

**Trust Board in Public
Thursday, 06 June 2024**

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| Title of Report | Clinical Governance Committee Annual Report 2023 - 2024 | Agenda No. | 4.7.2 |
| Nature of Report | <input checked="" type="checkbox"/> Official <input type="checkbox"/> Official Sensitive | | |
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| Lead Executive | Denise Thiruchelvam, Chief Nursing Officer | | |
| Non-Executive Director Sponsor | Professor Charlie Craddock | | |
| Presented for | <input type="checkbox"/> Approval <input checked="" type="checkbox"/> Information <input checked="" type="checkbox"/> Assurance <input type="checkbox"/> Update | | |
| Purpose of the report and key issues | | | |
| <ul style="list-style-type: none"> The purpose of this report is to summarise the main activities of NHSBT Clinical Governance Committee (CGC) during 2023/2024. This report has provided assurance that the CGC have largely achieved its objectives and responsibilities as set out within the committee's terms of references. However, challenges arise in maintaining comprehensive oversight of key performance indicators, including complaints, compliments, and clinical incidents, due to variations in management and presentation across directorates. Moreover, the lack of interoperability and linkages between systems, or the absence of a digital system, exacerbates this issue, emphasising the need for an integrated system and dashboard to enable cohesive oversight. | | | |
| Previously Considered by | | | |
| | | | |
| Recommendation | This paper is provided for information and assurance of compliance of the committee's Terms of Reference. | | |
| Risk(s) identified (Link to Board Assurance Framework Risks) | | | |
| PR-01 Patient and Donor Safety | | | |
| Strategic Objective(s) this paper relates to: [Click on all that applies] | | | |
| <input checked="" type="checkbox"/> Collaborate with partners <input checked="" type="checkbox"/> Invest in people and culture <input checked="" type="checkbox"/> Drive innovation <input checked="" type="checkbox"/> Modernise our operations <input checked="" type="checkbox"/> Grow and diversify our donor base | | | |
| Appendices: | <i>Appendix A - CGC attendees / deputies log May 2023 – March 2024.</i> <i>Appendix B - Standing Agenda items discussed at CGC bi-monthly meetings.</i> | | |

1. BACKGROUND

NHSBT Clinical Governance Committee (CGC) was established in January 2023 and replaced NHSBT Clinical Audit, Risk and Effectiveness (CARE) committee. The purpose of this report is to summarise the main activities of the CGC's and provide assurance that the CGC had achieved its objectives and responsibilities as set out within its terms of reference during 2023/24.

The terms of reference of the CGC define its purpose as:

*'to provide assurance to the Board that the NHSBT has a robust **framework** for the management of all critical clinical systems and processes. This is a **framework** through which NHSBT is accountable for continuously improving the quality of services and safe-guarding high standards of care by creating an environment in which excellence in clinical care will flourish.'*

2. QUORATE MEETINGS

In the last financial year (1 April 2023 - 31 March 2024), the following six quorate meetings were held; (see appendices A for attendance log):

1. 09 May 2023
2. 14 July 2023
3. 28 September 2023
4. 17 November 2023
5. 12 January 2024
6. 8 March 2024

Standing agenda items (see Appendix B) are discussed during the bi-monthly CGC meetings, which reflect the level of governance and assurance oversight provided.

3. MEETING CGC OBJECTIVES

The following CGC activities during 2023/24 demonstrate how the committees have achieved their objectives as per NHSBT governance framework and its terms of reference.

- a) NHSBT CGC oversaw the Directorate CARE groups and reviewed annual reports from corporate areas contributing to clinical effectiveness, including information governance, infection prevention and control, medico-legal activities, clinical risk and clinical audit (Appendix B).
- b) The Blood Supply (BS), Clinical Services (CS), Organ and Tissue Donation and Transplantation (OTDT) and Plasma for Medicine (PfM) continue to hold directorates specific bi-monthly CARE group meetings which are chaired by the Chief Nurses (CN) or delegates. The groups have overseen the work of the operating directorates' clinical governance groups and monitored the performance of the groups in achieving clinical effectiveness during 2023/24. The CGC received and reviewed regular reports from each Directorate CARE Group.
- c) CARE groups have responsibility for monitoring the number of clinical and near miss incidents within their areas of responsibility. The CARE groups have monitored incident trends which informed decisions related to issues raised on the local risk registers and potential areas for clinical improvement. The Directorate CARE groups have ensured learning from serious incidents, discussed at CGC meetings, were shared across directorates.

