NHS Blood and Transplant

Board Meeting in Public

Tuesday, 26 March 2024

Title of Report	Patient Safety Incident Response Framework (PSIRF) Implementation	**Agenda No.**	4.4
Nature of Report	☒ Official	☐ Official Sensitive	
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Presented for	☒ Approval ☒ Assurance	☐ Information ☐ Update	

Purpose of the report and key issues

The purpose of this paper is to provide an overview of the policy, plan and overarching governance structure that will underpin the implementation of PSIRF within NHSBT.

PSIRF will be implemented from 2nd April 2024, replacing the Serious Incident Framework (SIF 2015). Implementation will be phased to allow the organisation to develop new approaches to learning from Patient and Donor Safety Incidents (PDSI's).

The policy sets out our intention and approach to learning from patient and donor safety incidents. It will form a fundamental shift in the culture of these incident management practices, promoting learning and proportionality in our response(s). The plan (also in the review room) sets out how we shall respond to and learn from PDSIs. These will be supported with a suite of documents that will provide detailed guidance on how staff are to apply the policy and plan.

Phase 1 (April – October 2024):
Organ & Tissue Donation and Transplantation (OTDT) go live with the full PSIRF process whilst other directorates begin the identification and assessment of PDSI's which will lead to improved understanding of their incident profile. The SI investigations will be replaced by PSI Investigations from the 3rd June 2024

Phase 2 (October 2024 – April 2025):
PSIRF will be implemented in full across the clinical directorates, with learning response leads undertaking the management of PDSI's. This will also include the development of improvement plans to manage themed incidents and a review of the Clinical Governance oversight structures to ensure their effectiveness in bringing systematic improvement in patient and donor safety.

Previously Considered by

Update provided to ET 13th April 2022, 4th January 2023, 7th December 2023
Approved by ET on 27th February 2024.
Bi-monthly updates provided at Clinical Governance Committee (CGC).
Approved by CGC on 8th March 2024

Recommendation	1. Endorse the approach to implementing PSIRF within NHSBT. 2. Endorse the approved PSIRF Policy. 3. Endorse the approved PSIRF Plan.

Risk(s) identified (Link to Board Assurance Framework Risks)		
PR-01 Patient and Donor Safety.		
Strategic Objective(s) this paper relates to: [Click on all that applies]		
☒ Collaborate with partners	☒ Invest in people and culture	☒ Drive innovation
☒ Modernise our operations	☒ Grow and diversify our donor base	

Appendices:	PSIRF Policy PSIRF Plan

Patient Safety Incident Response Framework (PSIRF)

1. Introduction

The PSIRF is a new framework developed by NHS England and published in August 2022 (available here).

1.1. It sets out the NHS approach to developing and maintaining effective systems and processes for responding to patient (and donor) safety incidents (PDSIs) for the purpose of learning from and improving patient (and donor) safety.

1.2. It replaces the current NHS England Serious Incident Framework (2015) which only focused on robust responses to the most serious incidents. PSIRF does not differentiate between lower harm/impact patient (and donor) safety incidents and serious incidents.

1.3. It encompasses a broader and more inclusive approach towards incidents and investigations by including all incidents which caused, or could lead to, harm, no matter the severity.

1.4. It aims to ensure systematic improvements are made and not just for the most serious incidents.

2. NHSBT PSIRF Policy

2.1. The Clinical Governance and Quality teams have worked collaboratively to create a plan for the implementation of PSIRF that aligns with the business operating model. It enables phased development and implementation of PSIRF for a safer and more robust patient and donor safety system.

2.2. The approach is encapsulated within a PSIRF policy that will be published on the NHSBT website, after approval from NHSBT ET, Board and the Department of Health and Social Care (DHSC), our sponsor, who will act as our external oversight body.

2.3. The policy provides information on how NHSBT's patient and donor safety culture will change by implementing new approaches to learning from safety incidents, providing role specific training to colleagues, improving the quality of our data, utilising tools to support analysis and sharing learning from incident responses across the organisation.

