NHS
Blood and Transplant

Patient and Donor Safety Incident Response Policy

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Contents

Purpose

This policy supports the requirements of the NHS England Patient Safety Incident Response Framework (PSIRF) and sets out NHS Blood and Transplant's approach to developing and maintaining effective systems and processes for responding to patient safety incidents and issues and in particular how we will learn from such events and improve patient safety. In the context of NHS Blood and Transplant the scope of PSIRF will encompass patient and donor safety. We will refer to patient and donor safety throughout the policy and refer to a patient or donor safety incident as a PDSI.

The PSIRF advocates a co-ordinated and data-driven response to patient and donor safety incidents. It embeds patient or donor safety incident response within a wider system of improvement and prompts a significant cultural shift towards systematic patient and donor safety management.

This policy supports development and maintenance of an effective patient and donor safety incident response system that integrates the four key aims of the PSIRF:

- compassionate engagement and involvement of those affected by patient or donor safety incidents
- application of a range of system-based approaches to learning from patient and donor safety incidents
- considered and proportionate responses to patient and donor safety incidents and safety issues
- supportive oversight focused on strengthening response system functioning and improvement.

Scope

This policy is specific to patient and donor safety incident responses conducted solely for the purpose of learning and improvement across NHS Blood and Transplant.

We will begin to introduce new terminology that is associated with improved engagement and activity in relation to safety incidents. As an example, we will begin to use ‘learning response’ instead of ‘investigation’ as this is associated with a positive outcome from an incident rather than the negative connotations of an investigation.

Under this policy learning responses will follow a systems-based approach to examining patient and donor safety incidents for the purposes of facilitating learning and improvement. Reviewing patient and donor safety incidents within large, complex and dynamic systems like healthcare is challenging. Patient and donor safety is a fundamental and essential component of the healthcare system: in which, safety is provided by interactions between components and not from a single component. Responses should not take a ‘person-focused’ approach where the actions or inactions of people, or ‘human error’, are stated as the cause of an incident. There is no remit to apportion blame or determine liability, preventability or cause of death in a response conducted for the purpose of learning and improvement.

Where the principle aims of processes differ from those of a patient or donor safety response they will be considered to fall outside the scope of this policy. These are listed below:

- Claims handling
- Human resources investigations into employment concerns
- Professional standards investigations
- Coronial inquests
- Criminal investigations
- Any complaint, incident or deviation where a PDSI has not occurred

Information from a patient or donor safety response process can be shared with those leading other types of responses as applicable, but other processes will not influence the remit of a patient and donor safety incident response.

Our patient and donor safety culture

NHS Blood and Transplant has a well-established culture of quality management. Through conformity with standards and guidance and formal review of associated incidents we aim to ensure that patient, donor and product safety is prioritised. Furthermore, we ensure that all opportunities are taken to understand the causes of any incidents and actions taken accordingly in accordance with a Just Culture. With the introduction of PSIRF and a data driven approach to safety improvement we will move to developing systematic improvement plans for recurrent incident types.

We work closely with our regulators and partners to develop and maintain systems that lead to safe and effective practices in all areas of our work and minimise the associated risks for our service users.

We are committed to creating an open and fair culture in which staff members are confident in reporting incidents and near misses. Evidence suggests that by creating an open reporting culture, organisations can improve their ability to learn when things go wrong and improve patient and donor safety. We support an open and transparent reporting culture by way of policies which promote and encourage reporting, such as our incident reporting policy as well as our guide to incident reporting and our Just Culture policy.

NHS Blood and Transplant has adopted the principles of 'Just Culture' which means that we focus on creating a culture of fairness, openness and learning in NHS Blood and Transplant. The aim is to develop a culture where colleagues feel confident to speak up when things go wrong, knowing that the focus is on learning and improvement rather than apportioning blame.

Supporting colleagues to be open about mistakes allows valuable learning and helps to prevent the same mistakes being repeated.

Associated with the Just Culture approach is the work being undertaken by the Freedom to Speak Up Guardian and the Equality, Diversity and Inclusion leads to promote freedom of speech, encourage all colleagues to be confident to discuss concerns without fear of negative impacts.

Further work is planned to reinforce the safety culture through internal staff network groups, professional networks, education and training and active promotion of the 'Safety II' approach within NHSBT in line with the NHS England Patient Safety Strategy. (Hollnagel et al., (2015) From Safety-I to Safety-II: A White Paper). Proactive, Safety II horizon scanning will support insight and further support a culture of learning by triangulating with learning from excellence and near misses.

