NHS
Blood and Transplant

Board Meeting in Public
Tuesday, 22 July 2025

Title of Report	Clinical Governance Committee Report	**Agenda No.**	5.2.4
Nature of Report	☒ Official	☐ Official Sensitive	
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Non-Executive Director Sponsor	Lorna Marson, Clincial Governance Committee Chair		
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) held on 10 July 2025.

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: [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 the Clinical Governance Committee (CGC) held on 10 July 2025.

2. Infected Blood Inquiry (IBI)

The Committee received a report, which summarised recent developments related to the implementation of the Infected Blood Inquiry (IBI) recommendations. NHSBT remains a critical delivery partner in this work, particularly in relation to transfusion safety, digital transformation, education, and equity of care for historically underserved patient cohorts. While the programme's ambition remains significant, emerging constraints, particularly those related to funding, cadence, and governance alignment, require close monitoring and strategic co-ordination.

Meetings between UK Healthcare, the Department for Health and Social Care (DHSC), NHS England, NHSBT, the UK Health Security Agency and others are being held regularly. Within NHSBT meetings with groups of affected persons are extremely well supported and plans for a memorial are being progressed.

The Chair of the Infected Blood Inquiry, Sir Brian Langstaff, published an Additional Report on Compensation on 9 July 2025. At an event to announce the report he received a standing ovation. It was noted that the process to prove psychological impact for families was onerous and changes were proposed.

3. Risk Review

The Committee endorsed the decision to merge principal risks P-01 and P-06 subject to a further review to consider risks that can't be fully controlled, and that the nuances of P-06 risks are otherwise represented within P-01 contributory risks.

4. Clinical Quality and Safety Governance Group (CQSGG) Integrated Report

The Committee received the Integrated Report which summarised the work of the CQSGG and highlighted matters for committee oversight and scrutiny. Specifically, the report included CARE Group reports. The Committee in particular discussed and noted:

a) Clinical Directorate risks and incidents
b) Safeguarding workforce is currently in Business Continuity
c) Safeguarding portfolio mapping against statutory guidance has commenced. A service level agreement with St Georges, Epsom and St Helier Hospital Group is being developed with strategic subject matter expertise. Size shape and function of the workforce mapped against guidance is in progress
d) Legionella: at the Filton site with a CQC notification and Colindale with a pending CQC notification. Portfolio review with strategic subject matter expert is in progress
e) Infection prevention and control Board Assurance Framework is in progress with strategic subject matter expertise. Observational audits with the strategic subject matter expert have been completed with a report and recommendations being prepared.
f) Three patient safety incident investigations (PSII) have been completed.
g) Customer service updates
h) NICE standards
i) Improvements to clinical incidents at Sheffield

j) A look back on tissue retrievals following an incident and an independently commissioned review
k) Seasonal readiness

5. Patient/Donor Safety

Patient Safety Incident Investigations

The Committee considered three closure reports for Patient Safety Incident Investigations (INC88614, INC87703 and Q140569). INC88614 was downgraded following initial investigations. The Committee received the reports for information and assurance and after discussion noted the circumstances of the incidents and the actions taken, or planned, to mitigate future risk.

The Committee discussed the length of time taken for reports to be finalised which was agreed to be a concern. Where cross organisation liaison was required this often extended the timeframe. NHSBT wished to honour the duty to patients and families when things go wrong by investigating and reporting on incidents promptly and it was agreed that where necessary delays should be escalated.

Patient Safety Incident Response Framework (PSIRF) Phase 1evaluation and 2025/26 Transition plan

The Clinical Governance Committee considered a report that evaluated phase one of PSIRF and provided a transition plan for 2025.26. In May 2025 stakeholder feedback was sought that provided helpful insights and data on the experience of the process of PSIRF thus far. This feedback and the mapping of implementation achievements against the agreed deliverables for phase 1 has informed the next stage of the transition plan.

6. Clinical and GIAA Audit: 2025/26 Clinical Audit Programme update and end of year summary re: Tenable system

The Committee received a report in relation to the clinical audit programme and an end-of-year summary in relation to Tendable, a digital audit and inspection system used in Therapeutic Apheresis Services (TAS). Possible expansion of its use into Blood Supply and Plasma was noted to be being discussed by management. Tendable allows easy reporting of identified clinical issues by staff and has tracking and reporting of such issues. Where trends can be seen in reporting, action can be taken to address these.

