NHS
Blood and Transplant

Board Meeting in Public
Tuesday, 26 March 2024

Title of Report	Clinical Governance Report	**Agenda No.**	5.3.2
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 8th of March 2024. Key issues:

- During this reporting period, no new Serious Incidents (SIs) were reported within NHSBT. Three SIs remain open in the final stages of closure. Additionally, three cases of transfusion-transmitted infections have been reported, and investigations are underway.
- Following a review prompted by two equipment-related serious incidents, NHSBT's equipment management practices were deemed aligned with best practices and regulations. The organisation maintains 16,009 equipment pieces, managed through the QPulse system since 2007. The United Kingdom Accreditation Service (UKAS) inspections found no non-conformities in the past year, confirming regulatory compliance. Quality Assurance actively monitors equipment-related incident trends to share best practices across regulatory bodies and internal teams.
- A new policy regarding incidental findings for genotyping has been approved. Endorsed by various committees including CS CARE, CS SMT, and CGC, this policy highlights NHSBT's commitment to incidental findings governance. It prioritises patient confidentiality, adherence to professional standards, and legal obligations while ensuring efficient information management. The policy defines clear procedures for reporting incidental findings and considers unique aspects of the National Blood Group Genotyping Programme within its framework.
- The ICO has engaged with NHSBT regarding concerns over liver allocation algorithms, promoting necessary discussions and preparations.
- The PSIRF policy and plan have been endorsed by the committee and are scheduled for implementation within NHSBT, commencing on April 1st, 2024, pending Board approval.

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 January and February 2024). Three previously discussed SIs remain open and currently being finalised for closure.

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): This incident pertains to unintentional ABO-mismatched solid organ transplantation. NHSBT has concluded its internal investigation, and closure is pending the external report led by NHS England.

1.3.2 Blood Supply **SI QI36303**: A fault was detected in the Malaria antibody screen machine (DS2), potentially leading to inaccurate negative results for positive malaria tests. No patient harm has been reported, and the closure report awaits final approval.

1.3.3 Clinical Services **SI QI36772**: This incident involves a severe haemolytic transfusion reaction experienced by a patient after receiving incompatible blood units. The closure report has been completed and is pending final approval.

1.4 Other incidents

Three transfusion transmitted infections were reported:

1.4.1 Hepatitis B Virus (HBV) infection (reference PTY/ 01/23, QI37911):
A man with myelodysplasia developed acute HBV infection after regular blood transfusions. Investigation implicated two donors with past HBV infection although neither had detectable levels of DNA in their archive samples. Transmission could not be confirmed but circumstantial evidence of this donor originating from the region where the patient's viral genotype D/E is prevalent further supports transmission. Both donors were removed from the panel. The case will be reported to Serious Hazards of Transfusion (SHOT), as a probable transfusion transmitted infection.

1.4.2 Hepatitis E Virus (HEV) infection (reference PTE/05/23, RPT91475):
A patient received blood products and was later diagnosed with HEV infection. On archive testing two donations tested positive for HEV Ribonucleic Acid (RNA) with very low levels of RNA, indicating possible transfusion transmission. Further confirmation work could not be carried out due to low viral loads. The case will be reported to SHOT as probable transfusion transmitted infection.

1.4.3 *Plasmodium malariae* infection (reference PTMAL/12/23, QI38698):
A suspected case of transfusion-transmitted *Plasmodium malariae* infection is under investigation. The patient is recovering after treatment, and the donor has been removed from the donation pool. While the implicated donor had not disclosed malaria risk factors, further investigation revealed a history of fevers treated with homeopathy. The archive sample was negative for malaria antibodies using our routine screening testing, however a subsequent fresh blood sample although negative on routine antibody screening was positive for malaria DNA. To assess potential transmission risks, a lookback into the donor's previous donations has begun.

Recipients have been identified and the clinical teams looking after these people have been asked to talk with their patients about what has happened and obtain consent to submit samples to NHSBT for malaria testing. The Hospital for Tropical Diseases are investigating the strain of malaria from both the patient and donor. The case will be reported to SHOT, initially as probable but likely to be a confirmed transfusion transmission once investigations are complete. Discussions with national experts are ongoing to assess further mitigations.

