NHS
Blood and Transplant

Board Meeting in Public
Tuesday, 30 January 2024

Title of Report	Clinical Governance Report	**Agenda No.**	5.1.2
Nature of Report	☒ Official	☐ Official Sensitive	
Author(s)	Samaher Sweity – Head of Clinical Governance, Clinical Services Andrew Broderick – Chief Nurse and Corporate Clinical Governance Lead		
Lead Executive	Denise Thiruchelvam, Director of Nursing		
Non-Executive Director Sponsor	Professor Charles Craddock		
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 January 2024. Key issues:

- During this reporting period, no new Serious Incidents (SIs) were reported within NHSBT. Of the existing five open SIs, two have been closed, while the remaining three are in the final stages of closure.

- A SI (*QI33517)* deep dive review regarding an analyser fault at an NHSBT site, impacting 548 Fresh Frozen Plasma units was presented. Delays in risk escalation, confusion in the SI process, and non-compliance with SOP timescales were identified. The review informed the NHSBT Patient Safety Incident Response Framework, emphasising a shift to Patient Safety Incident Investigations (PSIIs), standardised record-keeping, and updated policy for clearer guidance. Training will enhance incident response capabilities. Further assurance is required on consistent machine maintenances and validations across the organisation to prevent future incidents.

- The Organ and Tissue Donation and Transplantation (OTDT) Biovigilance Annual Report indicated that in the past financial year, OTDT recorded six (out of 728 reported incidents) cases of infection, virus transmission, and malignancy. The report highlights the low rate (~0.008%) of infections and diseases associated with organ transplantation. The report will be shared with the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) and all key stakeholders.

Previously Considered by	
N/A	
Recommendation	The Board is asked to note the report and discuss where relevant.
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. Serious Incidents (SIs)

1.1 Summary

No new SIs in NHSBT during this reporting period (i.e., during December and November 2023). Overall, two of the current five open SIs have been closed. The remaining three are in the final stages of being closed.

1.2 New SIs - There are no new SIs recorded in NHSBT during this reporting period.

1.3 Open SIs - Three SIs previously discussed remain open:

1.3.1 The Organ and Tissue Donation and Transplantation (OTDT) **SI INC6524** (Never Event) is still pending closure awaiting the external, NHS England-led report. NHSBT has concluded its internal investigation into this Never Event, involving unintentional ABO-mismatched solid organ transplantation.

1.3.2 Blood Supply SI QI36303 – A fault was discovered in the Malaria antibody screen machine (DS2), which could potentially lead to positive malaria test results being inaccurately shown as negative. A lookback exercise of this incident identified three blood units with inconclusive results, which were issued and transfused to patients. Fortunately, no patient harm has been identified. The closure report has been finalised and is scheduled for discussion, along with shared learning, in the upcoming meeting.

1.3.3 Clinical Services SI QI36772 - This incident involves a patient who experienced a severe haemolytic transfusion reaction following the transfusion of incompatible blood units. The laboratory received verbal advice from an NHSBT medical consultant to provide antigen-negative units, documented on paper and attached to the laboratory information management system (Hematos), but not linked to the correct sample. A corrective action plan has been agreed upon, and the closure report is in progress.

1.4 Closed SIs and shared learning - Two SIs have been closed:

1.4.1 Clinical Services **SI QI33203** - The joint SI closure report was discussed regarding a patient who developed sepsis after receiving Plasma Exchanges (PEX) treatment via a central line in one of the Therapeutic Apheresis Units.

Key learnings from the incident include the importance of having a well-defined and regularly reviewed agreement for services with clear roles and responsibilities. The incident also highlighted the need to enhance clinical documentation practices, establish care and management plans for devices inserted into patients for therapeutic treatments, and provide adequate orientation and support for staff covering unfamiliar areas. Workshops are ongoing to reflect on the joint closure report process with another organisation and incident escalation procedures.

