NHS
Blood and Transplant

Board in Public

Tuesday, 29 November 2022

Title of Report	Clinical Governance Report	**Agenda No.**	3.2
Nature of Report (tick one)	☒ Official	☐ Official Sensitive	
Author(s)	Samaher Sweity, Head of Clinical Governance, Clinical Services		
Lead Executive	Dr Gail Miflin, Chief Medical Officer		
Non-Executive Director Sponsor (if applicable)	Professor Charles Craddock		
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 NHSBT CARE held on 3rd November 2022.

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

Two new Serious Incidents (SIs) were recorded within NHSBT during this reporting period. The first one was reported previously to the board and classed as a 'Never Event'. It is in relation to unintentional ABO-mismatched solid organ transplants for three recipients. The second SI is regarding 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 now needs another transplant.

An investigation into a previously reported probable occult Hepatitis B (HBV) infection through blood transfusion has concluded and two HBV transmissions from one donor (donated prior to the implementation of anti-HBc screening) have been confirmed. This highlights the importance of the ongoing anti-HBc screening and extended lookback investigations.

The Care Quality Commission (CQC) Quality & Compliance Group are formulating an action plan to respond to the CQC findings following recent inspections. This is covered in a separate paper to the Board and not repeated here.

Risks related to workforce challenges continue across directorates, which are negatively impacting clinical care and services, such as delays in patients' treatment, delays in completing projects and improvement events, and increased rates of overdue issues, incidents, and incompliance with mandatory training and Personal Development and Performance Review (PDPR). Directorates are continuing to review and manage risks and related challenges, however, a wider and more effective NHSBT approach to address the challenges and prioritise work should be considered.

Recruitment into STRIDES study has completed. The study is a collaboration between NHSBT and the University of Cambridge, which aims to improve blood donor experience. The study recruited more than 1.3 million donors, making it one of the largest cluster randomised trials in the world.

2. Serious Incidents (SIs)

2.1 **Open SIs -** Two new SIs were recorded within NHSBT during this reporting period:

- **SI INC6524** - This incident has been previously reported to the Board, which is classed as a 'Never Event'. This was in relation to three unintentional ABO-mismatched solid organ transplants. In the donor hospital, it was recorded in their IT system that the donor was blood group O. However, following transplantation of the donor's two kidneys and liver, it was discovered that the donor was in fact blood group B. The incident was discovered by chance by a Specialist Nurse Organ Donation (SNOD) whilst completing post transplantation documentation and going through the hospital system the next day. This is not a usual practice, nor process. A recipient also rejected their graft the same day so it is likely that it would have been discovered through this route too. The other two recipients have required additional treatment for their care.
  All three transplant centres have received a letter of apology. NHS England are monitoring closely and facilitating investigation with all parties involved.

- **SI QI30748** - A cornea was issued and transplanted to a patient in May 2022. However, the day after the cornea was transplanted, a growth was identified in microbiology samples still being incubated in the eye bank. Cornea grafts are issued with “negative to date” microbial screening results, and identification of growth in the eye bank after issue is a known risk, albeit very rare. Growth of organisms is usually related to sampling /sample contamination as opposed to genuine graft contamination; this particular organism was one that the eye banks identify relatively more commonly in this context, but usually *prior* to graft issuing, in which case the graft is discarded. The hospital medical team was immediately informed when the growth was identified, initially there was no patient impact, and the incident was managed as a Major Quality Incident and the investigation found no evidence of error or omission. The patient subsequently developed an infection in the cornea and requires another graft. On receipt of this information the incident was further considered, and processes were changed to include an additional antifungal medicine in the growth medium, as is routine practice in other eye banks. Given this and the patient harm, this incident has been reclassified as a SI. The SI is currently being closed.

2.1 **Closed SIs and shared learning**

Apart from the above new SIs, none is currently open.

3. Risk Management

Currently, there are 44 functional level (child) risks assigned to the principal strategic risk, Board Assurance Framework (BAF)-01 Donor / Patient Safety. The risk status for BAF-01 is moderate, with the worst child, functional level residual risk score currently recorded at 12.

A review of the Organ and Tissue Donation and Transplantation (OTDT) risks showed that two risks are high (Limit Zone) and the team are managing these appropriately, but some external factors are more difficult to control: these are that the lack of funding may cause us to fail to meet the NHS’ strategic objectives for organ donation and transplantation. Although controls are in place, they do not fully mitigate the risk. Secondly, there is a risk that tissue donation activity is inadequate to meet demand; resulting in TES being unable to provide products and services, leading to patient harm through delayed procedures. Actions are being taken to mitigate this risk.

4. Clinical Audit

Seven out of the planned 14 clinical audits for 2022/23 have now been completed. Six are currently on track to be completed as planned and one will be delayed. One completed audit was reviewed and approved during this meeting - Audit of Pain Management during Blood Donation (AUD3857): This audit assessed the management of arm pain for blood/blood products donors. The results provided a *moderate* assurance of the management of arm pain during donation sessions. The results showed a good practice in relation to recognition and subsequent management of the serious arm pain symptoms (suspected nerve irritation, nerve or tenson injury or arterial puncture), use of distraction techniques for vulnerable donors and documentation of needle adjustments undertaken, however, they also highlighted the need for improvements around multiple needle adjustments practices and communication with donors throughout this process. During the action plan development, it has been confirmed that the main issues identified by this audit have already been included in recent revisions of training programmes for new staff. The results will be widely shared and fed into current ongoing projects to review donor consent and information leaflets.

