NHS Blood and Transplant

Title of meeting: Board in Public
Date of Meeting: Tuesday, 30 July 2024

Title of Report	Clinical Governance Report	**Agenda No.**	5.6.2
Nature of Report	☒ Official	☐ Official Sensitive	
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Presented for	☐ Approval ☒ Assurance	☒ Information ☒ Update	

Purpose of the report and key issues

This paper summarises the Clinical Governance Committee (CGC) meeting held on the 12th of July 2024. Key issues:

- On June 3rd, NHS Blood and Transplant (NHSBT) transitioned from the Serious Incident (SI) Framework to the Patient Safety Incident Response Framework (PSIRF), underscoring its commitment to enhancing patient and donor safety through effective incident response and learning. Significant incidents are now investigated under Patient/Donor Safety Incident Investigations (PSII). The newly formed Patient and Donor Safety Incident Review Group (PDSIRG) ensures thorough incident reviews, appropriate harm grading, and the implementation of suitable responses and learning mechanisms.

- Since the implementation of the PSIRF, two incidents have met the threshold for a PSII. The first PSII (QI40259) involved a mix-up in blood sample testing, leading to the unnecessary administration of Plerixafor to an allogeneic donor, who showed no adverse reactions and is being monitored for delayed effects. The second PSII (ODT-INC-8070) involved hemolysed samples from two eye donors, requiring additional samples, and one sample was misplaced, resulting in the release of corneas without complete serology results; the risk to recipients is deemed very low.

- Recent business continuity incidents highlight the need to ensure a robust system. These incidents included an O Negative red cell shortage, a Synnovis cyber-attack affecting southeast London hospitals pathology, Macopharma leucodepletion failures, a short-term NHSBT network outage, and equipment maintenance issues at Newcastle Hospital Services. The Clinical Governance Committee supports reviewing NHSBT's policy with key external Trusts and stakeholders to enhance wider system resilience and safety.

Previously Considered by

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Recommendation	The Board is asked to note the report.

Risk(s) identified (Link to Board Assurance Framework (BAF) Risks)

PR-01 Donor / Patient Safety & PR-06 Failure to Monitor Clinical Outcomes

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:	None

1. Patient and Donor Safety

1.1 Patient and Donor Safety Incident Review Group (including PSII)

1.1.1 ***Summary***

On 3rd June NHSBT transitioned from the Serious Incident (SI) Framework to the Patient Safety Incident Response Framework. This transition represents the organisation's commitment to developing and maintaining effective processes for responding to patient and donor safety incidents for the purpose of learning and improving patient safety. Under the new framework the most significant incidents will be investigated as patient/donor safety incident investigations (PSII).

The Patient and Donor Safety Incident Review Group (PDSIRG) has been formed to support the provision and maintenance of an effective organisation-wide patient and donor safety response system.

Its principal aim is to bring together expert membership, to ensure that all patient and donor incidents are reviewed in line with national and local guidance to determine harm grading, agree proportionate response (e.g. PSII, AAR) and ensure appropriate mechanisms are in place for reporting, investigating and learning from incidents to prevent reoccurrence and improve patient and donor safety.

The first phase of the Patient Safety Incident Response Framework launched on 3rd June 2024, the first PDSIRG was held 6th June 2024

In the period prior to 3rd June, no SIs were declared under the previous framework. Two incidents have met the criteria to be investigated as PSII in this reporting period.

1.1.2 ***New PSIIs*** -

a) PSII- QI40259 (Cellular and Molecular Therapies): On July 1 2024, three blood samples were sent to one of NHSBT's Stem Cells & Immunotherapies (SCI) laboratories for analysis: two from patients donating their own cells (autologous) and one from a donor giving cells to another person (allogeneic). One autologous sample was mistakenly tested as the allogeneic sample, leading to an incorrect result being reported to the hospital.

The reported result showed a lower cell count than expected for the allogeneic donor, prompting a retest request from the hospital. During the retest period, the donor was given Plerixafor, by the hospital medical team, based on the incorrect result. Plerixafor is used to increase peripheral blood stem cells in autologous patients but is not licensed for use in allogeneic donors however, it can be used "off license" at the medical teams discretion. The retest revealed that the initial cell count was much higher, meaning Plerixafor was unnecessary. This constitutes a harm incident.

The donor is currently well and has shown no side effects or adverse reactions to the medication. The donor's blood count will be reviewed again to ensure there are no delayed effects.

b) PSII- ODT-INC-8070 (Tissue and Eye Services): Two donors from two different Hospices were referred for eye donation, Donor A and Donor B.

On 13th June 2024, samples for both donors were received at Microbiology Services Laboratory (MSL). Both samples were assessed and deemed unsuitable for testing as haemolysed. Therefore, attempts were made to source additional samples for both donors to enable microbiological testing.

A sample was located for Donor A at a local hospital. On 14th June 2024 it was reported to have been taken by courier to Colindale. No additional samples could be located for Donor B.

On 18th June, a full serology result was provided by MSL for Donor B. However, it is believed no suitable sample was located to enable testing to be completed. On 19th June 2024, the corneas for Donor B were released for clinical use.

