Patient safety incident response plan

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Introduction

This Patient Safety Incident Response Plan sets out how the British Pregnancy Advisory Service (BPAS) intends to respond to patient safety incidents over a period of 12 to 18 months. The plan is not intended as a permanent 'rule'. The organisation will remain flexible, both to the specific circumstances of incidents that occur and the needs of those affected.

The introduction of PSIRF at BPAS was delayed by 9 months to allow the delivery of the first phase of an organisation wide improvement programme, including a review of clinical risk and quality improvement approaches. This has delivered improvements in both the resources and oversight for clinical risk, bringing it into the Nursing, Midwifery and Quality team and seen the creation of quality improvement programmes for key risk areas such as suitability and safeguarding. As a result, BPAS is now able to focus its investigative resource on areas where clinical risk is not understood.

Our services

BPAS offers two core services:

- Termination of pregnancy which can be:
    - Medical without scan up to 9 weeks and 6 days
    - Medical with scan up to 10 weeks and 0 days
    - Surgical under local anaesthetic to 13 weeks 6 days
    - Surgical under conscious sedation to 17 weeks 6 days
    - Surgical under general anaesthetic to 23 weeks 6 days
    - Miscarriage management

- Vasectomy

Patients undergoing termination of pregnancy also have access to contraception and STI testing as well as pre, and post-abortion counselling.

The operations team led on mapping of all services to understand the patient journey through BPAS.

Swim-lane maps highlighting the transitions between different elements of the service were completed for complex sub-processes including:

- Safeguarding. This was done with the safeguarding team. This map can be found in Appendix A and an example of the mapping work conducted. The Head of Safeguarding, Divisional Governance Partner for Telemedicine, the Operational Manager for Telemedicine and a number of front-line telemedicine staff members conducted detailed mapping of individual patient journeys against this map to identify areas of risk and inform improvement work.
- Scanning where a patient receives the scan from USD. This map was completed with the contract manager for USD and the risk and governance team and shared with operational staff for feedback.

Detailed mapping of the incident management pathway was conducted, and a revised map was developed, ensuring that the processes aligned to PSIRF.

Defining our patient safety incident profile

Overview

The patient safety profile considers all services provided by BPAS. However, the majority of risks highlighted through the process are specific to the abortion care pathway.

Data Sources

An initial review of data was conducted in June 2023:

- Incident data was reviewed for the period 01/06/2020 to 31/05/2023 and divided by sub-category. This information was taken from the Datix system.
- Serious Incident and lower-level formal investigation data was used from 07/01/2021 to 01/07/2023. This information was taken from the Risk and Governance team records.
- The corporate risk register for July 2023 was used to identify the key risks which had been identified in relation to patient safety for the organisation.

A second review of data was conducted in May 2024, to understand the changes in risk profile and identify the key areas for focus.

Stakeholder Engagement

The initial development of the Patient Safety Incident Profile was done with the PSIRF programme group, which consists of representatives from clinical, legal, complaints and risk and governance, as well as the BPAS Patient Safety Partner.

The Director of Nursing, Midwifery and Quality held an engagement event with the Quality Matrons to share the plan and gain feedback.

Following approval of the first draft by the Director of Nursing, Midwifery and Quality and Medical Director and review by Executive Leadership Team, BPAS held engagement events with the Operational Quality Managers, and open consultation events for all staff.

Cheshire and Merseyside ICB were approached to be the lead ICB for BPAS to work with on development of the PSIRP; they were consulted in detail on the plan. Engagement was offered to other ICBs, some of whom contributed feedback to this plan.

Following feedback from the Cheshire and Merseyside ICB and the delivery of the first phase of the Better BPAS improvement plan, the patient safety priorities were revised. The initial draft was created based on patient safety discussions held at incident response meetings (lead nurses, unit managers, quality matrons, operations managers and regional clinical directors), event response group (regional clinical directors, quality matrons, the senior quality matron, the executive triumvirate) and in the Better BPAS improvement board.

A final draft will be confirmed following internal and external consultation.

Our Patient Safety Priorities

BPAS is now 12 months into the Better BPAS improvement programme, including a radical review of how we manage clinical risk and the introduction of a clinical taskforce, reporting into the Chief Executive and delivering improvements on our key patient safety risks.

Our priorities for 2024/25 are to continue to create the space for our clinical teams to focus on our improvement projects, delivering transformation and to continue on our journey to excellence by using our patient safety learning to draw out the contributory factors for risks we do not yet fully understand.