1.4.2 Clinical Services **SI QI35832** – It is in relation to a sickle patient encountered an air embolism, receiving 10-15 ml of air during Red Cell Exchange procedure due to an error in setting up the apheresis machine. The patient experienced shortness of breath and chest pain but ultimately recovered and completed the treatment. Key casual factors included lack of standardised training and lack of alerting system of air within the blood

coil warmer attachment. NHSBT reported this incident to MHRA and to the manufacturer and discussions are ongoing regarding issuing a Field Safety Notice in the UK.

The shared learning emphasises the need to assess whether NHSBT utilises any machines for intravenous fluids or therapies, with a particular focus on safety mechanisms related to air embolism. Identified risks require immediate escalation to the Senior Management Team (SMT) and CARE group for further management. Additionally, consistent training in the priming procedure must be ensured across relevant departments, with regular competency updates. Clinical directorates are required to ensure a standardised clinical training across departments, review training materials for formal national documentation, and create such documents if needed.

1.5 A deep dive into the Blood Supply SI QI33517

A deep dive was conducted into this SI regarding an intermittent fault in an analyser used for screening blood components at one of NHSBT sites, led to intermittent false negative results on the high titre positive control, potentially causing mislabeling of samples as low titre. The issue impacted 548 Fresh Frozen Plasma (FFP) units, with 357 issued to hospitals. Fortunately, communication with the hospitals that received the affected units provided reassurance that no harm occurred to patients due to this incident.

The deep dive review areas for improvements, including delays in escalating risks and confusion around the SI process, leading to SI declaration delays. Non-compliance with specified timescales in SOPs and MPDs was noted, as decisions were deferred to involve the right personnel in investigations and learning. A lack of standardised record-keeping for SI was also identified. These findings inform the development of the NHSBT PSIRF, emphasising a shift to Patient Safety Incident Investigations (PSIIs). The PSIRF promotes timely learning responses, changes in the e-QMS for standardised record-keeping, and updates to SOPs and MPDs for clear guidance, an escalation pathway, and defined roles. Training will be provided to enhance incident response capabilities, aligning practices with top standards in patient safety.

Considering previous and current SIs about machine failures, the committee has sought an additional assurance concerning shared learning. Specifically, assurance is required on consistent machine maintenances and validations across the organisation to prevent future incidents.

2. Patient Safety Incident Reporting and Feedback (PSIRF) implementation plan.

Phase 1 of PSIRF implementation is starting on April 1st. This phase will involve making small adjustments to enhance the learning processes from quality incidents, and formalising oversight functions. Phase 2, scheduled for October 2024, will build upon the activities initiated in Phase 1. It aims to extend the implementation of PSIRF across the entire organisation, incorporating improved data capture, analysis, and reporting mechanisms to facilitate effective improvement planning**.** Patient and donor involvement are crucial elements, and the PSIRF working group is actively working to capture their voices to ensure the successful implementation of the plan.

3. Organ and Tissue Donation and Transplantation (OTDT) Directorate Safety Culture Survey

The pilot survey assessed patient safety culture within the OTDT Directorate. It revealed a robust safety culture, achieving an 82.29% positive score across critical questions, despite a lower response rate of 34% from approximately 750 staff compared to the NHS-wide survey (46.8%). Feedback highlighted concerns about discouragement in reporting and a prevalent blame culture. Proposed actions include collaboration with leadership team to address reporting barriers,

implementing training sessions, and anticipating positive impacts from the upcoming PSIRF implementation. While the results suggest a strong baseline, the report emphasises the continuous need for initiatives to enhance patient safety culture within OTDT and the wider NHSBT. The survey questions will be incorporated into the next staff Peakon survey.

4. OTDT Biovigilance Annual Report

In the 2022/23 financial year, 1,429 deceased and 958 living organ and tissue donors enabled 4,533 transplants, reflecting a 4% increase from the previous year but still 5% below pre-pandemic levels. Transplant waiting lists have returned to 2014 levels, with 439 patient deaths and 732 removals in 2022/23.

During the past financial year, there were 728 clinical incidents reported to OTDT in relation to organ donation and transplantation including six cases of infection, virus transmission, and malignancy.

The report highlights the low rate (~0.008%) of infections and diseases associated with organ transplantation. The report was circulated for information to committee members and will be shared with SaBTO and all key stakeholders.