5. Care Quality Commission (CQC) inspection updates

Following the publication of the recent CQC inspection report, the CQC Quality and Compliance Group have started formulating an action plan to respond to the issues raised by the CQC. This will be reviewed by the Board elsewhere in the meeting agenda.

6. Directorate CARE updates

6.1 **Workforce challenges -** Clinical workforce challenges continue, which impacting clinical services and care, such as delayed or rescheduled patients' treatment, increased rates of overdue issues/documents and incidents, delays in completing projects and improvement events, and incompliance with mandatory training and Personal Development and Performance Review (PDPR). The challenges include staff shortage, turnover, skill mix gap, recruitment and retention challenges (e.g., external staff recruitment and pay competitions) and the added pressure on colleagues to cover gaps and train new staff. Although there has been some progress with recruitment, and each directorate is continuing to review their workforce issues with HR partners, nevertheless, challenges continue to persevere. A wider and more effective NHSBT approach to address the challenges and prioritise work should be considered.

6.2 **STRIDES (STRategies to Improve Donor ExperienceS) Study** – Recruitment into the STRIDES study has completed. The study is a collaboration between NHSBT and the University of Cambridge, which recruited 1.37 million donors into the trial component and ~83,000 into the BioResource, making it one of the largest cluster randomised trials in the world. The study aims to improve blood donor experiences by conducting research into donor management and addressing wider public health issues, to implement changes to the standard practice of blood donation. The results of the study will be shared once analysis has been completed.

7. Clinical Claims

7.1 Historical issue of a small group of pre-cut corneas that had the potential to have been cut too thickly. Not all of the patients were covered by NHS Indemnity where they were issued to private hospitals. The issuing of corneal grafts to private establishments is now covered by our contingent liability notice. The service is currently paused and will restart soon. To reduce risk of recurrence, an Optical Coherence Tomography (OCT) instrument is now installed and validated and will be used to measure the thickness of a graft before issuing once the service has restarted.

7.2 NHSBT has recently been notified of a potential cohort of mostly historical claims relating to the subject matter of the Infected Blood Inquiry.

7.3 Work on the blood donor consent is underway for a number of reasons including Health Research Authority (HTA) requirements, but this is pertinent to the prevention of future claims too. A claim relating to historical practice has recently been settled.

8. Safety Policy Update

The Occult Hepatitis B Infection (OBI) project team is currently working on phase 2 of the OBI project, which includes implementation of the PULSE change that will enable donations to be released if a donor has a negative anti-HBc on the system. Therefore, donors will only need to be tested once. However, this will have a significant impact on testing. The estimated time for implementation is March 2023.

Up to 7th November, 18% of donors have been tested, and 13% have had repeat testing. The percentage of donation tested has increased over the past few months with 76% of these donations have been tested in October 2022, which is better than the set target.

9. **Confirmed Hepatitis B (HBV) transmissions** - In May 2022, we reported to the Board a case where a patient was diagnosed with HBV infection that was probably transmitted via blood transfusion (QI29558). Based on retrospective testing, one donor has evidence of occult HBV infection, and HBV DNA has been detected in the index donation. The implicated donation was the donor's first blood donation, and they have subsequently donated twice. The donor did not disclose any risk factors at the time of donation or subsequently that would have made them ineligible to donate blood. There was no error in any processes during blood donation and testing. Lookback investigations into their subsequent blood donations have now concluded and have unfortunately identified another patient who also acquired HBV infection post transfusion from the same donor.

   The DNA analysis of samples from the donor and the two infected patients indicated that they shared a high sequencing DNA similarity, meaning that the HBV transmission is likely due to the blood transfusion received from this donor. We recognise that occult HBV carries an additional and higher risk, and this had already prompted a review of the UK Blood Services screening policy by the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO). As a result of this review, SaBTO recommended the implementation of HBV core antibody (anti-HBc) screening of blood donations. Following ministerial instruction, implementation of anti-HBc screening has started in England in May 2022.

10. **Information Governance (IG)**

    Subject Access Requests (SARs) and Freedom of Information Requests (FOIs) continue to be a demand and challenge on the team, from a complexity, sensitivity and time perspective, in part due to an increase in media activity about the organisation. The Data Security, Privacy, and Records Management (DSPR) Team are leading the end-to-end processes to ensure we are complaint from a legislative and regulative perspective. The team is also working on further improvements to the process such as templates, review of escalation routes and communication with customers.

11. **National Standards of Healthcare Cleanliness (NSHC) 2021**

    Implementation work of the NSHC is ongoing. The commitment to cleanliness charters is now being displayed across the organisation facilities. A newly designed electronic audit tool will allow us to monitor items to be cleaned, performance parameters and frequencies, data will be used to generate audit reports and star ratings. Staff are currently receiving an introduction to the standards through a video on LINK or via manager cascade.