7. CQC Self-assessment process

In 2024 work to self-assess NHSBT against CQC's quality statements and standards commenced. A report on the findings was received by the Committee. It was noted that some elements were not applicable for NHSBT and where this is the case the reasons why are clearly recorded.

NHSBT is registered with the Care Quality Commission to provide the following services:

a) Treatment of disease, disorder or injury at Therapeutic Apheresis Service (TAS) units and the Photopheresis unit
b) Management of supply of blood and blood derived products at the blood donor centres.

c) Matching and allocation of donor organs
d) The supply of tissues or tissue-derived products for transplant, grafting or use in surgery. For example, this will include supply of organs or tissue by NHS Blood and Transplant or any other provider of transplant organs.

A CQC Quality Statement portal has been developed, to enable relevant directorates to record compliance with the standards, link to risks and record an action plan where full compliance cannot be demonstrated.

8. Terms of Reference Reviews: Clinical Governance Committee/Governance Group

The Committee considered its Terms of Reference and following discussion requested further changes to be made and an updated version of the document to be circulated to Committee members ahead of amendments being proposed to the Board for approval. They also ageed the principle of future reporting for the Committee, the detail of which to be agreed ahead of the next meeting.

The Committee approved the new form of the Clinical Quality and Safety Governance Group Terms of Reference, noting that consideration of the alignment between these and the Terms of Reference of the CGC and directorate CARE Groups was planned to be carried out.

9. Reports

The Committee reviewed the following Reports:

- Regulatory Radar
- Management Quality Review Annual Report
- Safeguarding Annual Report
- Information Governance Annual Report
- Clinical Claims Annual Report
- Non-clinical issue Annual Report

Whilst received the Non-clinical issue annual report will be rescheduled to a future meeting for presentation.

In relation to the Management Quality Review, it was noted that work continues through the Quality Assurance team's support of directorates to address the number of overdue actions. It was confirmed that there has been no increase in serious incidents and the outstanding actions do not create an immediate risk to patient/donor safety.

In relation to Clinical Claims, the Committee discussed arrangements related to indemnity where there is a provision of blood, tissues and services to private patients at private hospitals, which varied from the arrangements for NHS funded patients. This is to be discussed further through the Audit, Risk and Governance Committee.

10. Data Security and Protection Toolkit - Cyber Assurance Framework update

NHSBT is required to submit an annual Departmental Security Protection Toolkit and Cyber Assessment Framework return (DSPT-CAF) in June 2025. This important return measures NHSBT in terms of its security and 'trustworthiness' in relation to protection of data and systems. The return has a direct operational impact, in that, failure to meet minimum standards, without a credible and funded plan to address gaps, may cause loss of access

to NHS patient data and systems, investigations by NHSE and reputational damage, directly affecting patient care.

The Committee noted the likely output of the 2024/2025 submission, audit assurance from GIAA on the representations in the return and the improvement work that is underway. It was noted that there had been an increase in the standards required and it was expected that NHS organisations and ALBs may not achieve all standards initially. An effective improvement plan to work towards a long-term aim of compliance has been put in place.

11. Exploring challenges and opportunities for successfully establishing an integrated clinical governance strategy within NHSBT

The Committee received a paper presenting the findings of an independent research study completed in March 2024 as part of a Master of Business Administration (MBA) programme, titled "Exploring Challenges and Opportunities for Successfully Establishing an Integrated Clinical Governance Strategy within NHS Blood and Transplant (NHSBT)." The study explored how NHSBT could develop a more unified and effective clinical governance framework to support safety, consistency, and learning across its diverse services. The paper proposes five strategic recommendations to support governance development. The full study paper has been shared with key stakeholders.

12. Items for escalation to the Board

The following items were agreed to be presented to the Board and Audit, Risk and Governance Committee (ARGC):

<u>Board – for assurance/approval</u>

- PSIRF Phase 1 update to be presented to Board. Assurance to be included that PSIIs are being reviewed by CGC and additional information in relation to the time taken to conclude investigations to be added. The outstanding never event action has been chased with NHSE.
- Amendments to Committee Terms of Reference to be presented to the Board for approval, following further amendment and agreement with Committee members.

<u>ARGC, for discussion:</u>

- Clinical Claims discussion on supply to private patients in private hospitals.