Priorities for PSII

Patient safety incident response plan

We anticipate conducting no more than 12 PSIIs each year. Our priorities for the first 18 months will be:

1. Consent

Everyone attending BPAS should expect to be supported to give informed consent. Serious incidents involving consent are rare, and therefore the contributory factors have not been fully explored. Therefore, this is a key priority for BPAS in 2024/25.

Any incident where a patient has treatment without full, informed, consent – including those where there has been a failure to identify the need for further mental capacity assessment – will be recommended for a PSII.

2. Effective identification of patients of greater-than-expected gestation

Delivery of a pregnancy of greater-than-expected gestation is a known risk of early medical termination without scan and a known, but smaller, risk of medical termination with scan. All patients are consented for this risk. However, there are significant clinical risks associated with the provision of early medical abortion to women over 24 weeks and therefore BPAS' processes are designed to reduce this risk as low as possible. Therefore, any delivery of a live baby or of a foetus of greater than 23+6 gestation where an initial review identifies gaps in the BPAS process will be recommended for a PSII.

3. Compliance with legal obligations in relation to the provision of abortions

Any failure to comply with regulation, including the correct completion of HSA1 paperwork and the correct use of controlled drugs, is a significant risk to BPAS and will be recommended for a PSII.

4. Information Governance breaches that represented a safeguarding risk to the patient

As an abortion provider, BPAS handles information that has the potential to put vulnerable patients at risk if not managed appropriately. Any incident where a failure in appropriate information governance places a patient with safeguarding needs at risk of serious physical or psychological harm will be recommended as a PSII.

5. Checking the effectiveness of completed improvement projects

Where BPAS has identified significant risks and completed improvement programmes, we would not expect to see further significant incidents but where these do occur it would represent new learning both about the risk and about the delivery of improvement projects. For 2024/5 these areas of focus are:

- Proactive management of supplies critical to the delivery of patient care (including emergency trolley supplies). The system for managing supplies is now automated.
- Management of foetal remains in accordance with the patient's wishes.

Priorities for AAR and Thematic Review

1 Effective working with NHS Trusts

BPAS is not a stand-alone provider and is dependent on good working relationships with NHS Trusts to deliver care for patients who either do not meet our suitability criteria or require emergency review or treatment. We will look to conduct joint AARs where a patients access to care is delayed due to ineffective collaboration.

2 Effective management of patients awaiting urgent scan

Patients who contact BPAS with signs and symptoms of an ectopic pregnancy at any stage in their journey or with signs and symptoms of a complication post treatment may require an urgent scan within 48 hours. Lack of available appointment within 48 hours is BPAS' largest theme in incidents. This is associated with BPAS' operating model with some small local units, offering increased choice of location but on limited days. There is an improvement project underway to improve scan capacity. However, where patients cannot be seen within 48 hours BPAS needs to ensure appropriate clinical management, including escalation where needed. Where an initial review identifies gaps in the clinical management, including missed opportunities to refer, an AAR will be conducted.

Defining our patient safety improvement profile

BPAS is currently delivering an organisation wide service transformation programme, called The BPAS Integrated Improvement Plan. This is the starting point for the patient safety improvement profile. As part of the improvement plan, a formal consolidated list of all improvement and transformation underway across the organisation will be developed and maintained.

The current safety improvement profile below was gathered through:

- Current improvement plans implemented in response to SIs
- Improvement plans relating to the corporate risk register, which relate to patient safety risks
- Consultation with the clinical quality, medical and operations team to ensure all key workstreams are captured.

It is recognised that there are local improvement projects underway to address safety improvements at individual unit level. These are being drawn together into the BPAS improvement asset register.

Clinical Taskforce

The Clinical Taskforce has been superseded by the Clinical Model of Care Task and Finish Group. This group will be reviewing the current model of care, this will culminate in a new model of care that ensures all pathways are designed with patient safety and a positive experience at the core, with the further ambition of driving efficiencies and reducing wait times for people who use our services. The clinical model may identify further workstreams to enhance patient safety and these will be fed into the patient safety plan during 2024/25.

