NHS Blood and Transplant

Board Meeting in Public

Tuesday, 01 December 2026

Title of Paper	Clinical Governance Committee Board Report	**Agenda No.**	5.3.1
Nature of Paper	☒ Official	☐ Official Sensitive	
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Presenter(s) at Meeting	Charlie Craddock, Clinical Governance Committee Chair		
Presented for	☐ Approval ☐ Information ☒ Assurance ☐ Update		
Is there a plan to communicate this to the organisation?	☐ Yes ☒ No ☐ Yet to be determined		

Executive Summary

This report is submitted to the Board to draw attention to the main items discussed at the Clinical Governance Committee (CGC) held on 12 October 2026

Previously Considered by

N/A

Recommendation

The Board is asked to note the report for assurance.

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:

☐ Modernising One NHSBT ☒ Optimising Donor Experience and Meeting Demand
☐ Campaigning & Identity ☐ Data, AI and Interoperability ☒ New Treatments

Appendices:	

1. Background

This report is submitted to the Board to draw attention to the main items discussed at the Clinical Governance Committee (CGC) held on 12 October 2026.

2. Safety and Experience Integrated Report

The Committee received updates from the Blood Supply, Clinical Services, Plasma for Medicines (PFM), and Organ and Tissue Donation and Transplantation (OTDT) CARE Committees and received assurance regarding quality, safety and operational performance across these areas.

Key matters highlighted included the management of a new donor weight risk, a confirmed case of transfusion-transmitted hepatitis E under investigation, extension of the Post Donation Testing feasibility study, progress on donor eligibility changes relating to Sex Assigned at Birth (SAAB), and the absence of Patient and Donor Safety Incident Investigations (PDSIIs) within Blood Supply during the reporting period.

The Committee noted ongoing Patient Safety Incident Investigations (PSIIs) within Clinical Services, corrective actions arising from infectious disease marker reporting audits, continued management of operational and workforce pressures, and progress in addressing Histocompatibility and Immunogenetics (H&I) incidents, estates risks and clean room remediation activities.

With regard to Plasma for Medicines, the Committee received assurance that plasma donation continues to operate safely and effectively, noting progress at the Reading Multi Product Centre, positive clinical audit findings, development of a new donor pathway to improve donor experience and reduce adverse events, and ongoing research activity through the SHAPE and Nipah Vaccine studies.

Within OTDT, Members noted increasing post-donation genetic findings, ongoing investigations into the pager breach and donor screening PSIIs, continued work with specialist genetics services, challenges relating to out-of-hours histopathology provision, and the increasing complexity of complaints and enquiries, including those generated using artificial intelligence. The Committee also received assurance regarding safeguarding, infection prevention and control, digital clinical safety, and staff support initiatives.

3. Clinical Governance Review Update Phase 1

The Committee received an update on the ongoing review of the clinical governance framework and noted that Phase 1 was nearing completion. Members noted progress in mapping existing governance arrangements, developing a Responsible, Accountable, Consulted and Informed (RACI) framework aligned to the seven pillars of clinical governance, and identifying opportunities to strengthen governance, assurance and risk management arrangements across NHSBT. The Committee welcomed the progress made and supported the continued development of the framework.

4. BAF P-01 Donor and Patient Safety/Clinical Risk Report

The Committee reviewed Principal Risk 1, which remains at the Risk Limit, primarily due to limitations within the National Transplant Database and the resulting impact on organ allocation processes. Members noted contributory risks relating to clinical decision-making, manual processes and meeting complex blood requirements, alongside ongoing

vulnerabilities associated with ageing clinical systems and workforce capacity. Assurance was received that mitigating actions are being progressed through clinical governance, workforce planning and digital transformation programmes.

5. Patient and Donor Safety Incident Closure Report: QI48987

The Committee received assurance from the Patient Safety Incident Investigation into delays in the processing and escalation of antenatal samples with unresolved serology. Members noted that, although no harm occurred to the mother or baby, the incident identified weaknesses in sample processing, escalation and communication processes. The Committee welcomed the prompt implementation of safety actions, including strengthened oversight, revised escalation arrangements and enhanced communication with referring hospitals, and supported the actions arising from the investigation.

6. Clinical Audit: 2026/27 Clinical Audit Programme & Activity Update

The Committee received assurance from the Clinical Audit Programme, noting improvements in the management of re-bleeds, satisfactory findings from the audit of discretionary testing in stem cell donors, and progress in implementing related improvement actions. Members also noted the approval of new audits, progress with planned audit activity, successful implementation of the TempRE system, a significant reduction in overdue audit actions, and completion of all actions arising from the GIAA audit of clinical audit processes.

7. GIAA Internal Audit Final Reports: Infection Prevention and Control Audit

The Committee received assurance from the Government Internal Audit Agency (GIAA) advisory review of NHSBT's Infection Prevention and Control (IPC) Board Assurance Framework. Members noted that the review provided moderate assurance and identified opportunities to strengthen governance, oversight, documentation and monitoring arrangements. The Committee noted that all recommendations had been accepted and that actions were in place to enhance governance processes, action tracking and ongoing Board Assurance Framework review.

8. Scientific Advisory Committee (SAC) Report

The Committee received assurance from the Scientific Advisory Committee (SAC) regarding NHSBT's research governance arrangements. Members noted continued progress in strengthening governance, including enhanced oversight of research awards, development of a Knowledge Asset Management Strategy and interim arrangements to support research infrastructure. Members received assurance that no new externally reportable incidents had been identified and that no immediate escalation was required.

9. Annual Reports

The Committee received the following annual reports:

- Medical Revalidation and Revalidation Annual Report 2025-26
- Annual Report - Nursing Revalidation
- Clinical Claims Annual Report
- Serious Hazard of Transfusion (SHOT) Annual Report
- Joint NHSBT/ UK Epidemiology Annual Report
- Infection Prevention and Control: Annual Report 2025-26

10. Management Quality Review Reports (MQR) Quarterly Report

The Committee received the Quality Management Review (QMR) report and noted that the Quality Management System (QMS) remained effective and controlled, supported by improvements in incident management, a strong reporting culture, regular review of Board Assurance Framework risks, business continuity and incident management training, and positive inspection outcomes. Members also noted NHSBT's participation in an exercise which provided assurance regarding organisational resilience and collaborative working across the UK blood services.

11. Quarterly Regulatory Radar

The Committee received an update on key regulatory developments, including licence variations, the review of the Substances of Human Origin (SoHO) framework and the 23rd edition of the Blood Guide. Members noted NHSBT's engagement with the Department of Health and Social Care (DHSC), regulators and wider stakeholders to support the simplification and harmonisation of regulatory requirements. The Committee also noted ongoing developments relating to digitalisation, business continuity, regulatory alignment and critical SoHO activities, and received assurance that appropriate arrangements were in place to monitor and implement changes necessary to maintain compliance. Members welcomed the increasing emphasis on proportionate, risk-based regulation.

12. Items for escalation to the Board

- Infection Prevention and Control Annual Report 2025-26
- The achievements of the SHOT team, including receipt of the International Haemovigilance Network Award, shortlisting for a Health Service Journal (HSJ) Patient Safety Award, and recognition in the Healthcare Quality Improvement Partnership (HQIP) Excellence Awards for communications and impact. **(Available in the Review Room as SHOT Summary of Key Awards, Recognition and Certification Received to date)**
- Update on the Hepatitis E transmission case