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- d) NHSBT Data Security and Protection Toolkit (DSPT) full assessment was submitted at the end of June 2023 to comply with the statutory requirement for reporting to the NHS Digital to provide assurance that there is practising of good data security and that personal information is handled correctly.

The Information Governance (IG) team also provided the Committee updates on any IG incidents including management and reporting to relevant external agencies.

- e) To gain assurance that clinical risks are managed as set out in the NHSBT Risk Management Manual, clinical risks were presented at each CGC meetings throughout 2023/24, using Ideagen Risk Management software. Additionally, regular deep dives into the strategic clinical risks were completed and presented.
- f) There were no never events, and six serious incidents (SIs) reported during 2023/24 versus one never event and five SIs in 2022/23. Each SI was formally investigated and reported to the relevant Director or Deputy, who oversaw the completion of the action plan. Each SI was also reviewed at the relevant CARE group and CGC meetings to ensure organisational learning and minimise the risk of a similar incidents occurring in other parts of NHSBT.

These incidents were also presented to the Board to provide assurance that clinical governance mechanisms are in place and effective, meeting the terms of reference for the committee and supporting the Governance Statement. Details of these incidents are presented to this CGC meeting within the Serious Incidents and Never Event annual report.

- g) In 2023/24 the Board received clinical governance and serious incident summary reports on a 2-monthly basis. In addition, the Board was informed offline about any new SIs and received regular updates on them between meetings.
- h) CARE groups also review key clinical incidents, but CGC encounters challenges in maintaining comprehensive oversight clinical incidents, due to variations in management and presentation methodologies across directorates. Furthermore, the lack of interoperability and linkages between systems, or the absence of a digital system altogether, exacerbates this issue, underscoring the imperative for an integrated system and dashboard to facilitate cohesive oversight.
- i) The Clinical Governance Committee (CGC) has been actively overseeing the transformation of clinical governance structures in preparation for the implementation of the Patient Safety Incident Response Framework (PSIRF). This includes the planning and development of an organisational Policy for Patient and Donor Safety Incident Management, as well as an associated response plan. Developed by NHS England, the PSIRF replaces the current Serious Incident (SI) Framework, offering a broader scope that outlines the NHS approach to establishing and sustaining effective systems and processes for addressing patient/donor safety incidents, with a strong emphasis on learning and improvement. The CGC is currently overseeing NHSBT's transition to phase 1 of the PSIRF implementation plan.
- j) Furthermore, the Directorate CARE Reports provide updates on current clinical complaints (as well as compliments) at each CARE meeting, showcasing the team's monitoring and response mechanisms to complaints, and their efforts in sharing lessons learned. However, the CGC lacks comprehensive oversight of complaints and compliments, primarily because each directorate manages or presents them differently. This inconsistency stems from the absence of an integrated system and dashboard designed to facilitate unified oversight.
- k) The CGC maintained oversight of the management of medico-legal claims. The Clinical Claims interim and annual reports were submitted to the CGC in May and November 2023. These reports provided an overview of clinical and non-clinical claims, ex gratia payments,

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Inquests, Court of Protection cases and Judicial Review proceedings. Details of the individual claims can be reviewed within the Clinical Claims Annual report.

- l) The CGC reviewed and approved the annual clinical audit programme, which was also agreed between the Clinical Audit Manager and relevant functions and Directorate CARE Groups. The Directorate CARE groups reviewed the final reports of relevant audits, and all audit reports were reported to CGC to ensure organisational learning and implementation have taken place.

