NHS
Blood and Transplant

Board Meeting in Public
Tuesday, 31 January 2023

Title of Report	Clinical Governance Report	**Agenda No.**	3.3.2
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 paper summarises the clinical governance meeting discussed at The Clinical Governance Committee (CGC) held on 17th January 2023.

Key issues are outlined in the summary below.

Previously Considered by

N/A

Recommendation	The Board is asked to note the report.

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

(BAF)-01 Donor / Patient Safety

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. Summary

This was the inaugural meeting of the newly formed Clinical Governance Committee (CGC), which replaces NHSBT CARE. The Terms of reference and workplan of the committee have been approved.

Two new Serious Incidents (SIs) were recorded within NHSBT, one within this reporting period and one outside the reporting period. The first SI (QI33203) is about deficiencies in NHSBT handover process of a patient central line care to the hospital referring team, leading to patient harm; sepsis and heart clot. The second SI is regarding a fault in an analyser machine, where we may potentially have wrongly labelled several units of high titre blood products as low titre, which, if transfused, could potentially cause serious blood transfusion reaction.

A deep dive into the SI INC84203 indicated that we followed our SI management policy. However, the SI deep dive and shared learning showed that patient/donor safety errors related to manual processes across the organisation is a recurrent theme and requires an organisational wide approach and prioritisation of longer-term digital solutions.

The OTDT Biovigilance annual report was discussed, which will be shared with SaBTO and transplant centres. Learning from incidents has also been widely shared. Additionally, results from FAIR (For the Assessment of Individualised Risk) post-implementation monitoring were discussed. Overall, there has been no increase in recently acquired infections related to FAIR and no evidence of increase in higher risk behaviours. The CGC have strongly recommended that the results are published, which will have a global impact on practice.

2. The Clinical Governance Committee (CGC) Terms of Reference (ToR)

This was the inaugural meeting of this newly formed Clinical Governance Committee (CGC). The Terms of reference and workplan have been approved subject to a few minor changes. The Committee's updated ToR are presented for approval under the 'For Approval' section.

3. Serious Incidents (SIs)

3.1 Open SIs

3.1.1 One new SI was recorded within NHSBT during this reporting period, and another reported outside of this reporting period:

- **SI QI33203** - A patient was referred to a Therapeutic Apheresis Services (TAS) Unit for Plasma Exchanges (PEX) treatment. The patient was referred back to the referring team to arrange a central venous catheter (tunnelled Line) insertion to perform the required PEX as the peripheral access failed. Following receiving 4 sessions of PEX, the patient was discharged for a four-week break before commencing the remaining PEX sessions. At this point, TAS team should have handed the patient back to the referring team and this handover should have emphasised that the patient needed to be follow up to care for the line during this period. However, there was missed, and the patient did not receive line care whilst at home. So, whilst the primary responsibility for the patient being looked after in the community should lie with the Hospital referring team, who put the line in, this omission by NHSBT was a chance to pick up a system failure.

The patient was later admitted to a hospital with sepsis originating from the tunnelled line. Whilst inpatient, the patient was found to have a clot in their heart as further complication of the line. The patient was subsequently discharged after spending a total of 35 days in hospital.

NHSBT preliminary investigation indicated that poor communication and handover from TAS staff to the referring hospital has contributed to the mismanagement of the line and the patient subsequently developing sepsis/clot. The investigation also highlighted several areas for improvement and learning. Further investigations to include the referral hospital is being planned.

- **SI QI33517** occurred outside of this reporting period – this is in relation to a blood analyzer machine fault. As a result of this fault, there were potentially several high titre blood products being wrongly labelled as low titre, which, if transfused, could potentially cause serious blood transfusion reaction. A total 260 Fresh Frozen Plasma (FFP) units potentially impacted and issued to hospitals were recalled and another 190 FFP units in NHSBT were put in quarantine and will be used for non-clinical issues.

  A lookback investigation is being conducted to ascertain the fate of the above and other blood products units potentially implicated and issued (and the number of these), and whether there has been any patients' impact. Additionally, a root cause analysis has been arranged to understand why the fault has occurred.

3.1.2 A previously reported Never Event SI in relation to unintentional ABO-mismatched solid organ transplants for three recipients is still open and currently being investigated through NHS England.

3.2 **Closed SIs and shared learning**

The SI **QI30748** has been closed. This is about a cornea that was transplanted, but later, a growth was identified in microbiology samples still being incubated in the eye bank. The patient subsequently developed an infection in the transplanted cornea and required another transplant.

3.3 **SI deep dive**

A deep dive into the SI INC84203 and another similar but Major incident (INC82778) indicated that: robust SI investigations were performed with all related actions were completed; the SI investigations followed our SI policy (MPD772), but it took slightly longer to close (i.e., 98 days instead or a maximum of 90 days); the SI closure report is of good quality; the mitigations against the risks have been successful so far as no recurrence of similar incidents has occurred; and shared learning has taken place across directorates.

However, a longer-term mitigation of manual processes risks would primarily include digital solutions. Patient/donor safety errors related to manual processes across the organisation is a recurrent theme and requires a wider organisational approach and prioritisation of longer-term digital solutions. As part of shared learning and improvement, a list of key manual processes, related to patient/donor safety, across the organisation that require digital solutions will be presented and discussed in the next meeting. Decisions and concerns will then be escalated to the Board.