No result was produced for Donor A. It appeared that the sample sent from the local hospital for Donor A had not been received by MSL between 19th June 2024 - 3rd July 2024. Discussions were had to locate the sample sent for Donor A.

On 5th July 2024 MSL confirmed results could not be provided and the retrieved corneas from Donor A were authorised for discard.

Whilst initial samples for Donor A and Donor B were haemolysed, molecular testing was completed. This includes HIV, Hep B, Hep C and Hep E. All results were negative. Molecular testing does not include Syphilis, HTLV or Hep B anti-core (anti-HBc). Outcome of meeting with Consultant Transplant Medicine to discuss risk to recipients identified very low risk due to corneas being avascular.

1.1.3 ***Open SIs*** - *One* previously discussed SI (Never Event) remains open:
The Organ and Tissue Donation and Transplantation (OTDT) **SI INC6524** (Never Event) from September 2022: This incident pertains to unintentional ABO-mismatched solid organ transplantation. NHSBT is still awaiting the external closure report led by NHS England.

1.1.4 **Closed SIs –** One serious incident was closed:
The SI (QI39087) - On 3rd January 2024 the British Bone Marrow Registry (BBMR) received a donation request from the Czech registry. This was accepted and a collection date of 19th/20th February 2024 was planned. Due to a change in the patient's clinical condition the transplant centre requested a three to four week postponement. BBMR facilitated the postponement request and rebooked the collection for 27th/28th March 2024 based on availability at the collection centre. This collection date was communicated to and acknowledged by the Czech registry.

The Czech registry requested new collection dates of 19th/20th March 2024. On 5th March 2024 an email was sent to the Czech registry agreeing to a collection date of 19th/20th March 2024. This was based on mistaking the original collection dates (19/02/24) for confirmation that 19/03/24 was available for collection in an email thread received on the same day.

The disparity in collection dates was not identified until the Czech courier called The London Clinic enquiring about product pick up.

The patient had received conditioning (usually chemotherapy, radiation, or both to suppress the immune system and clear space for new stem cells) and subsequently experienced an unexpected period of pancytopenia (reduction in the number of red and white blood cells, and platelets in the peripheral blood) due to the ineffective coordination and communication of dates between agencies.

The investigation has found that at the time the incident occurred there was not a defined single source to identify confirmed collection date, there was no check or validation process for donation date and communication of the collection date was predominately via multiple individual user email accounts.

There were missed opportunities to identify the discrepancy in dates. The investigation has identified that the Donor Final Clearance form generated from Hematos includes a collection date field, this

information was not available in Hematos at the time it was generated, and the form was not configured to mail merge out the donation date. This form was sent without the date being entered. The Czech registry confirmation documents included dates that were not picked up by BBMR as different to the BBMR schedule.

With support from The London Clinic, Alcura and the Donor, collection was successfully achieved on 25th March 2024, 2 days earlier than scheduled. No known actual physical harm has come to the patient. It has been reported that the patient's condition is stable and they received their stem cell transplant on 26th March 2024. No information on patient engraftment status has yet been shared with BBMR.

2. Infected Blood Inquiry (IBI)

The Infected Blood Inquiry's final report outlines 12 primary recommendations and 57 sub-recommendations, emphasising areas such as compensation, a formal government apology, enhanced healthcare and support services, improved transparency in public health communication, and monitoring long-term health impacts. Established in May, the NHSBT Implementation Group, led by the Chief Nursing Officer, has held two meetings, focusing on recommendation 7 related to blood transfusion, and will continue reviewing progress on other recommendations. Meeting outcomes are shared via intranet, internet, and bulletins, involving key stakeholders and affected members. A Department of Health and Social Care (DHSC) led programme board, set up on 11th of June, ensures coordination of health bodies' responses, with NHSBT contributing significantly to the implementation of these recommendations to provide justice and support to those affected.

3. Business Continuity Incidents

Business continuity incidents were discussed, highlighting their impact on patient and donor safety. Key incidents included a persistent blood shortage of O Negative red cells, a cyber-attack on Synnovis affecting pathology support in south-east London, failures in leucodepletion processes with Macopharma products, a short-term network outage in NHSBT's infrastructure, and equipment maintenance discrepancies at Newcastle Hospital Services. These incidents highlight the need for a resilient business continuity management system. The Clinical Governance Committee has supported a comprehensive review of NHSBT's business continuity policy in collaboration with trusts that rely on NHSBT services, aiming to enhance overall system resilience and safety.
Of note, the Synnovis cyber incident has significantly increased the workload at NHSBT, with staff deployed and work reprioritised to support services across impacted hospitals.

4. Safety policies

4.1 HAV/B19 Screening and Automated Recall Preparation

The Therapeutic Products Safety Group (TPSG) approved starting HAV/B19 screening ahead of an automated recall system for plasma testing positive for B19 or hepatitis A, with current testing on frozen plasma stock from 2022 and measures to hold any stock at NHSBT sites. The microbiology clinical team will manage reactive samples and notify donors and hospitals. Approximately 85% of donors currently provide plasma samples, potentially increasing to nearly 100%. Key issues to resolve before real-time testing include processing samples within 48 hours, establishing an automated recall system, and managing rapid B19 outbreak scenarios. A working group will address these issues, with insights from countries like Canada. Ambient plasma testing is expected to start in December 2024, ahead of schedule.