Patient and donor safety partners

NHS Blood and Transplant does not yet have lay representatives in role as Patient and Donor Safety Partners. A proposal for the establishment and recruitment of Patient and Donor Safety Partners is in development with an intention to recruit into these roles during Phase 1 of the PSIRF implementation.

Three groups will be involved in the oversight of patient and donor safety incidents within NHS Blood and Transplant. Two groups are newly established, the Patient and Donor Safety Incident Review Group and the Clinical Quality and Safety Oversight Group. The purpose of the two groups is to provide oversight of all patient and donor safety incidents as they occur, to ensure appropriate management of the incidents and then to ensure that actions and learning are completed in a timely manner and to a satisfactory standard.

Both the above groups feed into the Clinical Governance Committee (CGC), which is a sub-group of the NHS Blood and Transplant Board. The CGC will provide the formal oversight function of PDSI activity.

It is intended that each of these three groups will have patient and donor safety partner representatives who will be fully engaged and supported to further develop the safety culture within NHS Blood and Transplant. The remit of the representatives is to explore the delivery of patient safety guidance related activity, to hold NHS Blood and Transplant to account against the PSIRF policy and PSIRF plan and to advocate on behalf of service users.

Addressing health inequalities

NHS Blood and Transplant recognises the importance of reducing health inequalities of the population. We further recognise that it is vital we collect and utilise information and data effectively to ensure that we are responsive to known or developing health inequalities that may disproportionately affect people in different areas of the country and the devolved administrations that we serve. We will ensure that we utilise information, data and feedback to design services around the needs of the population, working to ensure equality of access and service provision.

Under the Equality Act (2010), as a public authority, we have statutory obligations that we are committed to delivering on. We will also gather and analyse data to explore whether any patient or donor safety risks or incidents disproportionately affect certain cohorts of the population.

We will undertake a thorough analysis of all patient and donor incident data, complaints and freedom to speak up reports. This flexible approach and intelligent use of data will help to identify inconsistent risks to service users with specific and/or protected characteristics and enables the development of processes to drive improvements to address these risks.

Engaging and involving patients, families and staff following a patient or donor safety incident

The PSIRF recognises that learning and improvement following a patient safety incident can only be achieved if supportive systems and processes are in place. It supports the development of an effective patient safety incident response system that prioritises compassionate engagement and involvement of those affected by patient safety incidents (including patients, donors, families and staff). This involves working with those affected by patient safety incidents to understand and answer any questions they have in relation to the incident and signpost them to support as required.

NHS Blood and Transplant has a well-developed culture of transparency throughout the organisation and with service users. The work undertaken by engaging and involving service users and staff groups following a patient or donor safety incident has been used to inform our plans. However, we also recognise that improvements can be made and as such we are working to improve how we engage with patients, donors, families and staff by listening and by recognising and building on areas of excellence.

Duty of Candour

Promoting a culture of openness and transparency is an important aspect of improving patient safety and the quality of healthcare systems. It involves explaining and apologising for what happened to patients, blood donors, and deceased donor families who have been harmed or involved in an unexpected incident or as a result of an error of healthcare treatment.

Patient or donor safety incidents can have long term physical and emotional consequences for patients/donors, their families and carers, and can be distressing for the professionals involved.

NHS Blood and Transplant, works in accordance with all of the health administrations in the UK and is committed to supporting a culture of openness and transparency and fully supports the principles of Being Open and the Duty of Candour. This commitment includes acknowledging, apologising, understanding, and explaining what has happened to patients and their families, blood donors, deceased donor families, living donor's/families and / or relevant persons when things have gone wrong within any element of our services. When engaging with patient families and living donor families, NHS Blood and Transplant will seek the consent of the patient or living donor to do so as appropriate, recognising that it may not always be possible, for example in incidents involving deceased donors.

NHSBT will continue to fulfil its legal and moral duty to inform patients, blood donors, and deceased donor families who have suffered harm or loss while receiving care or services provided by NHSBT in line with the organisational Being Open and the Duty of Candour policy.

Patient and donor safety incident response planning

The PSIRF supports organisations to respond to incidents and safety issues in a way that maximises learning and improvement, rather than only basing responses on potentially subjective definitions of harm. Beyond nationally set requirements, NHS Blood and Transplant will explore patient and donor safety incidents relevant to the context of our services and the populations we serve, rather than only those that meet a certain defined threshold. This means we can respond proportionately dependent on our assessment of the significance of an incident.

The development of a harm/impact assessment tool will guide the learning response that should be undertaken and therefore a proportionate and systematic learning response will be defined, in some cases this may be associated with an existing improvement plan.

In line with existing agreements, we will ensure that we continue to meet our regulatory responsibility to report incidents to our regulators.