2. Patient Safety Incident Response Framework (PSIRF) Policy and Plan

The PSIRF policy and plan have been endorsed by the committee and are scheduled for implementation within NHSBT, commencing on April 1st, 2024, pending Board approval. This framework replaces the current Serious Incident Framework (SIF 2015) and represents a significant shift in the organisation's approach to responding to patient and donor safety incidents (PDSIs), aiming to foster a culture of learning and proportionality in incident management practices. The rollout will be phased, starting with OTDT before expanding across all clinical directorates. Additionally, a review of oversight structures is planned to ensure continuous improvement in patient and donor safety.

3. Clinical Risk Management

3.1 The process of transferring clinical principal risks from the Chief Medical Officer (CMO) to the Chief Nursing Officer (CNO) is underway.

3.2 A deep dive into Principal Risk 1 (PR 1) titled "Risk of harm occurring to a donor or patient owing to failure to control the safety of NHSBT clinical activities" identified the addition of one risk (CS-02 'Incorrect clinical decision making'), bringing the total contributing risks to six. The principal risk score increased to 12 (judgement zone) in November 2023, primarily due to the inclusion of the new risk associated with poor accessibility and integrity of digital patient records, leading to patient harm incidents. This increase was prompted by a serious (QI36772) and a near miss (QI37715) incidents involving medical approval of special products, revealing previously unidentified risk control gaps.

Additionally, several other risks have been clarified for better understanding, and ongoing actions to mitigate the six contributory risks including establishing a clinical risk review group for enhanced collaboration across clinical directorates, investigating control gaps for CS-02, applying new clinical risk impact guidance, continuously reviewing existing and emerging clinical risks, and monitoring progress of mitigating actions to ensure patient and donor safety.

4. Equipment Management and Qualification Assurance

After conducting a recent review prompted by two equipment-related serious incidents, the committee has acknowledged that NHSBT's equipment management practices are in line with best practices and regulatory standards. NHSBT effectively oversees a substantial inventory comprising 16,009 equipment pieces. Since 2007, the implementation of a standardised system (Qpulse) has facilitated the documentation of procedures for equipment registration, maintenance, calibration, and validation.

This adherence to internal processes ensures regulatory compliance, as confirmed by zero non-conformities identified during the past year's UKAS (UK Accreditation Service) inspections. Quality Assurance proactively monitors equipment-related incident trends and aims to share best practices and lessons learned across relevant regulatory bodies and internal teams.

5. Safety Policy updates

5.1 **Sex Assigned at Birth (SAAB) and manufacturing processes** - Controls have been implemented in PULSE to ensure that only donations from donors with confirmed male sex assigned at birth are manufactured into Fresh Frozen Plasma (FFP).

5.2 **B19 testing for plasma for medicine donations -** Due to operational reasons these have had to be revised resulting in increased sensitivity of the test. This change will not impact on component safety but may result in more reactive donations being discarded due to the increased sensitivity of the test.

5.3 **Low Factor XI levels in Fresh Frozen Plasma (FFP) -** Concerns arose regarding low Factor XI levels in FFP, prompting an investigation with Macopharma, the blood bag manufacturer. The investigation revealed a filter change as a potential cause, with a permanent solution anticipated by July. Short-term mitigation strategies, such as using alternative manufacturing packs, were initiated in March. The Blood Supply SMT is closely monitoring the situation, guided by the Therapeutic Products Safety Group (TPSG). A clinical risk assessment received endorsement, and operational adjustments will limit FFP production from affected filters until the permanent solution in July. TPSG supports the plan for complete risk removal by July.

6. Clinical Audit

6.1 **The Government Internal Audit Agency (GIAA) review of NHSBT Clinical Audit process:** The GIAA review findings suggest a **limited assurance**. Deficiencies were noted in control operations, audit trail retention, and reporting quality, which hinder effective oversight. Key areas for improvement include enhancing documentation of planning decisions, establishing a central audit management system, conducting consistent internal reviews, standardising reporting practices, and ensuring evidence provision for recommended improvements. Areas of good practice were acknowledged, including template use, learning dissemination, and timely report publication. An action plan has been initiated to address GIAA audit findings and improve the clinical audit process within NHSBT.

