable injury to 1 or more people that has requires further treatment by a healthcare professional to prevent death or serious harm
    - actual or alleged abuse; sexual abuse, physical or psychological ill treatment, or acts of omission which constitute neglect, exploitation, financial or material abuse, discriminative and organisational abuse, self-neglect, domestic abuse, human trafficking, and modern day slavery where healthcare did not take appropriate action or intervention to safeguard against such abuse occurring or where abuse occurred during the provision of NHS funded care
- an incident (or series of incidents) that prevents, or threatens to prevent, an organisation's ability to continue to deliver an acceptable quality of healthcare services (full details are provided in the SI framework)
- major loss of confidence in the service, including prolonged adverse media coverage or public concern about the quality of healthcare or an organisation
- a never event, all never events are defined as Sis, not all never events result in serious harm or death

11.2 Reporting of a serious incident to the ICB

All providers are required to report all SIs on STEIS and email the ICB serious incident email address ciosicb.si@nhs.net within 2 working days of the incident being identified. Once the SI has been reported on STEIS an automated email will be sent to the ICB which provides a unique identifier number.

This policy in no way interferes with existing lines of accountability and does not replace the duty to inform the police and or other agencies or organisations where appropriate. A no harm or near miss event in relation to any of the above should also be recorded by NHS provider organisations and potential aggregated trends and clusters analysed using root cause analysis. Any emerging trends, which constitute a significant risk in any of the above categories, should be reported using this policy.

11.3 Retraction of SI's

All incidents meeting the threshold of an SI must be investigated and reviewed according to the principles set out in the framework.

If, after initial investigation, the provider organisation feel that it no longer meets the criteria for an SI, then a request should be submitted to ciosicb.si@nhs.net in writing requesting downgrade, stating the reason for this, including the 72 hour report (template appendix 2). The report will be considered by the quality team staff from the ICB; if the request and rationale are considered appropriate, the SI will be downgraded from the

STEIS database. The ICB may request that any ongoing investigation and learning is shared to inform any themes or trends.

11.4 SIF reporting requirements

The NHSE SI framework indicates that an initial update should be sent to the ICB within 3 working days of reporting the incident. This is to provide more detail to the ICB with regards to immediate action taken, duty of candour and terms of reference.

The investigation should be completed, and a final report and action plan submitted within 60 working days of the incident being reported. This report should be submitted to ciosicb.si@nhs.net with the STEIS number (for example 2020/****) in the subject. Action plans should be submitted with the final report with clear actions described, responsibilities and action deadlines set and plans to monitor and review including planned follow up audits to gain assurance that the learning has been implemented and changes embedded into practice.

11.5 Requests for extensions

If there is a likelihood that the report will not be completed within the 60 day time frame, then an extension request can be submitted to the ICB. All requests for extensions must be made in writing via the SI inbox at least 7 working days prior to the original date the final report was due. Extensions will be granted for justifiable circumstances such as inquest, safeguarding investigations, criminal proceedings, new information coming to light which requires further investigation, multi-organisation incidents, incidents of significant complexity, significant local or national NHS pressures (for example pandemic) or similar.

12. Patient safety training requirements 2022 to 2023

The ICB recognises that those involved in the review of patient safety incident and investigations and those providing an oversight function require specific knowledge and skills. This includes knowledge of systems thinking and system based approaches to learning from patient safety incidents. The ICB is committed to providing access for staff to appropriate, high quality training patient safety training.

Those involved in the quality assurance of patient safety incident response (for example provider boards or executive leads) must have knowledge to constructively challenge the strength and feasibility of recommendations and safety actions to improve underlying system issues. They must be able to recognise when safety actions following patient safety incident response do not take a system based approach, for example, inappropriately focusing on individual behaviours or not appreciating why an adaptation to the system was necessary with recommendations targeted at ‘retraining’ or additional policies and checks lists.

Those in system oversight roles (for example provider board PSIRF lead(s), ICS PSIRF leads, CQC relationship managers and inspectors) must have knowledge of effective oversight and supporting processes including effective use of data for assurance and patient safety incident response system development.