OTDT Directorate will continue their Assisted Function Role on behalf of the Human Tissue Authority (HTA).

Resources and training to support a patient or donor safety incident response

The PSIRF standards have defined the competencies required for individuals leading PSIRF within organisations including those who will undertake oversight roles, learning response leads, and engagement leads.

All colleagues in these specified roles will have undertaken the PSIRF stipulated training programmes and will be supported to maintain competency through CPD. We have agreed a training programme for all involved in Patient and Donor Safety Incidents which is specific to the roles that each individual will perform.

We are ensuring that we develop a robust network of learning response leads so that the organisation has the necessary resources to undertake learning responses in a timely manner. They will ensure that recommendations are developed following an incident and that we have the knowledge and capability to drive necessary improvements in our service delivery models.

Our patient and donor safety incident response plan

Our plan sets out how NHS Blood and Transplant intends to respond to patient and donor safety incidents over a period of 12 months from 1st April 2024.

The plan has been developed with organisation wide input in relation to the types and severity of incidents that occur within the organisation, knowledge and experience of different types of incident and learning responses, knowledge and experience of the benefits and dis-benefits of existing systems and processes, data analysis related to all incidents that occur in NHS Blood and Transplant, organisation readiness for change, capacity for clinically led learning responses and oversight processes and mechanisms.

As we have developed a phased approach to implementation, it will be necessary to regularly monitor delivery against the plan and as such we will maintain a project management oversight throughout Phase 1 as we prepare and plan for a successful delivery of Phase 2. With this approach, it is important to recognise that the plan is not a permanent set of rules that cannot be changed. We will remain flexible and consider the specific circumstances in which each patient or donor safety incident occurred and the needs of those affected, as well as the plan.

Reviewing our patient and donor safety incident response policy and plan

Our patient safety incident response plan is a ‘living document’ that will be appropriately amended and updated as we use it to respond to patient and donor safety incidents. We will review the plan every 18 to 24 months to ensure our focus remains up to date; with ongoing improvement work our patient and donor safety incident profile is likely to change. This will also provide an opportunity to re-engage with stakeholders to discuss and agree any changes made in the previous 18 or 24 months.

Updated plans will be published on our website, replacing the previous version.

A rigorous review of incident data and associated planning exercise will be undertaken every 18 -24 months and more frequently if appropriate (as agreed with our DHSC oversight team) to ensure efforts continue to be balanced between learning and improvement. This more in-depth review will include reviewing our response capacity, mapping our services, a wide review of organisational data (for example, patient safety incident investigation (PSII) reports, improvement plans, complaints, claims, staff survey results, inequalities data, and reporting data) and wider stakeholder engagement, particularly with the devolved health administrations and international equivalent services.

Responding to patient and donor safety incidents

Patient and donor safety incident reporting arrangements

We are committed to creating an open and fair culture in which staff members are confident about reporting incidents and near misses. We have clear procedures for reporting incidents, exploring and understanding the circumstances leading to events and recording learning, as well as monitoring processes which are set out in our incident reporting policy. We plan to develop the current processes for incident reporting to harmonise the processes and reduce complexity. This will include the introduction of a generic incident reporting data set.

Patient and donor safety incident response decision-making

PSIRF supports organisations to respond to incidents in a way that maximises learning and improvement from all incidents rather than those that have been defined as the most significant or serious.

A multidisciplinary patient and donor safety incident review group will be established whose purpose is to review patient and donor safety incidents reported through the quality management system and agree the type of response required. This may include a systems-based learning response, a full patient safety incident investigation (PSII) or monitoring and review in line with an improvement plan, as specified within the patient safety incident response plan (PSIRP). This will require close alignment with the directorate clinical governance/ patient and donor safety teams to ensure that relevant PDSI's are reviewed, that trends are identified and that opportunities are made to develop improvement plans.

The group will discuss and agree the response to incidents, based on the following options described in the patient safety incident response framework (PSIRF) and plan:

- Contributory (system) factors not well understood - learning response indicated
- Safety issue well-understood and/or improvement plans are in place and robust – consider not undertaking an investigation as no additional learning
- Unclear whether a learning response is required – the group will discuss and agree response based on information provided and opportunity for learning / improvement.

Responding to cross organisational incidents/issues

The clinical governance/patient safety team's from across Directorates will identify cross organisational incidents or issues during review at the Patient and Donor Safety Incident Review Group. The appropriate learning response will be recommended and work will be initiated whilst NHS Blood and Transplant work with external providers and their relevant Integrated Care Boards to agree how the organisations will work together, to facilitate the free flow of information and minimise delays to joint working and determine the activity that each organisation will undertake in response to the incident. The relevant Directorate clinical governance team/patient safety team will act as the liaison point for such working and will have supportive

processes to ensure that this is effectively managed and in particular how safety actions will be developed, and how the implemented actions will be monitored for sustainable change and improvement.

