NHS
Blood and Transplant

Board Meeting in Public
Tuesday, 24 September 2024

Title of Report	Clinical Governance Committee Report	**Agenda No.**	5.2.2
Nature of Report (tick one)	☒ Official	☐ Official Sensitive	
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Presented for (tick all that applies)	☐ Approval ☒ Assurance	☒ Information ☐ Update	

Purpose of the report and key issues

This report is submitted to the Board to draw attention to the main items discussed at the Clinical Governance Committee (CGC) on Friday 13 September 2024.

Previously Considered by

N/A

Recommendation	The Board is asked to note the report.

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

The Clinical Governance Committee is a key aspect in the governance and oversight of risks to Donor and Patient Safety (P-01).

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. Background

This report is submitted to the Board to draw attention to the main items discussed at Clinical Governance Committee (CGC) on 13 September 2024.

2. Infected Blood Inquiry

The Committee received an update in relation to the NHSBT programme of work in relation to the Infected Blood Inquiry (IBI) Report. It was noted that the main focus of discussion with wider stakeholders was in relation to Recommendation 7 which aligns to NHSBT's Transfusion Transformation strategy which will follow Transfusion 2024 as a strategic plan. The funding required for this is yet to be determined by NHSBT. The NHSBT IBI Implementation Group meetings continue to be held and progress updates are made to the Clinical Quality and Safety Governance Group.

3. Patient and Donor Safety

Civil Unrest and Amber Alert

The Committee received a report on the clinical impacts of recent civil unrest and the Amber alert. It was noted that 5 blood donation sessions had been impacted by the civil unrest with almost 300 donations cancelled. The clinical impacts of the Amber alert were noted. The Committee also noted that business continuity processes had been implemented to manage the impacts of both the blood shortage itself, and provision of pathology support due to the cyber-attack on Synnovis who manage laboratory software for NHS trusts in South-East London.

Principal Risk 01 Donor and Patient Safety

The Committee undertook a deep dive review of Principal Risk 01 Donor and Patient Safety, and its seven contributory risks. The deep dive provided wider understanding and awareness of the risk to donor and patient safety and the mitigating controls and actions in place and their effectiveness. The risk is currently within the Judgement Zone for NHSBT.

Clinical Quality and Safety Governance Group Integrated Report

Following the establishment of the Clinical Quality and Safety Governance Group the Committee received the first integrated report from the Group. The CQSGG provides assurance in the management of clinical incidents, complaints, claims and adverse events and is responsible for monitoring alerts received via the Central Alerting System and action taken in relation to relevant alerts. The Committee noted and discussed the report and supported further development of the integrated report. In particular, the Committee discussed an incident in May at University Hospitals Birmingham. A patient had received a stem cell transplant from her son which was rejected, requiring a second transplant to be conducted from her other son. NHSBT undertook HLA typing and antibody screening for the patient and the two donors. Testing identified a high level of antibodies between the donor of the first stem cell transplant and the patient which would likely lead to rejection. This information was not provided to UHB. The patient subsequently died from sepsis following the second transplant. A Coroner's inquest has submitted a request for NHSBT to provide information by the 1 October 2024 and a witness will be required to give evidence in January 2025. This incident has resulted in a review of the process, which was followed, yet, may have contributed to the outcome. A PSII will be opened by UHB, and NHSBT will participate in a joint investigation with the hospital.

4. Directorate Care Reports

The Committee received reports from the four Clinical, Audit, Risk and Effectiveness (CARE) Groups:

- Clinical
- Organ and Tissue Donation and Transplantation
- Blood Supply
- Plasma for Medicines

5. Other Reports

Clinical Audit

The Committee an overview of all clinical audit activity within the 2024/25 Clinical Audit Programme. It was noted that eight audits were included in the plan, with two having been completed to date. An outline plan for 2025/26 was provided to the Committee.

In particular the full audit report on the management of blood donors with a suspected chlorhexidine reaction was received by the Committee. It was noted that the audit provided limited assurance. A substantial action plan has been agreed to address points raised in the audit.

A report in relation to the completion of actions arising from clinical audits was also provided to the Committee.

Therapeutic Product Safety Group

The Committee received a report from the Therapeutic Safety Product Group (TPSG) and noted that they had reviewed annual reports from SHOT and the Epidemiology Unit. The SaBTO recommendation for HEV screening and different approaches to screening for HEV across the UK was discussed by the TPSG, and the Committee received a separate report on this. The Committee noted that both Wales and Scotland are planning on taking a more precautionary stance in terms of their screening methodology. The TPSG and Executive Team have both reviewed the position and agree that NHSBT should continue its current HEV testing processes and to acknowledge the difference in sensitivity of screening across the UK. This is consistent with the SaBTO recommendation. The Committee noted and supported the agreed NHSBT approach.

The TPSG had also received a progress update in relation to additional risk reduction measures for apheresis platelets suspension in platelet additive solution which the Committee noted.

Annual Reports

The Committee received annual reports as follows:

- Joint NHSBT/PHE Epidemiology
- Medical Revalidations
- Safeguarding

The Committee agreed that the following annual reports be presented in November 2024:

- Mandatory Training of Clinical Workforce
- Nursing Revalidations
- Scientific Revalidations
- SHOT Report (Timing of this to be aligned with Joint NHSBT/PHE Epidemiology report in future)

6. Governance

Regulatory Radar

The Committee received a report outlining key variations made to NHSBT regulatory licences as a result of changing requirements. There were no such variations reported. It also outlined upcoming new or amended guidance, legislation and/or regulations that may impact on NHSBT activities. It was noted that a number of consultations had ended and updated standards/guidance were awaited.

Management Quality Review

The Committee received the Management Quality review and noted that there had been positive performance in the quarter. Improvements had been seen in the number of serious adverse events of donation and recall events, and no serious incidents were recorded. It was noted that overdue events continue to be a challenge. The Committee noted that a major finding was received from the MHRA in June, for which investigations and actions are ongoing.

Safeguarding Policy

The Committee reviewed the Safeguarding policy which had been transferred to the new board level policy format. It was noted that work was taking place to review the policy detail and that this would be brought to the Committee early in 2025. In the meantime the new format of the policy was recommended to the Board for approval.

7. Items for escalation to the Board

- Note format of Safeguarding Policy has been updated to Board Level Policy format, copy in Convene Review Room. Policy content will be reviewed in January 2025

- Note the agreed NHSBT approach to HEV Screening Approach.