Staff in oversight roles must receive appropriate training to support the practical application of PSIRF oversight principles and standards.

12.1 Training procurement framework

An NHS suppliers training framework has been developed to assist with identifying training suppliers for the following required PSIRF training courses:

- systems approach to learning from patient safety incidents
- involving those affected by patient safety incidents in the learning response process
- oversight of learning from patient safety incidents

12.2 Patient safety syllabus

As part of the NHS patient safety strategy, work is underway to develop and deliver NHS wide patient safety training. The national patient safety syllabus was published by Health Education England in May 2021 covering 5 levels of training. Level 1 (essentials for patient safety) and level 2 (access to practice) became available for all NHS staff via the eLearning for health platform in October 2021.

Please see table 2 for a breakdown of training requirements.

Levels 3 to 5 will be developed and released throughout 2022.

Table 1 training requirements for those in PSIRF oversight roles

Topic	Minimum duration	Content
Systems approach to learning from patient safety Incidents	2 days or 12 hours	• introduction to complex systems, systems thinking and human factors • learning response methods: including interviewing, and asking questions, capturing work as done, data synthesis, report writing, debriefs and after action reviews • safety action development, measurement, and monitoring

Topic	Minimum duration	Content
Involving those affected by patient safety incidents in the learning process	1 day or 6 hours	• duty of Candour • just culture • being open and apologising • effective communication • effective involvement • sharing findings • signposting and support
Patient safety syllabus level 1: essentials for patient safety	e-Learning	• listening to patients and raising concerns • the systems approach to safety, where instead of focusing on the performance of individual members of staff, we try to improve the way we work • avoiding inappropriate blame when things don't go well • creating a just culture that prioritises safety and is open to learning about risk and safety
Patient safety syllabus level 2: access to practice	e-Learning	• introduction to systems thinking and risk expertise • human factors • safety culture
Continuing professional development	At least annually	• to stay up to date with best practice (for example through conferences, webinars.)

13. Implementation plans and monitoring effectiveness

This policy will be introduced through a series of lunch and learning sessions, a link will be shared in the weekly bulletin and via email. Teams will be asked to share the policy in staff meetings.

It will also form an integral part of the countywide patient safety meeting.

Annual review and monitoring of provider organisation's patient safety incident report plans will indicate the effectiveness of the policy at system level.