Our patient safety incident response plan: national requirements

Patient safety incident type	**Required response**	**Anticipated improvement route**
Incidents meeting the Never Events criteria	PSII	Create local organisational actions and feed these into the Integrated Improvement Plan
Deaths clinically assessed as more likely than not due to problems in care	PSII	Create local organisational actions and feed these into Integrated Improvement Plan
Maternity and neonatal incidents meeting HSIB criteria	Refer to HSIB for independent PSII	Create local organisational actions and feed these into Integrated Improvement Plan
Child deaths	Refer for Child Death Overview Panel review. Locally led PSII (or other response) may be required alongside the Panel review	Create local organisational actions and feed these into the Integrated Improvement Plan
Deaths of persons with learning disabilities	Refer for Learning Disability Mortality Review (LeDeR). Locally led PSII (or other response) may be required	Create local organisational actions and feed these into the Integrated Improvement Plan

	alongside the Panel review	
Safeguarding incidents which involve: Babies, child and young people are on a child protection plan; looked after plan or a victim of wilful neglect or domestic abuse / violence. Adults (over 18 years old) are in receipt of care and support needs by their Local Authority The incident relates to FGM, Prevent (radicalisation to terrorism); modern slavery & human trafficking or domestic abuse / violence.	Refer to local authority safeguarding lead. Healthcare providers must contribute towards domestic independent inquiries, joint targeted area inspections, child safeguarding practice reviews, domestic homicide reviews and any safeguarding reviews (and enquiries) as required to do so by the Local Safeguarding Partnership (for children) and local Safeguarding Adults Boards.	Create local organisational actions and feed these into the Integrated Improvement Plan
Incidents in screening programmes	Refer to local Screening Quality Assurance Service for consideration of locally led learning response.	Create local organisational actions and feed these into Integrated Improvement Plan
Deaths in custody (e.g., police custody, in prison, etc.) where health provision is delivered by the NHS	In prison and police custody, any death will be referred (by the relevant organisation) to the Prison and Probation Ombudsman (PPO) or the Independent Office for Police Conduct (IOPC) to carry out the relevant investigations. Healthcare providers must fully support these investigations where required to do so.	Create local organisational actions and feed these Integrated Improvement Plan
Deaths of patients detained under the Mental Health Act (1983), or where the Mental Capacity Act (2005) applies,	Locally led PSII by the provider in which the event	Create local organisational actions and feed these into the quality improvement strategy

where there is reason to think that the death may be linked to problems in care (incidents meeting the Learning from Deaths criteria)	occurred with BPAS participation if required	
Mental health related homicides	Referred to the NHS England and NHS Improvement Regional Independent Investigation Team for consideration for an independent PSII Locally led PSII may be required with mental health provider as lead and BPAS participation if required	Create local organisational actions and feed these into the quality improvement strategy
Domestic Homicide	A Domestic Homicide is identified by the police usually in partnership with the Community Safety Partnership (CSP) with whom the overall responsibility lies for establishing a review of the case. Where the CSP considers that the criteria for a Domestic Homicide Review (DHR) are met, they will utilise local contacts and request the establishment of a DHR Panel. The Domestic Violence, Crime and Victims Act 2004, sets out the statutory obligations and requirements of providers and commissioners of health services in relation to domestic homicide reviews.	Create local organisational actions and feed these into the quality improvement strategy

Our patient safety incident response plan: local focus

Key Risks for Improvement Plans.

Patient safety incident type or issue	Planned response	Anticipated improvement route	Anticipated number based on 2023/4 data
Any incident where the patient receives treatment for which they had not been consented or had not given informed consent.	PSII Near-miss (i.e. issue with consent noted prior to treatment)– AAR	Quality Improvement Plan to be created and fed into Integrated Improvement Plan.	4 (although 2 subsequently identified as documentation error) c.25 AAR's
Missed opportunities to identify that a patient needed a mental capacity assessment	PSII Near-miss - AAR	Quality Improvement Plan to be created and fed into Integrated Improvement Plan	2 No near misses identified
Unexpected delivery of a foetus of gestation exceeding 9+6 weeks following pills by post where following an initial review there are areas where the care pathway has not been followed correctly	PSII	Quality Improvement Plan to be created and fed into Integrated Improvement Plan	1
Controlled drugs not managed in accordance with regulation	PSII	Learning fed into medicines management improvement plan	2
HSA1 form not completed correctly	PSII	Quality Improvement Plan to be created and fed into Integrated Improvement Plan	1

Foetal remains not managed in accordance with patient's wishes	PSII	Quality Improvement Plan to be created and fed into Integrated Improvement Plan	1
Pro-active management of emergency trolley supplies	PSII	Quality Improvement Plan to be created and fed into Integrated Improvement Plan	0

Risks for local investigation (AAR/SWARM)