5. Clinical Audit

The following completed clinical audits were approved at directorate CARE groups and discussed at the CGC meeting:

5.1 Audit of the Ultrasound Guided Cannulation Technique (USGC) within Therapeutic Apheresis Services (TAS) (AUD4996) - This audit focused on the USGC within TAS and provided **substantial** assurance. The USGC proved successful in facilitating vascular access, reducing infection risk, and achieving a 99.4% success rate in three TAS units. The rollout of USGC will extend to all TAS units, with ongoing data monitoring for at least 12 months.

5.2 Audit of the Management of Cord Blood Units (CBU) Full Blood Count (FBC) Parameters - This audit aimed to enhance understanding of the overall range and distribution of CBU FBC, assessing compliance with out-of-range result management. While concerns were raised about minimal compliance in external communication (43% in donor follow-up) and internal communication on CBU FBC parameters (83%), the decision on the fate of CBUs demonstrated high compliance (99%), and hence and provided **moderate** assurance.

Additionally, the audit established reference intervals using 3,469 CBUs from 19 ethnic groups, informing a potential refinement of evaluation criteria for cord blood haematological parameters and contributing to the redesign of the process for escalation and management of out-of-range FBC results.

5.3 Plasma for Medicines (PfM) Healthcare Assistant (HCA) Extended Acceptance Criteria Audit (AUD4729) – This audit aimed to assess whether HCAs are adhering to the relevant guidance, ensuring the safety of donors and patients. A review of 126 Donor Safety Check (DSC) records found that HCAs made appropriate decisions in 91% of cases. Three donors were incorrectly accepted by HCAs, coincidentally failing to donate. Eight donors were wrongly referred to nurses when HCAs could have accepted or deferred, mostly due to medication issues, all correctly assessed by nursing staff. No risks were identified in audited cases. In one instance, a HCA correctly referred a donor, but the nurse incorrectly accepted due to documentation issues.

Actions included retraining nursing staff and reviewing approved medications, which have already been implemented. The audit provided **moderate** assurance with a plan to reaudit in 2027/28.

6. Directorate CARE updates

6.1 A cluster of graft failure following alpha-beta depleted stem cell transplants

Four cases of failed graft following alpha-beta depleted transplants were reported from Leeds Paediatric Unit. NHSBT investigation did not reveal any lab issues and confirming the viability of the cells as expected. Other transplants of this type have not experienced similar problems.

Nevertheless, a comprehensive lookback of all similar procedures conducted since January 2022 is underway. Preliminary review of the cases has not determined any commonality between cases. The cases have been discussed with the Human Tissue Authority (HTA). Following thorough investigations from both organisations, the consensus is to consolidate the information from these investigations and seek an independent expert's opinion to ensure that no further investigation is necessary.

6.2 Hepatitis A transfusion-transmitted infection (QI37591)

NHSBT received a notification of hepatitis A infection in a donor. The donor subsequently became symptomatic, was admitted to the hospital, and diagnosed with acute hepatitis A. The local health protection team investigated possible sources of infection. A lookback investigation was conducted, and red cells from the donation were issued before the hepatitis A case was reported. The red cells were transfused to a liver transplant patient, who subsequently developed hepatitis A. The patient recovered and was discharged. The clinical team was informed and plans to speak with the patient were made.

While hepatitis A is not part of routine screening, it will be introduced for donors donating plasma for fractionation. The process for health protection teams notifying NHSBT of donors with hepatitis A was successful, although infection prevention was not possible in this case. The transmission has been confirmed and will be reported to SHOT and the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO).

6.3 The use of WhatsApp

The use of WhatsApp for rapid information dissemination to retrieval surgeons, coordinators, and other relevant personnel has been highlighted as efficient, but some devolved administrations have discontinued its use. NHSBT has requested continued use until the implementation of Transplant Path, which will capture necessary information.

The committee was assured that the practice follows NHSE guidance but emphasised that decisions relating to patient identifiable information must have input from the Caldicott Guardian, in discussions and decisions, if any processes are outside NHSE guidance.