2.4. Patient and donor safety partners will be engaged to work alongside NHSBT within oversight groups to provide a voice from our service users, ensuring the delivery of meaningful responses and increased accountability.

2.5. During Phase 1 which will run from April 2024 – October 2024, NHSBT will:

2.5.1. Replace the current Serious Incident investigation process. Instead, system-based investigations will be led by trained practitioners to ensure a holistic view of factors that led to the incident being identified, enabling clearer understanding of what change is required.

2.5.2. Introduce a Patient and Donor Safety Incident review group which will review incidents occurring in all clinical areas each week and ensure appropriate and proportionate responses.

2.5.3. Redefine the Clinical Governance Oversight mechanisms to include a Clinical Quality and Safety Governance Group which will receive reports from all clinical areas, including the Patient and Donor Safety Incident Review Group.

2.5.4. Implement the full PSIRF process in OTDT whereby all incidents will be defined as PDSI or Non-PDSI then assessed for risk, impact and harm, overseen by a trained specialist in patient and donor safety and a proportionate learning response will be led by this practitioner.

2.5.5. Support the identification of PDSI or Non-PDSI in other clinical disciplines whilst they follow existing incident investigation processes during this transitional phase.

2.5.6. Develop an improved understanding of the number of PDSIs occurring, thematic analysis of these PDSIs and develop areas for further improvement plans to be initiated.
2.5.7. Deliver a structured organisation-wide communications plan which will educate colleagues of the purpose of PSIRF, focusing on the benefits of the changes to patient and donor care.
2.5.8. Provide further education and discussion forum in relation to 'Just Culture' and the impact this can have on reducing patient and donor safety incidents.
2.5.9. Publish an updated Duty of Candour Policy.

2.6. During Phase 2 which will run from October 2024 - April 2025, NHSBT will:
2.6.1. Identify additional learning response leads to enable a full implementation.
2.6.2. Systematically roll out the full PSIRF process across the clinical directorates as described at 2.5.4.
2.6.3. Commence a full data review to develop further improvement plans and enable further proportionality in incident response to be delivered.
2.6.4. Review the effectiveness of the PSIRF processes and relevant oversight groups and committees to ensure the delivery of meaningful change.
2.6.5. Review the effectiveness of Corporate Clinical Governance and Patient and Donor Safety structures and reporting.

