NHS
Blood and Transplant

Board in Public
Thursday, 06 June 2024

Title of Report	Clinical Governance Report	**Agenda No.**	4.6.2
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 14th of May 2024. Key issues:

- During this period, a new SI at the British Bone Marrow Registry highlighted communication issues causing delays in sending stem cells for a transplant recipient in mainland Europe, prompting process improvements. An open SI (Never Event) involving an ABO-mismatched organ transplant, still awaiting an external report. Two SIs were closed: one involving a malaria assay machine malfunction leading to false-negative results, and another involving a severe transfusion reaction in a sickle cell patient due to incompatible blood units. Additionally, an incident related to HHV8 testing raised concerns about test reliability, necessitating further investigation.

- Several annual reports were reviewed, including the Serious Incident and Never Event Annual Report, which highlighted six serious incidents (SIs) over the past year. The report also identified equipment malfunctions and incompatible blood supply issues, with an action plan to address these areas. The Infection Prevention and Control (IPC) Annual Report detailed adherence to cleanliness standards, staff immunisation, and governance improvements. The Clinical Audit Annual Report identified communication and documentation quality issues, with an action plan to address these concerns. The Non-Clinical Issue (NCI) Annual Report outlined operational challenges and financial outcomes, while the Clinical Claims Annual Report provided assurance on the appropriate management of clinical claims.

- Clinical Governance improvements were approved, including the initiation of the Clinical Quality and Safety Governance Group (CQSGG), reporting to the CGC, to consolidate and streamline clinical governance reporting processes, enhancing efficiency and oversight. Additionally, following a CGC effectiveness review, the CGC and relevant reporting groups will transition from bi-monthly to quarterly meetings starting in April 2025. This change aims to improve focus, preparation, decision-making, and resource utilisation while reducing meeting fatigue.

Previously Considered by	
Click or tap here to enter text.	
Recommendation	The Board is asked to note the report.
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. Patient and Donor Safety

1.1 Serious Incidents (SIs)

1.1.1 ***Summary***
One new SI occurred in NHSBT during this reporting period. Two SIs have been closed and one previously reported SI remains open.

1.1.2 ***New SIs*** - There is one new SI recorded in NHSBT during this reporting period.
The British Bone Marrow Registry (BBMR) received a donation request from an international registry, initially planning collection for an agreed specific date. However, due to the patient's clinical condition, the collection was postponed to a later agreed date. A request from the recipients registry and subsequent miscommunication led to BBMR mistakenly confirming earlier collection dates but not actioning these with the collection team, resulting in a delay and the prolongation of the patient's pancytopenia, increasing the risk of infection.

The absence of a centralised source for confirmed collection dates, inadequate validation processes for donation dates, and reliance on individual email communication contributed to the discrepancy. To address these issues, an action plan is being implemented to improve communication, establish a system for authorisation and confirmation, and introduce a second checker for dates. In the longer term, a Customer Relationship Management (CRM) system is required, and this is currently being explored. Despite these challenges, the collection was successfully completed, there was no known harm to the patient, and the patient received their stem cell transplant shortly thereafter.

1.1.3 ***Open SIs*** - *One* previously discussed SI (Never Event) remains open:
The Organ and Tissue Donation and Transplantation (OTDT) **SI INC6524** (Never Event) from September 2022: 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.

1.1.4 **Closed SIs –** Two serious incidents were closed, and the closure reports were presented:

a) The SI (QI36303) closure report details a malfunction in a malaria assay testing machine that led to potential false-negative results. The error was identified following routine maintenance. Retesting of twenty samples revealed seven reactive results. Five donations had inconclusive results, with three units transfused; none of the recipients developed malaria symptoms.

   Root causes included a faulty analyser, inadequate escalation processes, and insufficient staff training. Immediate actions taken included removing the machine from use, retesting samples, and notifying affected hospitals and donors. Recommendations focus on revising equipment return-to-service protocols, enhancing staff training, and improving escalation processes. Shared learning emphasises the importance of effective machine failure detection, robust post-maintenance checks, and prompt incident escalation. A subsequent review of equipment management process assures that NHSBT's equipment management practices comply with regulatory standards.

b) A patient with sickle cell disease experienced a severe haemolytic transfusion reaction after receiving incompatible blood units. The investigation identified failures in incorporating consultant advice into the Hematos System (results management system), inadequate

detection of antibodies, and oversight of referral records to another NHSBT lab for further testing. Contributory factors included poor communication and documentation.
Actions taken included removing the incompatible units, notifying relevant parties, and initiating a comprehensive investigation. Recommendations focus on improving the incorporation of consultant advice, enhancing communication and documentation, and refining the triage process.
Shared learning emphasises the importance of promptly recording clinical information, thoroughly reviewing records, and enhancing system interoperability. NHSBT has revised its procedures to prevent recurrence and improve patient safety.