4.2 Leucocyte Depletion Incident

A critical incident review was conducted following issues with leucocyte depletion in blood components using a new batch of Macopharma Top-and-Top whole blood collection packs. Since

17th June 2024, Quality Monitoring (QM) tests revealed that 2.6% of red cell units produced with these packs exceeded the acceptable white blood cell (WBC) limit, affecting approximately 200 units issued to hospitals. These units cannot be identified retrospectively.
Leucodepletion, intended to reduce vCJD risk and other WBC-associated risks, remains beneficial despite the current low vCJD risk. A clinical risk assessment indicated very low risk from the incident due to existing safety measures like irradiation and CMV testing. Recalling affected units would critically reduce red cell stocks, outweighing the clinical risk. The MHRA has been notified.

5. Clinical Audit

The 2024/25 Clinical Audit programme consists of seven audits. Of these, one clinical audit was completed during this reporting period: Audit of Serious Incident (SI) Actions within Organ & Tissue Donation and Transplantation (AUD4338). This audit reviewed the implementation of RCA action plans to ensure they are appropriate, effective in addressing identified issues, and implemented efficiently in OTDT. The audit revealed that 19% of actions were completed by the target date, 76% were completed within 1-90 days post-target, and 24% were delayed by more than 91 days. Additionally, 14% of actions had documented extensions or revisions. While 100% of risk impact assessments were documented. Recommendations include disseminating the findings and considering a re-audit after the new Patient Safety Incident Response Framework (PSIRF) is implemented.

6. Key Directorates' updates

6.1 NHSBT Partnership with Galapagos for Local CAR-T Therapy Production - NHSBT Cellular and Molecular Therapies (CMT) Function has entered a contract with Galapagos to produce Chimeric Antigen Receptor T-Cell (CAR-T) therapies at the Barnsley facility for clinical trials targeting blood cancers. NHSBT currently supports CAR-T products for other companies by collecting starting cells through Therapeutic Apheresis Services (TAS), handling cryopreservation, shipping, storage, and issuing CAR-T therapies manufactured in centralised facilities. The new partnership will enable localised manufacturing, resulting in quicker turnaround times and enhanced patient care. This development also positions NHSBT to potentially become a distributed manufacturer for novel therapies, as these treatments begin to replace current stem cell transplants supported by CMT and TAS.

6.2 Hospital Complaints Annual Report 2022/23 - The annual complaints report for 2022/23 was discussed at BSCARE and CS CARE groups. The report recorded 778 complaints: 417 in Blood Supply and 361 in Clinical Services.
Of the total complaints, 694 were upheld, and 95 had some form of patient impact. Notably, 65 complaints were related to delayed transfusions, raising significant concern. The committee recommended, and it was agreed, to conduct a thorough analysis of these delays using the Patient Safety Incident Response Framework (PSIRF). Findings from this in-depth analysis will be reported. Further investigations into specific complaint categories, reagent issues, and hospital collaboration are advised to address ongoing concerns.

6.3 Plasma for Medicine donation - The introduction of the 800ml plasma donation volume is paused due to concerns with overweight sourced plasma for medicine (sPFM) donations. While managed under the Quality Management System (QMS), further discussions within governance committees are ongoing to ensure actions effectively mitigate the risk of over-bleeding in donors assigned to 800ml donations.

7. Information Governance

7.1 Data Security & Privacy Toolkit (DSPT) – The DSPT is a mandatory annual assessment for organisations with access to NHS patient data. NHS Blood and Transplant (NHSBT), a Category 1 organisation, had a 'Standards Not Met' rating in 2022/23 and initiated an Improvement Plan with NHS England. In June 2023, NHSBT submitted its 2023/24 return and is expected to be rated 'Approaching Standards', showing progress but with some actions still pending.
From September 2024, the DSPT will adopt stricter requirements under the National Cyber Security Centre's Cyber Assessment Framework (CAF). This may reduce compliance for NHSBT and other critical health providers due to sector challenges and legacy technology. NHSBT is working with DHSC to understand the impact and will provide updates in the Cyber2 Programme reports.

7.2 Compliance with standards - Previously, NHSBT encountered challenges concerning email communication with other NHS organisations. These difficulties were primarily attributable to non-compliance with the DCB1569 email standard. Addressing these issues necessitated adherence to NHS England's DCB1596 Secure Email Standard, which mandates compliance with additional standards for clinical risk management of healthcare IT systems: DCB0129 and DCB0160.

After extensive efforts, NHS England confirmed NHSBT's accreditation to DCB1596 effective from 26th June 2024. DCB1596 requires annual re-accreditation, with progress updates to be reported to the Joint Clinical Safety & Digital Operations Group (JCSDOG).