6.2 **Completed Audits:** The following two clinical audits were approved at relevant directorate CARE groups and discussed at the CGC meeting:

6.2.1 Donor Carer Extended Acceptance Criteria Audit (AUD4324) - This clinical audit provided **moderate assurance**. It evaluated the adherence of Donor Carers (DCs) in Blood Donation (BD) to relevant guidelines during the Donation Safety Check (DSC) process, ensuring donor and patient safety. Among 632 potential donors reviewed, DCs made correct decisions in 92.9% of cases. The risk assessment indicated a low risk to patients and donors. The action plan includes improving documentation practices, ensuring better use of extended acceptance criteria, and addressing identification issues in DSC revisions for enhanced audit trails and adverse event reviews. Additionally, dissemination of relevant information and development of new protocols to optimise BD safety procedures.

6.2.2 *Audit of Communication of New Clinical Information During Organ and Tissue Donation (AUD4746)* - This clinical audit aimed to assess the sharing of new clinical information during organ/tissue donation processes. It provided **moderate assurance** and found that 95% of new clinical information was shared by the correct person, 91% was shared in a timely manner, and 95% was shared using the appropriate method. However, only 51% of SNOD phone calls sharing new clinical information were voice recorded. The audit revealed that 86% of new clinical information was shared correctly and appropriately, with 56% of verbal phone communications being recorded or witnessed. The main action item is for OTDT CARE to confirm the requirement for SNODs to voice record new clinical information and ensure access to the recording system if necessary.

7. Clinical Policy Approval/Updates

7.1 **NHS Blood and Transplant Policy for Incidental Findings for Genotyping** - The draft of a newly created policy regarding incidental findings for Genotyping was presented after approval by CS CARE. The policy outlines protocols related to incidental findings, particularly in the context of patient genotyping.

It specifies current typing using the Universal Blood Donor Typing (UBDT) array, does not detect genetic traits that pre-dispose to cancer. Some traits such as those on the X and Y chromosomes, will be used for quality control, but not return individual or identifiable data to NHSBT.

Sickle cell typing may return certain traits to NHSBT without reporting, unless clinically significant. Uncommon blood group alleles and platelet allotypes, if detected, may prompt informed clinical management decisions. Traits that predispose to certain conditions are fully masked, and results will not be returned unless there is a management policy in place. Any new policy would also apply retrospectively to ensure fairness to all tested patients or donors.

8. Data Security, Privacy and Records Management

8.1 **The Data Security Protection Tool Kit (DSPT) Improvement Plan -** The DSPT improvement plan outlines NHSBT's efforts to meet the National Data Guardian's 10 data security standards, aiming to regain trust after being initially rated as 'Standards Not Met' in June 2023 and later improved to 'Approaching Standards' in December 2023. The Improvement Plan working group has made demonstrable progress on remedial actions.

8.2 **The DSPT Submission -** The 2023/24 DSPT submission for NHSBT is progressing well, with 130 out of 140 assertions completed by the interim deadline in February 2024. Furthermore, NHSBT is working towards compliance with NHSE standards DCB0129, DCB0160, and DCB1596 for clinical risk management of IT systems used in healthcare. A Joint Clinical Safety and Digital Operations Group (JCSDOG) has been established to oversee health IT systems, and required policies and artefacts are being finalised, including a Clinical Safety Standards policy and a Secure Email Standard. Once these requirements are met, NHSBT aims to self-certify against DCB0160 and DCB0129 and seek formal accreditation with DCB1596.

8.3 **Information Commissioner's Office (ICO) Engagement on Liver Allocation Algorithm -** The ICO has contacted NHSBT regarding concerns over liver allocation algorithms, prompted by a dissatisfied family opposing the algorithmic process. In response, the committee recommended the involvement of appropriate NHSBT stakeholders and experts in discussions to prepare for the upcoming meeting with the ICO. These discussions will encompass topics such as automated decision-making, levels of human intervention, risk management, and compliance with legal standards under Article 22.