In the fiscal year 2023/24, NHSBT planned to conduct ten clinical audits, out of which nine were successfully completed. Additionally, an extra audit, initially scheduled for 2024/25, was finished ahead of schedule, bringing the total completed audits to ten. All audits received approval from the Clinical Governance Committee (CGC):

1. AUD4330 – Audit of Haemovigilance Reporting in Red Cell Immunohaematology (RCI)
2. AUD4326 – Audit of the Outcomes of Thawed and Washed Red Cells Issued by the National Frozen Blood Bank (NFBB)
3. AUD4630 – Re-Audit of the Appropriateness and Accuracy of Red Cell Immunohaematology (RCI) Antenatal Reporting
4. AUD4762 – Substitutions in Order of Rare Red Cells Audit
5. AUD4892 – Re-Audit of the Follow-Up of Pre-Cut Descemet Stripping Automated Endothelial Keratoplasty (DSAEK) Grafts from Filton Eye Bank
6. AUD4729 – Healthcare Assistant Extended Acceptance Criteria Audit
7. AUD5035 – Audit of the Management of Cord Blood Unit Full Blood Count Parameters
8. AUD4996 – Audit of the Ultrasound Guided Cannulation Technique within Therapeutic Apheresis Services (TAS)
9. AUD4746 – Audit of the Communication of New Clinical Information During Organ and Tissue Donation
10. AUD4324 – Donor Carer Acceptance Criteria Audit

The proposed audit programme for the fiscal year 2024/25 was reviewed during the CGC meeting in March 2024. The committee recommended conducting a review of serious incidents to assess whether additional clinical audits are necessary to address any identified risks before approval of the programme.

- m) The CGC received regular reports on the management of any safety alerts received via the National Institute for Health and Care Excellence (NICE), Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO), British Society for Haematology (BSH), Care Quality Commission (CQC) and Central Alerting System (CAS) in accordance with MPD734 *Managing notices from external bodies including those that subscribe to the Central Alerting Service of DHSC*.

In 2023/24 all relevant alerts were assessed for relevance to NSHBT by the Medical Directors and Senior Nursing Team and reviewed by the Quality Assurance team. Details of these publications are circulated to Directorate CARE Group leads for review and the identification of any relevance within their areas of responsibility.

During the period covered by this report eight alerts and guidance were relevant and implemented in NHSBT:

- Two of the CAS publications were identified as applicable within NHSBT:
 - Recall of Emerade 500 micrograms and Emerade 300 micrograms auto-injectors, due to the potential for device failure.
 - Medical beds, trolleys, bed rails, bed grab handles and lateral turning devices: risk of death from entrapment or falls.

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- NICE published two guidance documents that were identified as applicable within NHSBT:
 - COVID-19 rapid guideline: haematopoietic stem cell transplantation.
 - Suspected sepsis: recognition, diagnosis and early management' is relevant within the Therapeutic apheresis Services.
 - Three publications were issued by the SaBTO:
 - Pathogen inactivation technologies for platelets
 - Occult hepatitis B infection in UK blood donors
 - Recommendations to introduce universal serological screening of deceased donors for Kaposi's sarcoma associated herpesvirus (KSHV) infection.
 - One of the BSH publications was identified as applicable within NHSBT: Diagnosis and management of thrombotic thrombocytopenic purpura and thrombotic microangiopathies.
 - No CQC publication was identified as applicable within NHSBT.
- n) Furthermore, the Therapeutic Products Safety Group (TPSG) ensures that NHSBT is coherently engaged in the developing safety agenda within and beyond NHSBT, including:
- shaping the safety agendas of external bodies (e.g., SaBTO, JPAC)
 - responding to emerging threats to safety
 - providing advice to CARE groups, CGC and external stakeholders on safety matters
 - communicating safety matters to stakeholders and the public
 - proactively seeking and considering safety measures relevant to NHSBT

The clinical governance report to the Board included new matters of safety policy.