Timeframes for learning responses

Responses should start as soon as possible after an incident is identified and the learning response agreed by the PDSIRG. We aim for responses to be completed within 1 to 3 months but not take longer than 6 months depending on the response type and the complexity of the incident. The time frame for completing a PSII should be agreed with those affected by the incident and this will form part of the terms of reference for the local response.

There might be exceptional circumstances where timelines exceed 6 months, for example, if a partner organisation requests a pause to an investigation. In these circumstances, any extension to a timeline will be agreed with all parties involved in the incident, including the patient or donor, families, and staff.

The Clinical Quality and Safety Oversight Group will monitor timescales and progress of PSIIs.

Safety action development and monitoring improvement

The learning response should identify areas for improvement and describe recommendations. Best practice advises that learning responses should not define actions as this can lead to premature attempts to deliver a solution. We will develop processes to draw up safety actions in relation to each of the identified areas and set monitoring standards.

NHS Blood and Transplant will ensure that systems and processes are in place that enable us to design, implement and monitor safety actions and improvement plans. This will need to be undertaken with close collaboration with operational teams and through the use of evidence-based practices. This is an area still in development and will build on the robust systems and processes already in place. Any gaps identified during development will be addressed as part of our phased PSIRF implementation.

We will use the process for development of safety actions as outlined by NHS England in the Safety Action Development Guide (2022).

The Clinical Quality and Safety Governance Group will ensure that feedback is sought from patients, donors and colleagues to ascertain the effectiveness and appropriateness of safety actions and processes.

Safety improvement plans

NHS Blood and Transplant is in the early stages of developing formal safety improvement plans that are based upon systematic review of patient and donor safety incidents. A small number of improvement plans have been identified and included within the PSIRP. Safety improvement plans will be revised in response to any new learning, so that they represent the latest and best approach to dealing with a particular patient or donor safety issue. This includes revising improvement plans where evidence indicates that measures are not having the anticipated impact. Processes will be developed to ensure

that review periods are defined, and reviews take place accordingly with reports to the Clinical Quality and Safety Oversight Group.

Oversight roles and responsibilities

The following ‘mindset’ principles underpin the oversight of patient or donor safety incident responses:

1. Improvement is the focus PSIRF
   Oversight will focus on enabling and monitoring improvement in the safety of care, not simply monitoring investigation quality.

2. Blame restricts insight
   Oversight will ensure learning focuses on identifying the system factors that contribute to patient safety incidents, not finding individuals to blame.

3. Learning from patient safety incidents is a proactive step towards improvement
   Responding to a patient or donor safety incident for learning is an active strategy towards continuous improvement, not a reflection of an organisation having done something wrong.

4. Collaboration is key
   A meaningful approach to oversight cannot be developed and maintained by individuals or organisations working in isolation – it must be done collaboratively.
5. Psychological safety allows learning to occur
   Oversight requires a climate of openness to encourage consideration of different perspectives, discussion around weaknesses and a willingness to suggest solutions.

6. Curiosity is powerful
   Leaders have a unique opportunity to do more than measure and monitor. They can and should use their position of power to influence improvement through curiosity. A valuable characteristic for oversight is asking questions to understand rather than to judge.

Oversight Mechanisms

Oversight of Patient and Donor Safety incidents will be led by the Chief Nursing Officer with support from the Directorate Chief Nurses, Clinical Governance/Patient and Donor Safety Teams and the Quality Assurance teams who will ensure that we meet the national patient safety incident response standards.

The Chief Nursing Officer supported by the Clinical Quality and Safety Oversight Group and the Clinical Governance Committee, will oversee the development, review and approval of this policy and plan for patient and donor safety incident responses, ensuring that we meet the expectations set out in the patient safety incident response standards where relevant.

The Board will be given access to relevant information about the organisation's preparation for and response to patient and donor safety incidents, including the impact of changes following incidents and relevant summary information on learning responses underway and actions being undertaken. This will ensure that PSIRF is central to overarching patient and donor safety governance arrangements.

The Chief Nursing Officer, with support from the corporate clinical governance team will ensure:

- patient/donor safety incident reporting and response data, learning response findings, safety actions, safety improvement plans, and progress are discussed at the Clinical Governance Committee
- roles, training, processes, accountabilities, and responsibilities of staff are in place to support an effective organisational response to incidents.