14. Update and review

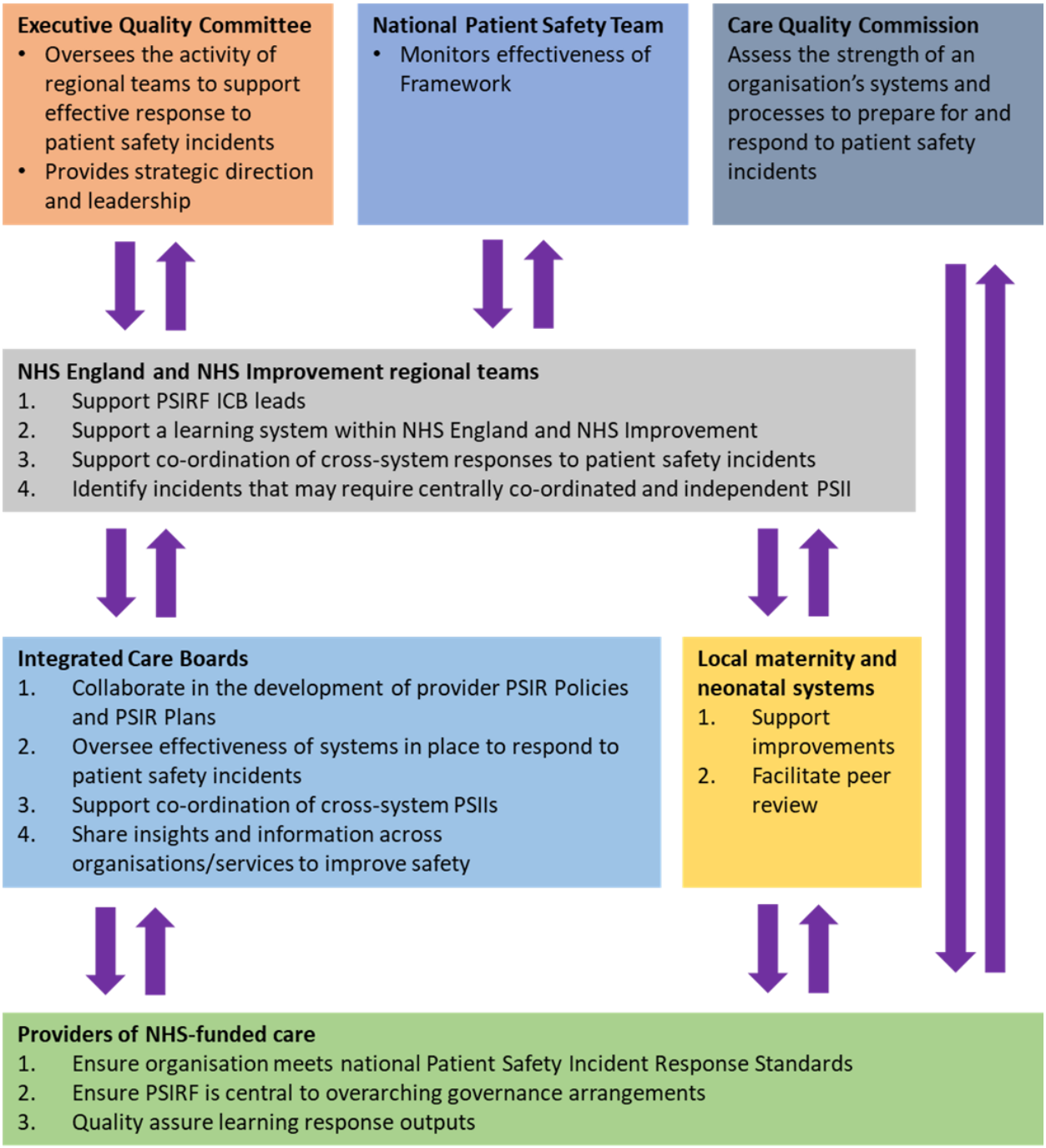
This policy document will be reviewed when the further national PSIRF guidance is published and thereafter annually.

15. Policies referred to in this document

- Incident management policy
- Data protection policy
- Information governance policy

- Pseudonymisation policy (2019)
- PSIRF
- Adult safeguarding policy
- Child protection policy and procedure
- Cornwall and Isles of Scilly Adult Safeguarding Board adult safeguarding policy
- Cornwall and Isles of Scilly Safeguarding Children Partnership procedures

Appendix 1: Overview of organisational responsibilities



Appendix 2: Priorities for PSII review

1. Nationally defined priorities for external PSII review

    - Maternity and neonatal for HSIB led PSII.
    - Mental health related homicides.
    - Child deaths.
    - Death of a person with a learning disability.
    - Safeguarding.
    - Incidents in screening programmes.
    - Deaths of patients in custody, in prison or on probation where healthcare was or 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 NHSE to commission an independent clinical review of the healthcare received.

2. Nationally defined priorities for local PSII review

    - never events
    - learning from deaths
    - death of a person with mental illness in accordance with Royal College of Psychiatrists
    - learning disability death where patient safety incident may have contributed
    - Suicide or self-harm of person in state care
    - deaths of patients in custody, in prison or on probation where there is reason to believe problems in healthcare may have impacted

3. Locally defined priorities for PSII review

    - 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
    - Locally predefined incidents prioritised based on all the following criteria:

        - actual and potential impact of incident
        - likelihood of recurrence
        - potential for learning

Appendix 3: Standard operating procedure independent mental health homicide

Number: 14

Author(s): Maria Patterson and Nikki Thomas

Date: September 2017 to March 2022

Review date: March 2022

Procedure overview

The process for investigation review of mental health homicides. All providers of NHS funded services are required to be open and transparent with families and patients when things go wrong with their healthcare. In April 2013 NHS England and NHS Improvement became responsible for commissioning independent investigations into homicides (sometimes referred to as mental health homicide reviews) that are committed by patients being treated for mental illness. The purpose of an independent investigation is to review thoroughly the care and treatment received by the patient so that the NHS can:

- be clear about what, if anything, went wrong with the care of the patient
- minimise the possibility of a reoccurrence of similar events
- make recommendations for the delivery of health services in the future

An independent investigation is carried out separately from any police, legal and coroner's proceedings. It is done by an independent, expert organisation, which is given access to all the information and reports about the individual patient's care and treatment (within the usual patient confidentiality rules), and who can also request interviews with any NHS staff involved.