3. PSIRF Plan

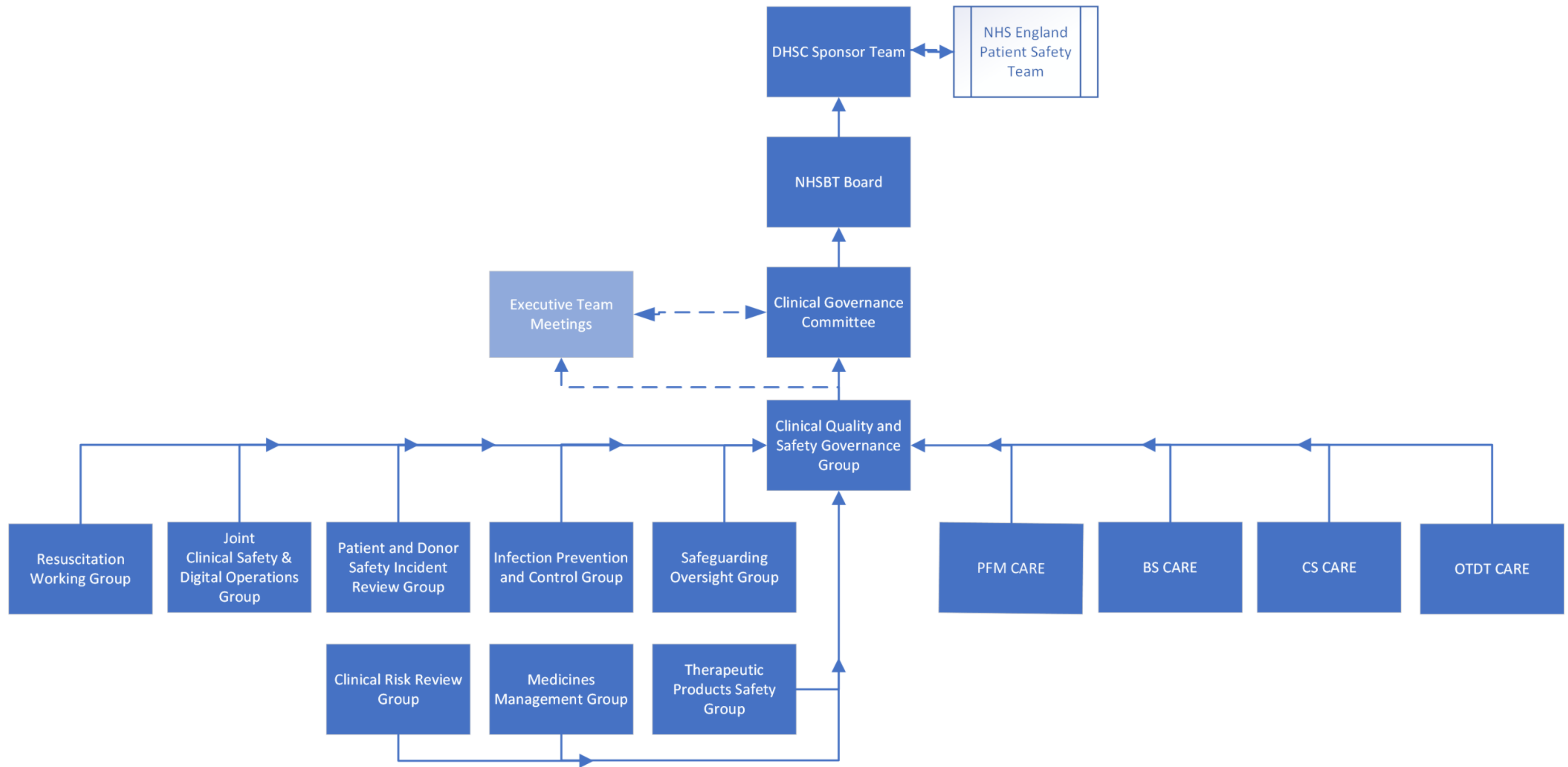
3.1. The PSIRF plan is developed and published to provide transparency in relation to how we will respond to and learn from PDSI's.
3.2. The plan will be effective for a period of 12 months and will then be reviewed and updated following the activities undertaken in Phase 2.
3.3. The plan includes information on the nationally defined PSII that must be undertaken, the PSII that we have defined as an organisation and how we will respond proportionately to other PDSI's.
3.4. The first iteration of the plan will incorporate the incident criteria currently laid out in the SIF 2015, thus, giving NHSBT a robust framework to support donor and patient safety.

4. Training

4.1. PSIRF is part of the wider patient safety strategy that was developed and published by NHS England in 2019 Patient Safety Strategy 2019 & updated in 2021 Patient Safety Strategy 2021 Update.
4.2. Within the strategy there is a commitment for all NHS staff in England to follow the same patient safety syllabus and for all those involved in healthcare to be trained accordingly.
4.3. The PSIRF delivery team have secured a patient safety strategy training provider and funding from NHS England for training delivery.
4.4. Training will be provided to select members of the Executive team, DHSC sponsor team, senior nursing team, senior quality team and selected colleagues who will undertake roles as learning response leads. In total we will train 180 colleagues.
4.5. Furthermore, we will ensure that links to the Patient Safety Syllabus Level 1 and Level 2 e-learning modules are made available for all colleagues who wish to learn more about this important area of healthcare governance.

Appendix 1 – Governance structure

The NHSBT Sponsor team within DHSC will provide oversight through the structure below:



Appendix 2 – PSIRF Future State

Event Identified (Internal or external via hospital customer services)

Note: Ideal state to consider single route of entry to QPulse and single module for recording patient/donor safety incidents

Event logged and recorded on Q Pulse

Occurence assessed by QA/CG as applicable

Does this incident require management as a PSI

No → Follow standard proceses for QI management including SOP 5920 QA incident management process and SOP 5039 Investigation and management of a quality incident

Yes → Is this a potential externally reportable incident?