Patient safety incident type or issue	**Planned response**	**Anticipated improvement route**	**Anticipated number based on 2023/4 data**
Any incident where a patient could not be offered a scan within 48 hours where appropriate clinical escalation/risk factors for urgency were missed.	AAR	Learning from AAR to be compared to the existing quality improvement plan by Quality Matrons to identify opportunity for further learning	12
Any incident where issues in collaboration between BPAS and an NHS Trust resulted in a delay in treatment or poorer outcomes for a patient	Joint AAR Annual thematic review	Local learning to be fed into local quality improvement plan. National quality improvement plan to be developed.	12

Failure to provide Anti-D	SWARM if discovered at the time or AAR if identified later Thematic review	Local learning to be fed into local quality improvement plan Thematic review to be fed into Integrated Improvement Plan	2
Missed opportunity to safeguard a patient leading to delayed intervention to prevent risk of serious harm	SWARM if discovered at the time or AAR if identified later	Findings to be checked by safeguarding lead against ongoing safeguarding improvement plan. Used for local learning and staff debrief/support.	6

Our patient safety incident response plan: resource

Our approach to patient safety is founded in collaboration. Our Event Response Group will ensure that each investigation has an appropriate team including:

- A Quality Matron for all incidents impacting patient care
- A Clinical Director for all incidents involving surgical care or management of medical risk
- A safeguarding lead for all incidents involving safeguarding risk factors
- A member of the medicines management team for incidents involving medications including controlled drugs
- A governance lead, with specialist training in patient and staff engagement and investigation techniques.

Our Patient Safety Partner is invited to all event response groups and final reviews. Where an incident is of special interest, they will shadow the investigation and may ask for additional questions to be addressed.

Role	Number in post	PSIIs requiring involvement	Av. per year per person	SWARM/AAR requiring involvement	Av. Per month

					per person
Governance lead	4	c.11	3	57	1.2
Quality Matrons	7	c. 11	1-2	51	1
Clinical Directors	3	c. 5	1 (2 per year to sit with the Deputy Medical Director)	20	1
Safeguarding Leads	7	c.3	0.5	24	0.3
Medicines Management Lead	1	2	0.5	2	0

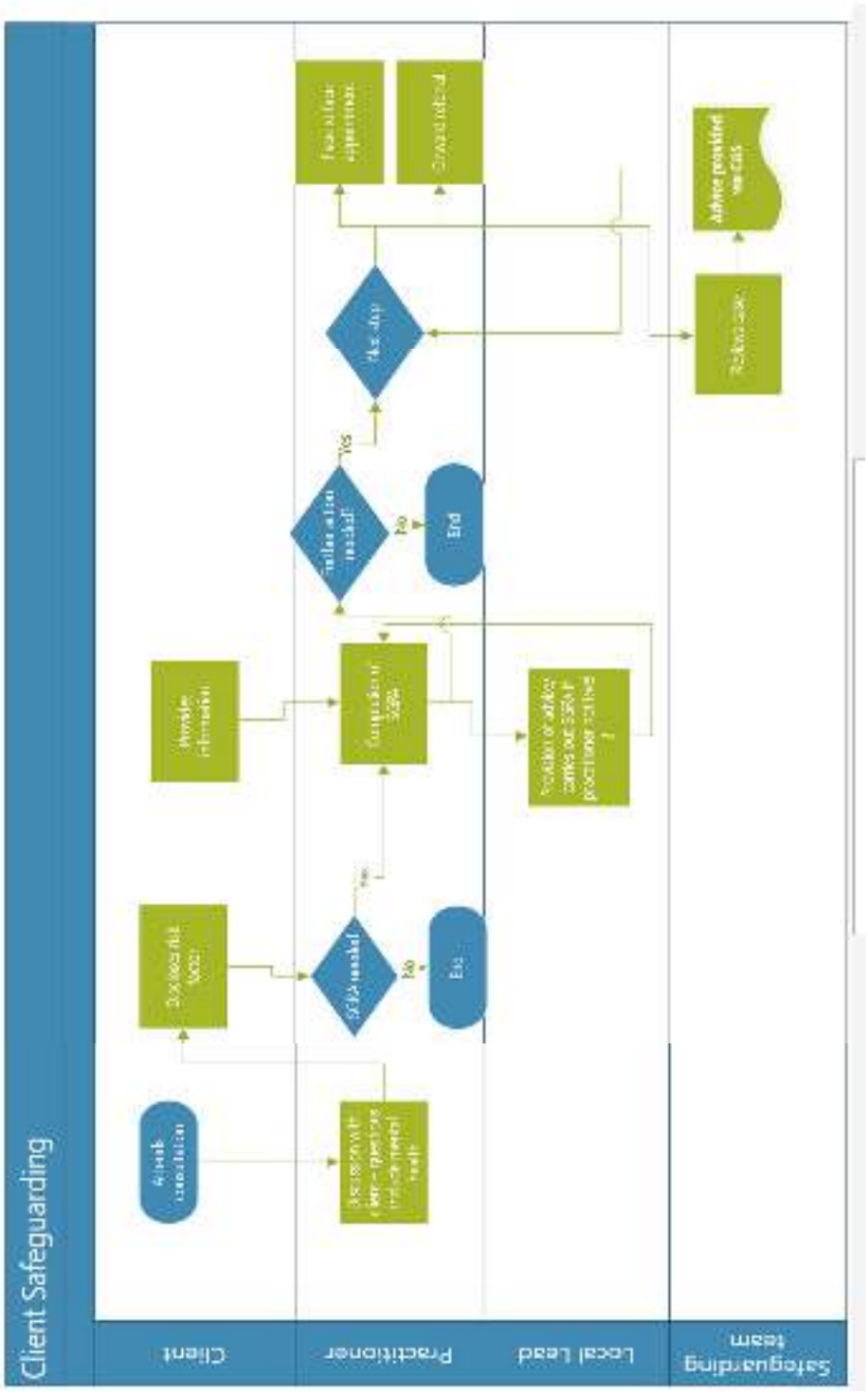
To meet the requirements of training and sufficient involvement in incidents, Learning Response Leads will normally be the Clinical quality and risk Lead. In addition, the following people will be trained and involved in a minimum of two investigations annually in order to act as Learning Response Leads where appropriate:

- The Senior Quality Matron
- 2 Quality Matrons with a special interest in patient safety/learning response.
- The Deputy Medical Director

PSIRP Review and Ratification Requirements

This Plan and the accompanying Policy are to be ratified and managed via the Clinical Governance Committee. The initial Plan will stand for 12 months before the first review and formal amendments to overarching plan. It should be noted that this plan is being implemented into BPAS at a time when there is a significant amount of improvement work ongoing and therefore the Plan may be subject to an earlier review.

Appendix 1: BPAS Safeguarding: Process for patient disclosing safeguarding concerns



Patient safety incident response plan

Appendix 2: Glossary

PSIRF

Patient Safety Incident Response Framework (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.

PSIRP

Patient Safety Incident Response Plan (PSIRP), Our local BPAS plan sets out how we will carry out the PSIRF including our list of local priorities. These have been developed through a coproduction approach and is supported by analysis of local data.

AAR

After Action Review (AAR) is a method of evaluation that is used when outcomes of an activity or event, have been particularly successful or unsuccessful. It aims to capture learning from these tasks to avoid failure and promote success for the future.

Duty of Candour

The duty of candour requires registered providers and registered managers (known as 'registered persons') to act in an open and transparent way with people receiving care or treatment from them. The regulation also defines 'notifiable safety incidents' and specifies how registered persons must apply the duty of candour if these incidents occur.

HSIB

Healthcare Safety Investigation Branch

Never Event

Patient safety incidents that are considered to be wholly preventable where guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and have been implemented by healthcare providers.

Patient Safety Incidents (PSIs)

Patient safety incidents are unintended or unexpected events (including omissions) in healthcare that could have or did harm one or more patients.

Patient Safety Partner (PSPs)

PSPs are patients, carers, family members or other lay people (including NHS staff from another organisation working in a lay capacity) who are recruited to work in partnership with staff to influence and improve the governance and leadership of safety.

PSII

Patient Safety Incident Investigation (PSII) A systems-based response to a patient safety incident for learning and improvement. Typically, a PSII includes four phases. Planning, information gathering, synthesis, and interpreting and improving.

SEIPS

Systems Engineering Initiative for Patient Safety (SEIPS) is a framework for understanding outcomes within complex socio-technical systems. Patient safety incidents result from multiple interactions between work system factors (i.e., external environment, organisation, internal environment, tools, and technology, tasks, and person(s). SEIPS prompts us to look for interactions rather than simple linear cause and effect relationships.

SWARM Huddles

Immediately after an incident, staff ‘swarm’ to the site to quickly analyse what happened and how it happened and decide what needs to be done to reduce risk. Swarms enable insights and reflections to be quickly sought and generate prompt learning.

Thematic Review

A thematic review may be useful for understanding common links, themes, or issues within a cluster of investigations, incidents, or patient safety data. Themed reviews seek to understand key barriers or facilitators to safety.