Criteria for an independent investigation

The criteria for an independent investigation to be carried out is:

- as outlined in appendix 1, 3 and 4 in the NHS serious incident framework
- to investigate the care and treatment of patients and establish whether a homicide could have been prevented and if any lessons were learned for the future
- increase public confidence
- provide an assurance framework for those trusts providing specialist mental health services and a platform for demonstrating learning from action plans

Requirements

- Access to STEIS database
- Access to the NHS Cornwall and Isles of Scilly Integrated Care Board (ICB) IRIS, quality team, serious incident register, reports and documents tile
- Access to the ICB quality team shared drive

Other (reference documentation)

- NHS England and NHS Improvements serious incident reporting framework
- NHS England and NHS Improvements patient safety incident response framework
- contact list of relevant teams to be notified by incident type, location or provider

Procedure

Ensure the following steps are considered or actioned as appropriate:

1. PSIRF investigation completed as per provider patient safety incident response plan.
2. Completed investigation report shared with patient safety forum and IIRG.
3. If independent investigation commissioned, quality and pathways of care committee informed via quality report (part 2).
4. Oversight and assurance of independent investigation process agreed with provider. Suggested quarterly reporting lead for each independent investigation appointed and appropriate staff engaged for example safeguarding, commissioner.
5. Escalation route as per quality assurance and accountability framework - integrated assurance meeting.
6. System partner in external oversight and assurance process as described by NHS England and NHS Improvement.
7. Record action in IRIS.

Appendix 4: Standard operating procedure: patient safety incident notification (from provider with access to STEIS)

Number: 1

Author(s): Maria Patterson and Heather Anderson

Date: September 2017 to March 2022

Review date: September 2022

Procedure overview

To review the information provided and determine appropriate response, to record the incident and actions taken.

Requirements

- Access to STEIS database
- Access to the NHS Cornwall and Isles of Scilly Integrated Care Board (ICB) IRIS database
- Contact list of relevant teams to be notified by incident type, location or provider.
- Access to the ICB quality team shared drive

Other (reference documentation)

- NHS England and NHS Improvement serious incident framework
- NHS England and NHS Improvement patient safety incident response framework

Procedure

Team support assistant shall monitor, control, and maintain the generic serious incidents inbox:

1. Notification received into the serious incident's inbox (displayed in link format).
2. Open STEIS, select 'search all incidents' searching on incident ID number supplied in notification and open record.
3. Sense check incident - concentrating specifically on incident occurred and incident recorded dates, site of incident, duty of candour, plus anything which may be deemed missing or questionable (particularly if recorded as a never event).
4. Are there any concerns that suggest people may be at ongoing risk of harm if so refer to quality manager discuss with safeguarding lead?

5. Are there any concerns that suggest the police or other agencies may need to investigate if so refer to quality manager discuss with safeguarding lead? If questionable, return to reporter with queries.
6. If correct, go to ‘correspondence history’ box entering disclaimer: <Days date> - ICB: Incident noted by commissioners (your initials).
7. Save and submit, to save record.
8. Save a pdf copy of STEIS record by right clicking ‘create record from the webpage’ and create and save in a folder under reporting provider by STEIS number on the shared drive.
9. Return to inbox, move notification (link) by colour coded action to ‘update to sitrep’ folder in preparation for following days’ upload to IRIS.

Appendix 5: Standard operating procedure: Determining a patient safety incident from provider without access to STEIS

Number: 2

Author(s): Maria Patterson and Heather Anderson

Date: September 2017 to March 2022

Review date: September 2022

Procedure overview

To review the information provided, determine appropriate response and record the incident and actions taken.