No → No action required

Yes → Follow SOP 5920, SOP 6347, SOP3147 or DAT 1985

Yes → Patient and Donor review led by directorate CG team

Note: Ideal state to implement minimum reportable dataset in QPulse for all patient/donor safety incidents

Desired State

Phase 1 - ODT Phase 2 - All Clinical areas

Actions:
1) Confirm event is a PDSI
2) Harm grading as per NHSBT harm grading guidance
3) Confirm risk and impact score
4) Confirm immediate actions required, including DOC requirement
5) Information gathering as required for discussion at weekly Incident Review Group
6) Review PSIRP for PSII requirement

Risk and Impact Confirmation

Note: Ideal state to develop digital solution to extract reports from QPulse

- 1-3 Monitor/ Acceptable → Manage locally
- 4-8 Other/ Manageable → Proportionate response Manage locally
- 9-14 Major/ Significant → Recommend proportionate response for approval by corporate PS review group
- 15-25 Critical/ High → PSII Escalate to Corporate PS review group

Interim State

Phase 1 - Blood Supply, CS, TAS & PFM

Actions:
1) Confirm event is a PDSI
2) Harm grading as per NHSBT harm grading guidance
3) Confirm risk and impact score
4) Review PSIRP for PSII requirement

Incident investigation led by QA with input from CG team

Weekly Patient and Donor Incident paper:
1) Incidents set to MONITOR/GREEN-FYI
2) Incidents categorised as OTHER/YELLOW- FYI
3) Incidents categorised as Major/ AMBER- For discussion
4) Incidents categorised as critical/RED- For discussion

Weeky Patient and Donor Safety incident review Group (Corporate Chair)

Note:Terms of Reference for PDSI review Group to be developed.

Actions:
1) Note incidents (MONITOR, OTHER)
2) Review incidents (MAJOR, CRITICAL)

- Agree risk and impact
- Confirm immediate actions
- Agree proportionate response (inc PSII)
- Confirm Learning Response Lead
- Agree TOR of response
- Agree DOC requirment
- Document discussion on QPulse

* Includes QA, Directorate representation, Corporate Clinical Governance/PS, Safeguarding, Medical, Scientific, Education, FTSU