4. Clinical Audit

Eight out of the planned 14 clinical audits for 2022/23 have now been completed. Five are currently on track to be completed as planned and one will be delayed.

One audit was completed and approved during this period - *Audit of the Use of FRM400 in Pre-Procedure Assessment for Therapeutic Apheresis Patients (AUD4793)*. The results provided a moderate assurance and indicated poor documentation practices rather than assessments / reviews not being completed. Actions emanating from the audit include reviewing and updating FRM400 to ensure that the form is fit for purpose and to pilot it before implementation. Additionally, a review of the whole documentation process around pre-procedure assessment is required to ensure that the process is simpler and to eliminate duplications.

5. Care Quality Commission (CQC) inspection updates

The progress of the action plan to address the CQC inspection findings is being monitored through the ET and Board. The CGC also emphasised on evaluating the actions on the longer term. Colleagues were also encouraged to continue being proactive in identifying and addressing clinical issues, not only those issues highlighted by the CQC.

6. The Patient Safety Incident Response Framework (PSIRF)

The PSIRF implementation plan and challenges were discussed. The PSIRF is a contractual requirement under the NHS Standard Contract and as such is mandatory, which Should be implemented by Autumn 2023. An accountable executive (AE) has been appointed to lead the PSIRF project, who will define the costs for the implementation and future resources. These will be reviewed and approved by the portfolio oversight group (POG) and transformation boards. This plan was approved by the ET and project progress will be regularly monitored through the CGC.

7. Directorate CARE updates

7.1 OTDT Biovigilance annual report (April 2021 - March 2022) was discussed and will be sent to SaBTO and transplant centres for information. The report covers events investigated for possible donor-derived transmission of infections, malignancies, and other cases of interest. There were 792 cases reported to OTDT and investigated during this period. Two clinical incidents have been confirmed as probable/confirmed donor transmission cases (Mycobacterium tuberculosis (MTB) and Hepatitis B infections). One incident in relation to a high-Grade Epithelioid Tumour was confirmed. Finally, two cases of interest were also reported; Ornithine Transcarbamylase Deficiency (OTC) donor derived disease, and a well-differentiated neuroendocrine tumour was found in a gall bladder and bile duct. Shared learning from these has been widely disseminated.

7.2 Two previously reported risks in the Clinical Services are still high and recorded as red in the risk register despite the mitigations put in place. The first is the ongoing workforce challenges in TAS, including staff shortage, turnover, skill mix gap, recruitment and retention challenges and the added pressure on colleagues to cover gaps and train new staff. The second risk is in relation to Dimethylsulfoxide (DMSO) Syringe supply shortages used to cryopreserve stem cells. Agency staff are employed to support mitigation of preparing bulk cryoprotectant in the cleanrooms. However, longer-term solutions are being explored including alternative supplier.

7.3 There is an increasing requirement for a donor engagement group/forum to inform policy and service developments in Blood Supply (BS). This gap has been highlighted with Donor Experience and will be raised with BS SMT to agree on a plan to move this forward.

7.4 Arm cleansing – BS is looking at contingency options in the event of a disruption to the supply of the 1mL ChloraPrep wand. The current cleansing device is a single point of failure and clinical risk has been updated on the risk register.

7.5 FAIR (For the Assessment of Individualised Risk) post-implementation monitoring report was discussed. Markers of infection in donors have been regularly monitored. As expected there has been a small number of new donors who have previously undiagnosed infections, however, importantly there has been no increase in recently acquired infections related to FAIR and no evidence of increase in higher risk behaviours. Overall FAIR has met with a favourable reaction from donors, staff and recipients with the potential to allow more people to donate blood whilst maintaining the safety of the blood supply. The CGC have strongly recommended that the results of this work to be published, which will have a global impact on clinical practice.

7.6 Research approval – The BS CARE committee approved the provision of anonymised residual blood donation samples obtained from syphilis-positive male donors identified in 2022 to study the monkeypox infection. This is a collaborative Blood and Transplant Research Unit (BTRU)-GEMS study between NHSBT, University of Oxford (PCR testing for monkeypox virus DNA) and UK Health Security Agency (UKHSA) (monkeypox serology). Furthermore, Plasma for Medicine (PfM) are working in partnership under the BTRU to design and implement another research study aimed at assessing the impact of donation frequency and volume on donor health and behaviour. Finally, OTDT CARE approved a study where biopsies from transplantable hearts to be used. The study relates to the organ preservation period for the cardiac allograft which looks at primary graft dysfunction rates and bulk RNA sequencing.

8. Safety Policy Update

8.1 Therapeutic Products Safety Group (TPSG) approved the recommendations of the Microbiology Strategy Group to monitor syphilis screening ahead of moving to a new testing platform in early 2023. The recommendation came in response to the recent failures on syphilis screening. Noting that no transfusion transmitted infections have been reported and that the clinical risk to patients was minimal.

8.2 TPSG approved the recommendation for testing cut off of 106 IU/ml for use in parvovirus B19 testing of Plasma for manufacture of medicines (PfM). Parvovirus B19 and hepatitis A virus screening of plasma is needed to avoid the discard of manufacturing plasma pools.

8.3 The Occult Hepatitis B Infection (OBI) project progress - Currently the team is on target, testing on average 80.5% of donations for hepatitis B anti-core. Between end of May to end of November 2022, 383,419 donors were screened, 1 donor identified as OBI positive and 1661 donors with donations repeat reactive on anti-HBc testing.