- o) For assurance the CGC received regular updates about the Infected Blood Inquiry (IBI). The final report is expected to be published around 20th May 2024.
- p) CGC Effectiveness Review - The CGC effectiveness review, conducted in November 2023 and an action plan has been established to address the gaps identified. This plan is designed to enhance governance processes within the CGC addressing various areas such as membership diversity, skills development, governance mechanisms, communication channels, and continual improvement to further strengthen the CGC's oversight role in ensuring clinical quality and safety of our donors and patients. The plan will be discussed at May 2024 meeting for review and approval.

4. CONCLUSION

This report provides a summary of the primary activities undertaken by the CGC during the 2023/24 fiscal year, offering assurance that the committee has largely met its designated objectives and responsibilities as outlined within its terms of reference. However, following an effectiveness review, an action plan has been proposed for approval by the CGC to address identified gaps and enhance the committee's effectiveness. Notably, the CGC encounters challenges in maintaining comprehensive oversight of key indicators, such as complaints, compliments, and clinical incidents, due to variations in management and presentation methodologies across directorates. Furthermore, the lack of interoperability and linkages between systems, or the absence of a digital system altogether, exacerbates this issue, underscoring the imperative for an integrated system and dashboard to facilitate cohesive oversight.

Appendix A

CGC attendees / deputies log April 2023 March 2024

| Name | Title | Department Directorate | Member attendance | Deputy Attended | Total of CGC Meetings represented |
|---|---|------------------------|-------------------|-----------------|-----------------------------------|
| Charlie Craddock | Non-Executive Director | Chair – Corporate | 6 | 0 | 6/6 |
| Denise Thiruchelvam -started in Nov 2023 | Chief Nursing Officer | Nursing | 3 | 0 | 3/3 |
| Gail Mifflin | Chief Medical Officer | Clinical | 6 | 0 | 6/6 |
| Peter Wyman | Chair NHSBT | Corporate | 2 | 0 | 2/6 |
| Helen Gillian | Director of Quality | Quality Assurance | 4 | 2 | 4/6 |
| Paul O'Brien | Director of Blood Supply | Blood Supply | 1 | 5 | 1/6 |
| Anthony Clarkson | Director of OTDT | OTDT | 4 | 2 | 4/6 |
| Iroro Agba | Assistant Director of Quality and Regulatory Compliance | Quality Assurance | 5 | NA | 5/6 |
| Derek Manas | Medical Director ODT | OTDT | 2 | 0 | 2/6 |
| Andrew Broderick | Chief Nurse & Corporate Clinical Governance Lead | Clinical | 5 | 1 | 5/6 |
| Olive McGowan | Chief Nurse | OTDT | 5 | 1 | 5/6 |
| Ella Poppit | Chief Nurse | Blood Supply | 3 | 3 | 3/6 |
| Donna Cullen | Head of Nursing | Plasma for Medicine | 1 | 5 | 1/6 |
| Ruth Clarke | Clinical Claims Manager | Clinical | 1 | NA | 1 |
| Angus Wells | Consultant in Donor Medicine | Plasma for Medicine | 1 | NA | 1 |
| Alia Rashid | Assistant Director - Plasma Operations (Collections) | Plasma for Medicine | 1 | NA | 1 |
| Farrah Shah | Medical Director for Transfusion | Blood Supply | 5 | 0 | 5/6 |
| Dave Lockett | Deputy Chief Information Officer & Chief Information Security Officer | DDTS | 4 | 2 | 4/6 |