The Corporate Clinical Governance team and Quality Directorate will ensure that mechanisms for the ongoing monitoring and review of the patient safety incident response plan, delivery of safety actions and improvement forms part of the overarching clinical governance arrangements and that it is supported by clear financial planning to ensure appropriate resources are allocated to PSIRF activities and safety improvement.

The DHSC Oversight team in collaboration with NHS England Patient Safety Team will provide external Integrated Care Board equivalent oversight of the organisations, patient and donor safety responses, the compliance with the PSIRF policy and plan and ensue that systematic learning is undertaken, actioned and shared with relevant third parties.

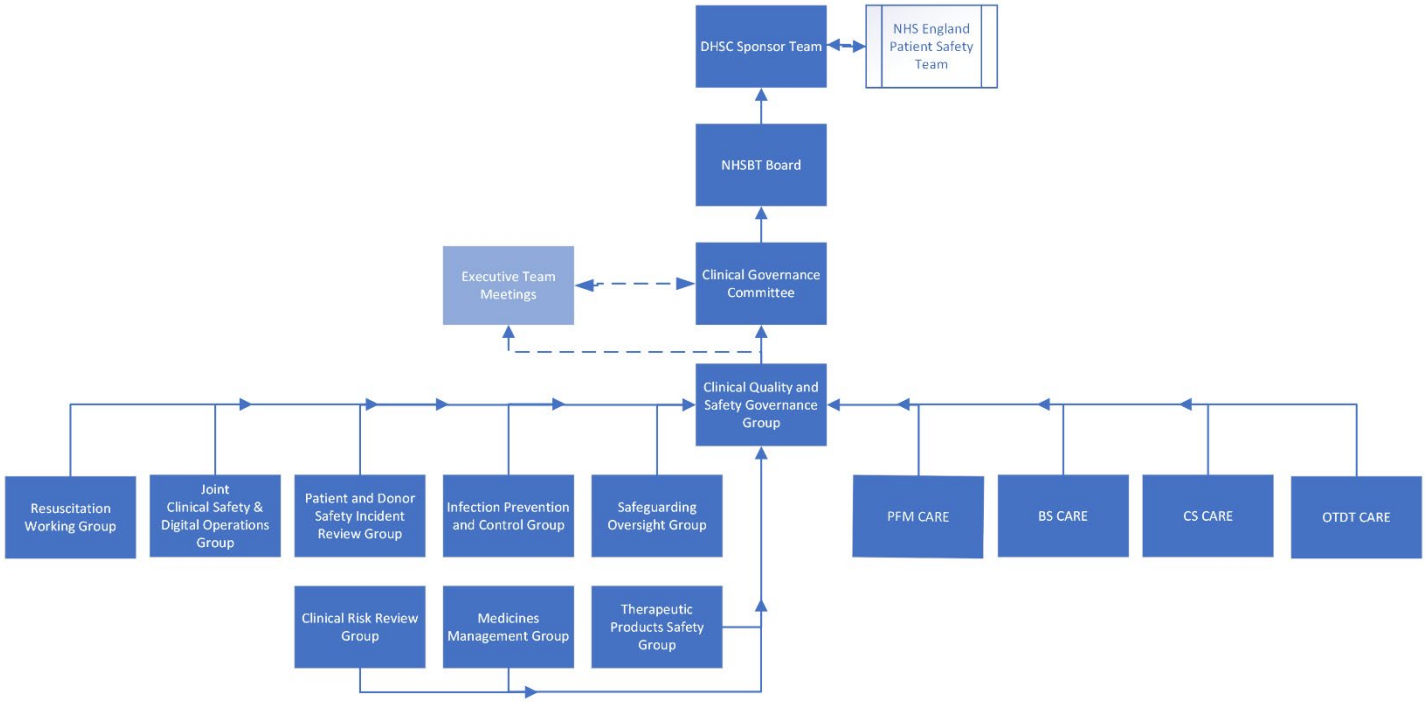

Fig 1. Corporate Clinical Governance Oversight Structure

Complaints and appeals

Even with ongoing engagement and involvement of those affected by patient or donor safety incidents there may still be times when people feel dissatisfied with the response the organisation has provided following a learning review.

In this event; It is the NHSBT's responsibility to seek early resolution to any issues raised, in line with the NHS Complaint Standards.

Initially there should be a discussion between the affected person and their lead contact.

If they are unable to resolve the issues this should be escalated to the Directorate Chief Nurse who will meet with the affected person.

In the event that this resolution is unsuccessful the Directorate Chief Nurse will support the affected person to log a formal complaint. This process will enable access to the complaints appeal process and the Parliamentary Ombudsman