1.1.5 **Other incidents**

An incident involving HHV8 (Human Herpesvirus 8) testing has raised concerns. A liver recipient initially received a negative HHV8 antibody test result. However, the patient later became unwell, and subsequent testing focused on a recurrence of the original disease. A later sample tested positive for HHV8, and the patient began treatment six weeks after receiving this result. Unfortunately, the patient did not survive. A report is being prepared for the HM Coroner. This incident underscores the necessity for a thorough investigation into the reliability and accuracy of HHV8 testing protocols. Investigations are currently underway.

1.1.6 **Safeguarding**

The Safeguarding Oversight Group (SOG) is aligning its governance with national priorities. Key issues include improving Level 3 safeguarding training compliance, currently below the 95% target, and establishing clear processes for managing staff allegations. Additionally, NHSBT needs to identify a Mental Capacity Act (MCA) lead and develop supporting policies.

2. Annual Reports

The committee received several annual reports that provided assurance of current clinical processes and identified gaps and action plans for improvements. These include the following:

2.1 Serious Incident and Never Event Annual Report for 2023/2024

The report highlights six SIs and no Never Events. Five SIs were closed, with one pending finalisation. Key incidents include failures to detect low haemoglobin, anaphylactic reaction, air embolism during procedures, malaria testing errors, transfusion reactions due to incompatible blood, and communication gaps in stem cell collection. Each incident prompted specific recommendations to improve training, procedures, and communication.

The summary of serious incidents indicates no clear trends. However, reflecting on this and last year's incidents, addressing equipment malfunctions promptly remains crucial, prompting a QA review confirming adherence to standards. The issue of supplying incompatible blood highlights the need for further assessment and improvement. Therefore, a thematic analysis into incidents related to the supply of incompatible blood is planned for this year to explore and address this issue.

NHSBT follows a structured incident management process, ensuring organisational learning and risk minimisation. The organisation remains compliant with the Duty of Candour, maintaining transparency when incidents occur. Starting in June 2024, the implementation of the Patient Safety Incident Response Framework (PSIRF) is expected to enhance the response to patient and donor safety incidents.

2.2 Infection Prevention and Control (IPC) Annual Report for 2023/24

The report outlines key initiatives, including implementing the National Standards of Healthcare Cleanliness 2021, enhancing staff immunisation programmes, improving hand hygiene practices, developing an IPC link nurse/practitioner network, and strengthening IPC Committee governance.
Most cleanliness audits achieved high ratings, with corrective actions implemented for any lower scores. Regular hand hygiene audits were conducted, resulting in policy updates such as 'bare below the elbow' requirements. The IPC team worked closely with Health Safety and Wellbeing to ensure staff vaccination status and supported the 2023 flu vaccine campaign by offering extended hours and efficient processes.

Additionally, there are plans to bring hepatitis B immunisation in-house for improved management and oversight. This initiative will have financial implications, including the time commitment for audits and potential costs, which will be offset by savings from the occupational health contract. Compliance with hand hygiene requirements is also expected to reduce staff grievance risks.

To further support infection prevention, a network of IPC link nurses and practitioners is being introduced. The IPC Committee, which now includes the Chief Nursing Officer and has plans to involve NHS colleagues, meets bi-monthly to review workplan activities, audit reports and governance activities.
The IPC team is committed to sustainability and collaborates on equality and diversity, completing an equality impact assessment for new policies.

2.3 Clinical Audit Annual Report for 2023/24

The report summarises clinical audit activities over the past year. Of the ten audits planned, nine were completed on schedule, with the last expected in April 2024. An additional audit, planned for 2025/26, was completed early, making a total of ten completed audits. Three provided substantial assurance, while seven provided moderate assurance; none were limited or unsatisfactory.