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|--------------------------------------|---|------------------------|---|----|-----|
| Dave Roberts | Medical Director Pathology | Clinical | 2 | 0 | 2/6 |
| Su Brailsford | Interim Associate Medical Director – Manufacturing & Microbiology | Blood Supply | 5 | 0 | 5/6 |
| Shruthi Narayan Started in Jan 24 | Consultant Donor Medicine/ Medical Director at SHOT | SHOT | 2 | 0 | 2/2 |
| Samaher Sweity | Head of Clinical Governance | Clinical | 6 | NA | 6/6 |
| Marc Lyon | Clinical Audit Manager | Clinical | 6 | 0 | 6/6 |
| Phil Tanner | Assistant Director – Safety Wellbeing & Governance | People | 2 | 0 | 2 |
| Kirstin Finning | Risk Lead – Observer | Clinical | 4 | NA | 4 |
| Andrea Head | Deputy Chief Nurse. | Blood Supply | 1 | NA | 1 |
| Phil Chatterton Started in Jan 24 | Deputy Chief Information Officer/CISO | DDTS | 2 | | 2/6 |
| Eleanor Ward | Head of Data Security, Privacy, and Records Management | Information Governance | 3 | NA | 3 |
| Tapiwa Songore | Interim Corporate Governance Manager | Corporate | 5 | NA | 5 |
| Omolola Majolagbe | Corporate Governance Officer | Corporate | 2 | NA | 2 |
| Charlotte Washington | Consultant in Donor Medicine | Plasma | 3 | NA | 3 |
| Uchechi Izuka | Assistant Director Business Development and Strategy | Clinical | 1 | NA | 1 |
| Bethany Hall | Deputy Corporate Lead Nurse | Corporate | 1 | NA | 1 |
| Kim Douthwaite | Plasma Specialist Nurse and Professional Nurse Advocate. | Plasma | 1 | NA | 1 |
| Jo Farrar | Chief Executive | Corporate | 1 | NA | 1 |

Appendix B

Standing Agenda items discussed at CGC bi-monthly meetings

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| 1. | <ul style="list-style-type: none"> • Welcome and apologies. • Conflict of interest Declaration • Approval of draft minutes of the last meeting. • Matters arising and Action Log. |
| 2. | <u>Serious Incidents (SI)</u> <ul style="list-style-type: none"> • Serious Incident Summary Report • SI Closure Report • SI Shared Learnings |
| 3. | 4. PSIRF Update |
| 5. | Risk Management: Clinical Risk Update and reports |
| 6. | <u>Directorate CARE updates and reports:</u> <ul style="list-style-type: none"> • Clinical Services (CS) • Organ and Tissue Donation and Transplantation (OTDT) • Blood Supply (BS) • Plasma for Medicine (PfM) |
| 7. | Therapeutic Products Safety Group (TPSG) updates |
| 8. | Management Quality Review (MQR) updates and reports |
| 9. | Regulatory Radar |
| 10. | Clinical Audit update and reports |
| 11. | Safeguarding updates |
| 12. | Workforce updates |
| 13. | Information Governance update and reports |
| 14. | Research Governance Update and reports (No updates were provided in 2023/24 as awaiting the establishment of Scientific Advisory group). |
| 15. | <u>Annual / six-monthly reports including:</u> <ul style="list-style-type: none"> • CGC Committee Annual Report • Clinical Audit Annual Report • Therapeutic Products Safety Group (TPSG) • Management Quality Review Annual Report • SI Deep Dive Annual Review • SI/Never Events Annual Report • Joint NHSBT/ PHE Epidemiology Annual Report • Clinical Audit Annual Programme - Sign Off • Review of Clinical Audit Policy Documents • IG Annual Report (incl. Toolkit submission Report) • Safeguarding Annual Report • OTDT Biovigilance Annual Report • IPC Report |

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| | <ul style="list-style-type: none"> • Clinical Claims Report • Complaints & Compliments Annual Report (OTDT) • Non-Clinical Issue Update |
| 16. | <u>Ad Hoc Agenda Items</u> <ul style="list-style-type: none"> • Infected Blood Inquiry updates • CGC self-effectiveness review GIAA audit report on clinical audit • Impact of Montgomery Consent Requirements in Blood Donation. • Update on Donor Consent for research • Approvals of committees ToRs • Safety Framework Review • Measuring Safety Culture |
| 17. | Any Other Business |
| 18. | <u>For information: Key reports</u> <ul style="list-style-type: none"> • Clinical Governance Board Report • National Alerts and Guidance Report • CGC Workplan |