Requirements

- Access to STEIS database.
- Access to NHS Cornwall and Isles of Scilly Integrated Care Board (ICB) IRIS database.
- Contact list of relevant teams to be notified by incident type, location or provider.
- Access to the ICB quality team shared drive.

Other (reference documentation)

- NHS England and NHS Improvements serious incidents framework.
- NHS England and NHS Improvements patient safety incident response framework.
- The ICB providers without access to STEIS form.
- The ICB patient safety incident notification (from provider) standard operating procedure.
- The ICB data import from STEIS to IRIS standard operating procedure.

Procedure

For incidents raised by providers without access to STEIS database. Patient safety team support assistant will process and respond to provider confirming identifier information as appropriate.

1. Initial incident notification received into serious incident inbox from reporting organisation.

2. Patient safety team support assistant to sense check submission for accuracy before forwarding to relevant area quality manager for review and decision against patient safety incident response framework.
3. Are there any concerns that suggest people may be at ongoing risk of harm if so refer to quality manager discuss with safeguarding lead?
4. Are there any concerns that suggest the police or other agencies may need to investigate if so refer to quality manager discuss with safeguarding lead?
5. Quality manager to email to patient safety team support assistant with decision outcome:
6. If no, a justification to be shared with reporting organisation.

6.2 If yes, patient safety team support assistant to email 'providers without access to STEIS' form to reporting organisation requesting completion and return via email.

7. On receipt of completed form, patient safety team support assistant will access STEIS database using the ICB login (UR11N) and password (blagrix678).
8. Copy and paste information from form to STEIS and save.
9. Create file in appropriate provider folder and save STEIS record.
10. Upon STEIS record notification email in inbox, select colour category 'await update to sitrep' in preparation for following day checking of successful upload of record to IRIS.
11. Email reporting organisation confirming unique STEIS number ID and expected (SIRI) completion date.

Appendix 6: Impact assessment

Equality impact assessment

Name of policy or service to be assessed: Patient safety incident response policy
Department or section: Nursing and quality
Date of assessment: 19 May 2022
Person(s) responsible for the assessment: Maria Patterson
Is this a new or existing policy? New

Aims, objectives and purpose of the policy

Describe the aims, objectives, and purpose of the policy

The patient safety incident response policy describes and defines the responsibility of for NHS Kernow as commissioners when proving oversight for organisations who have transitioned as 'early adopters' to PSIRF and for organisations for whom the serious incident framework (SIF) continues to apply. The policy sets out the general principles and processes for the management patient safety incidents (PSI's) and Serious Incidents (SI's) occurring within services commissioned by NHS Cornwall and Isles of Scilly Integrated Care Board (ICB).

Who is intended to benefit from this policy, and in what way?

Patients and staff with Cornwall are anticipated to benefit from the adherence with this patient safety policy due to improve learning and insight from patient safety incidents.

What outcomes are wanted from this policy?

- Understanding of the PSIRF process for Cornwall staff.
- Greater learning and insight generated from patient safety incidents with is shared across the system to improve safety for patients.
- Improved use of resources with a focus on maximising improvement rather than repeatedly conducting reviews where limited learning is possible.

What factors or forces could contribute or detract from the outcomes?

Failure to embed the PSIRF across the system due to other priorities, this risks a reduction in safety improvement and learning.

Who are the main stakeholders in relation to the policy?

The main stakeholders for dissemination of the policy directly is ICB staff and staff within provider organisations. The policy also greatly impacts upon patients, their families and carers and should be communicated to those involved in a patient safety incident.

Who implements the policy, and who is responsible for the policy?

ICB patient safety specialist

Differential impacts

Does this have a positive or negative impact on people who have a black, Asian and minority ethnic (BAME) background? How will any negative impact be mitigated?

There is some evidence that people from a BAME background may have poorer health outcomes and be adversely impacted by patient safety events. This policy will support the identification of any patient safety themes or trends for this population and provide opportunity to undertaken improvements if identified.

Does this have a positive or negative impact on people who identify as male, female or intersex? How will any negative impact be mitigated?