A total of 64 actions were generated from clinical audit activities. Of these, 35% were closed, 46.9% remained open with future target dates, 10.9% had extended deadlines, and 6.3% were overdue. All open actions are monitored, and any completion issues will be escalated to Directorate CARE.

Two recurring issues were identified: communication with external organisations and documentation quality. Audits revealed problems in reporting near misses, outcome information for units, variability in testing reporting, and sharing new clinical information. Documentation errors were also noted, including decision documentation by donors' carers and issues in Tendable data. These findings highlight the need for improved communication practices and better adherence to documentation standards across NHSBT.

Additionally, a management action plan is underway to enhance governance and oversight, addressing areas needing improvement identified by the Government Internal Audit Agency (GIAA) in clinical audit process, including control operations, audit trail retention, and reporting quality.

2.4 Non-Clinical Issue (NCI) Annual Report for 2023/24

The report details NHSBT's service for providing non-clinical donated materials. Despite staffing challenges, NCI maintained operations and achieved a successful audit. It generated £1.264 million, with leucocyte cones as the top seller, and supported 490 customer accounts. Key priorities for 2024/25 include developing a specific consent process for certain donor materials and replacing the legacy IT system to improve traceability.

2.5 **Clinical Governance Committee Annual Report 2023/24**
This report has provided assurance that the Clinical Governance Committee (CGC) has largely achieved its objectives and responsibilities as outlined in its terms of reference. However, the report also identifies challenges in maintaining comprehensive oversight of key performance indicators due to variations in management and the lack of an integrated system. An action plan has been proposed as part of the Committee's effectiveness review, to address these gaps and enhance the committee's effectiveness. The CGC continues to oversee the transition to the Patient Safety Incident Response Framework (PSIRF) and ensuring robust clinical governance across NHSBT.

2.6 **Clinical Claims Annual Report for 2023/24:**
The annual report on clinical and non-clinical claims was reviewed, offering a comprehensive overview of claims, ex-gratia payments, inquests, Court of Protection cases, and Judicial Review proceedings, providing assurance that these are managed appropriately.

3. Key Directorates' updates

3.1 Recent cases highlighted problems with accepting blood donors who have difficulty communicating in English, making post-donation discussions distressing, especially for those with positive infection markers. These issues are documented and linked to the Equality, Diversity, and Inclusion (EDI) team. Additionally, there are challenges in supporting existing databases and long-term solutions. An electronic system covering both screening and reference testing is needed to address these challenges effectively.

3.2 To address workforce challenges impacting clinical work, RCI has implemented proactive and successful measures to address challenges since September 2023. This includes recruiting 17 Biomedical Scientists across seven sites through a cohort recruitment drive. These new hires have increased the training workload which was addressed through three intensive new cohort training sessions conducted for these and other staff, with 27 individuals trained so far.

3.3 A new pilot research study has been launched, focusing on HLA-selected red cells to support patients on the renal transplant list. This pilot, in collaboration with Imperial, went live on April 2024. The study aims to improve patient outcomes by closely matching tissue type or HLA type, between blood donors and organ transplant recipients. This matching process is intended to reduce the likelihood of organ rejection, offering potential for improved outcomes in organ transplantation.

4. Governance Improvements

4.1 **The establishment of the Clinical Quality and Safety Governance Group (CQSGG) -** To enhance clinical governance within NHSBT, the Chief Nursing Officer has initiated the formation of the Clinical Quality and Safety Governance Group (CQSGG). This newly established group, with its Terms of Reference (ToR) approved by the CGC, will report directly to the Clinical Governance Committee (CGC), consolidating and streamlining the reporting processes of all relevant clinical governance groups under its umbrella. This restructuring aims to ensure thorough internal review and assurance of clinical governance matters before they reach the CGC, thereby optimising efficiency and strengthening the CGC's oversight effectiveness.

4.2 **Proposal to Transition CGC and reporting groups to quarterly meetings -** Following the CGC effectiveness review, improvements are proposed to optimise governance processes. The committee approved a proposal to change the CGC and other reporting groups from bi-monthly to quarterly meetings starting in April 2025. This change aims to support better focus and

preparation, improve decision-making, align with reporting timelines without conflict, and optimise resource use while reducing meeting fatigue.