Appendix 3 - Implementation Plan

Preparation	23.10.23	30.10.23	06.11.23	13.11.23	20.11.23	27.11.23	04.12.23	11.12.23	18.12.23	25.12.23	01.01.24	08.01.24	15.01.24	PSIRF Policy and Plan Project Board 24/01/2024	PSIRF Policy and Plan Clinical services SMT 31/01/2024	05.02.24	12.02.24	26.02.24	19.02.24	PSIRF Policy and Plan Executive Team 27/02/2024	04.03.24	11.03.24	PSIRF Policy and Plan Clinical Governance Committee 14/03/2024	18.03.24	25.03.24	PSIRF Policy and Plan Board Meeting 26/03/2024	01.04.24
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Action	1. Orientation		2. Diagnostic and Discovery		3. Governance and quality monitoring		4. Patient safety incident response planning		5. Curation and agreement of the patient safety incident response policy and plan	
	a	Confirm scope and ambition	a	Blueprint of all data being analysed, including source and flow of information	a	Define how system effectiveness will be monitored and how quality of incident response system and outputs will be reviewed in line with oversight roles (QA effectiveness review, reporting structure CARE, Patient and Donor Safety Group)	a	Map current state patient safety incident management per directorate including incident reporting, investigation, analysis, patient and donor engagement, improvement and shared learning	a	Draft PSIRP to supersede SI Management MPD 772, national and local PSII
	b	Decision required on introduction of harm grading tool	b	Top 3 themes to be identified by each directorate lead with support from QA Improvement plans to be developed	b	Develop process for reporting cross directorate issues, shared learning	b	Map patient safety incident management by directorate for Phase 1 implementation (ODT, TES, BD, CS, PFM)	b	Develop process for incident response decision making Draft PSII response plan & decision making process
	c	Decision required regarding change request to incident reporting tools	c	Regulatory engagement, explore regulatory expectations- individual CAPA/improvement plan/thematic analysis	c	Define reporting and monitoring of patient safety incidents and to triangulate insights and identify emerging themes and support phase 2 diagnostic and discovery	c	Map patient safety incident management by directorate for ideal state implementation (ODT, TES, BD, CS, PFM)	c	Phase 1 OTDT to update ODT process/ pathway documentation to fulfil PSIRF policy (Documentation of future state that OTDT are implementing first, process documented and transferable to the wider organisation. Including learning responses, tools to be used, engagement plans etc).
	d	Confirm deliverables of phase 1	d	Map current organisation improvement activities	d	Education and training plan for oversight requirements	d	Gap analysis against current state and ideal state and triangulate against incident response data from diagnostic and discovery to inform business case	d	Templates will be re-developed and introduced for learning response activities and reports to ensure consistency.
	d	Communication plan	e	Assessment of incident response capacity- quantity and spread of RCA investigations completed	e	develop detailed plans for the Corporate CG team to ensure all elements in place for phase 2 go live	e	Define process for how patient and donor engagement will be achieved for transition phase 1	e	Develop detailed plans for each directorate to ensure all elements in place for phase 1 go live
			f	Assessment of training needs capacity- Learning response and engagement lead requirement (QA, CG, NCQT)	f	Develop detailed plans for the QA team to ensure that all processes, documents and Qpulse changes are in place for phase 1 go live	f	Identify all documents requiring review / deviation and change request; plan how to manage temporary and long term changes	f	Policy and plan development and approval plan
			g	Review of current SI framework	g	Update oversight and investigation training plan	g	Process map patient safety incident response pathway	g	
					h	Confirm oversight structure agreements in DHSC	h	Q Pulse gap analysis as required and change request as appropriate Needs to include building in a question for phase 1: Is this a patient safety incident?		
					i	Develop and approve ToRs for PDSIRG and CQSOG				

1st April 2024 Phase 1 Deliverables

~ The oversight of Patient Safety Incidents by DHSC Sponsors and NHS England is agreed and processes are established
~ The oversight of Patient Safety Incidents within NHSBT is agreed and processes are established. This will include CARE Committees, Donor and Patient Safety Group, Clinical Governance Committee and Executive Team and NHSBT Board
~ Each directorate will have identified three priority Patient/Donor Safety incident types on which improvement plans will be developed.
~ Patient Safety Incident Investigations (PSII) will be introduced, led by colleagues who are trained and experienced in patient safety response methodology. Patient Safety Incident Investigations will replace the Serious Incident Policy and will be undertaken for all incidents defined by NHS England and patient safety incidents designated by NHSBT as the most serious and requiring a formal PSII
~ Patients, donors and families who are involved in PSII's will be contacted and engaged with throughout the PSII as defined in the PSIRF policy.
~ Incidents that are currently defined as a major will continue to be managed using the current approach of RCA led by the business area manager with support from QA and the CG teams
~ We will build on current Corporate oversight of PSI's to ensure systematic learning and the development of organisational capability to undertake clinically led learning responses
~ A standardised reporting dataset will be defined and rolled out across the organisation that captures key clinical information that will improve organisational oversight of PSI's, support development of further improvement plans and the reintroduction of a patient safety scorecard.
~ All PSI's will be reported electronically using existing tools that have been developed in readiness.
~ Templates will be re-developed and introduced for learning response activities and reports to ensure consistency.
~ The NHSBT Duty of Candour policy will be updated to reflect the changes related to the implementation of PSIRF and to align with the expectations of the devolved UK health administrations
~ Actions will continue to develop improved engagement with those affected by Patient Safety Incidents no matter the severity of harm and impact.