Neutral impact.

What is the positive or negative differential impact on people from the perspective of disability? How will any negative impact be mitigated?

The policy and procedure aims to improve patient safety by identifying any themes or trends and areas for improvement. Should disability be highlighted this will provide the opportunity to take action to improve outcomes.

Does this have a positive or negative impact on people who identify as heterosexual, lesbian, gay, bisexual, pansexual or asexual? How will any negative impact be mitigated?

Neutral: it targets any individual who may have been affected by a patient safety incident.

What is the positive or negative differential impact on people from the perspective of age? How will any negative impact be mitigated?

Neutral

What is the positive or negative differential impact on people from the perspective of religion or belief? How will any negative impact be mitigated?

Neutral: it targets people who may have been affected by a patient safety incident.

What is the positive or negative differential impact on people from the perspective of marriage and civil partnership? This is particularly relevant for employment policies. How will any negative impact be mitigated?

Neutral: it targets people who may have been affected by a patient safety incident.

Does this have a positive or negative impact on people who identify as trans or transgender, non-binary, or gender fluid? How will any negative impact be mitigated?

Neutral: it targets people who may have been affected by a patient safety incident.

Does this have a positive or negative impact on people who are pregnant, breast feeding mothers, or those on maternity leave? How will any negative impact be mitigated?

Positive: it targets people who may have been affected by a patient safety incident. Maternity cases will be investigated as a priority via harmful sexual behaviour (HSB).

Are they any other identified groups? How will any negative impact be mitigated?

No. Not applicable.

Human rights values

How have the core human rights values of fairness, respect, equality, dignity, and autonomy been considered in the formulation of this policy, service, or strategy?

Through improvement of health outcomes which impact on these values.

Which of the human rights articles does this document impact?

☒ To life
☒ Not to be tortured or treated in an inhuman or degrading way
☒ To liberty and security
☐ To a fair trial
☒ To respect for home and family life, and correspondence
☐ To freedom of thought, conscience, and religion
☐ To freedom of expression
☐ To freedom of assembly and association
☐ To marry and found a family
☒ Not to be discriminated against in relation to the enjoyment of any of the rights contained in the European Convention
☐ To peaceful enjoyment of possessions

What existing evidence (either presumed or otherwise) do you have for this?

Widespread national review of patient safety incident response policy Royal Cornwall Hospitals NHS Trust (RCHT) and Royal Devon and Exeter NHS Foundation Trust (RDE) are early adopters of this policy, learning has been captured nationally to demonstrate benefits.

How will you ensure that those responsible for implementing the policy are aware of the human rights implications and equipped to deal with them?

They will follow the procedures.

Public Sector Value Act 2020

ICB is committed and obliged to fulfil the requirements of the Public Sector Social Value Act 2012. This act requires the organisations to consider how services commissioned or procured might improve the economic, social, and environmental wellbeing of an area.

Please describe how this will support and contribute to the local system, wider system, and community.

This is a service improvement programme.

Describe how the policy contributes towards eliminating discrimination, harassment, and victimisation.

This is a service improvement programme.

Describe how the policy contributes towards advancing equality of opportunity.

Through positive action towards those affected by a patient safety incident.

Describe how the policy contributes towards promoting good relations between people with protected characteristics.

Neutral.

If the differential impacts identified are positive, explain how this policy is legitimate positive action and will improve outcomes, services and or the working environment for that group of people.

Explain what amendments have been made to the policy or mitigating actions have been taken, and when they were made.

Not applicable.

If the negative impacts identified have been unable to be mitigated through amendment to the policy or other mitigating actions, explain what your next steps are using the following equality impact assessment action plan.

Not applicable.

Equality impact assessment action plan

Issue to be addressed	Action required	Responsible person	Timescale for completion	Action taken
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable

Comments on action plan:

Not applicable.

Signed (completing officer): Maria Patterson

Date: 19 May 2022

Signed (head of department or section): Maria Patterson

Date: 19 May 2022

Please ensure that a signed copy of this form is sent to both the corporate governance team with the policy and the equality and diversity lead.