NHS
Blood and Transplant

Board Meeting in Public
Tuesday, 06 June 2023

Title of Report	Clinical Governance Report	**Agenda No.**	3.6.2
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 9th of May 2023.
Key issues:

- One new Serious Incidents (SIs) was opened. This involved a female blood donor who became unwell post donation requiring hospital admission and 4 units of blood transfused. A subsequent diagnosis of B12 deficiency was made.
- A deep dive into the strategic risk 'Failure to Monitor Clinical Outcomes (Board Assurance Framework (BAF) - 06) has been conducted and reviewed at CGC. The risk is aligned to the strategic theme of driving innovation and focuses on clinical outcomes with regards to blood usage, organs and tissues, stem cells and therapeutic apheresis and encompasses opportunities to identify and act upon health and health inequalities. Work is underway to identify specific strategic risks around each of the four areas and to identify the priority outcome measures in those areas that will be areas of focus for improvement.
- A question has been raised asking whether the consent given by blood donors is sufficient to allow the use of donated blood for specific research programmes without obtaining specific consent.
  This was discussed by the committee and agreed that donated blood that is supplied to academics for anonymised and REC approved research studies currently has appropriate consent, in line with HTA requirements.
- The committee noted that there were a significant volume of papers to read and cover in the meetings to date. Members were asked to ensure papers were focused and brief to allow a fuller discussion of important issues brought to the committee, which will be identified by the secretariat.

Previously Considered by

N/A

Recommendation	The Board is asked to note the report and discuss where relevant.

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

BAF-01 Donor / Patient Safety & BAF-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. **Serious Incidents (SIs)**

There were no new SIs recorded during the reporting period. However, it was noted that SI QI34949 was reported from Blood Supply after the meeting and is described below. Additionally, the Board were alerted last week to a further incident involving a blood donor who sustained a serious allergic reaction.

SI QI34949– this SI is in relation to a young female whole blood donor who attended for their second donation. The donor was fit and well at screening. Hb testing was performed using Copper Sulphate and result was recorded as a pass. The donation proceeded. The donation was found to be icteric (jaundiced) and this was reported to the Clinical Support Team. Information was received that after donation the donor felt unwell and attended hospital where her Hb was found to be 53g/l. Two units of blood were transfused followed by a further two units several days later. The donor has been diagnosed with a previously unknown B12 deficiency and the donation resulted in a 'decompensation' causing her to feel unwell. The donor has received treatment and has since returned to work.

SI QI33203: This SI was previously reported and is still open and currently being investigated: This is regarding a patient who received Plasma Exchange (PEX) treatment via a central line in one of the Therapeutic Apheresis (TAS) Units. The patient was discharged for a four-week break before commencing another PEX sessions. However, there were deficiencies in the handover process between TAS and the referring team. The patient was subsequently admitted to a hospital with sepsis and clot originating from the central line. The patient fortunately recovered and was discharged 35 days later. A full investigation has been completed in collaboration with the referring hospital and an action plan developed to mitigate the risks of a recurrence. A joint report is being written for submission to the next CGC meeting.

SI INC6524: (Never Event, unintentional ABO-mismatched solid organ transplantation to three recipients). The internal investigation has now been completed and as a result internal processes have been strengthened and a good escalation process is now in place. The learning will be shared with other directorates. We are still awaiting a final report on this from NHS England

SI QI33517 Closed: This SI related to the blood analyser machine fault that resulted in blood components being issued with potentially incorrect titre status. The investigation found that of 694 units followed up there were no reports of patient reactions. The analyser machine was repaired by an engineer before being returned to use. Additional checks have been implemented to mitigate risks of a recurrence. It was concluded that the machine had continued to be used beyond its recommended lifespan and needed replacement. The machines are being replaced as part of the Testing Development Programme.

2. Risk Management

2.1 A deep dive into the principal risk 'Failure to Monitor Clinical Outcomes' (Board Assurance Framework (BAF) - 06) was reviewed at CGC. The risk is aligned to the strategic theme of driving innovation and focuses on clinical outcomes with regards to blood usage, organs and tissues, stem cells and therapeutic apheresis and encompasses opportunities to identify and act upon health and health inequalities. A number of controls and gaps in controls have been identified with the main one being that there isn't a systemised mechanism to capture, analyse and understand outcomes in all the patients, beyond organs and corneas. Assurances around these risks have been identified.

Work is underway to identify both the outcome measures in these areas and the next step will be to identify the work required to mitigate the risk and to prioritise these into a proposed programme of work. This will be reported to the Board in due course. The Committee discussed the risk in detail, noting that the importance of the national registries and focus on quality of the data. The plan going forwards is to define the outcomes using workshops and focus groups.

3. Clinical Audit

3.1 The committee approved a revised clinical audit programme. Ten audits have been planned for 2023/24. Of these ten, one has been completed during April with the remaining to be completed throughout the year. The committee asked that the clinical audit team to benchmark the programme against other organisations to explore whether the programme is scaled sufficiently and whether there is sufficient capacity within the audit team.

3.2 The audit of Haemovigilance Reporting in Red Cell Immunohematology aimed to assure that all serious adverse events and serious adverse reactions within RCI were reported using the appropriate mechanisms. The report provided moderate assurance. It highlighted some issues around near miss events in relation to inconsistency in reporting and the potential misinterpretation of risk. An action plan had been developed to improve the documented processes around near miss events.

4. The Patient Safety Incident Response Framework (PSIRF)

A project board and an implementation group have been established to manage the development and delivery of the PSIRF policy and plan. This will include required changes within the organisation to ensure effective processes in line with NHS England patient safety policies. NHS England had set a target date of Autumn 2023 for the implementation of the PSIRF plans and policies. NHSBT had been working towards this timeline, however due to a number of challenges related to resourcing, the complexities of the organisation and the regulatory framework in which we operate and challenges with data analysis this was considered difficult to achieve. It has been agreed with NHS England that NHSBT will work towards implementation in March 2024.The identification of an oversight board (a function normally provided by Integrated Care Boards) will be discussed with the DHSC Sponsor Team.

5. Directorate CARE updates

5.1 Within the Clinical Biotechnology Centre (CBC) issues with manufacturing of plasmids have been identified. Subsequent external testing of the affected products has identified bacteriophage contamination of the bacterial cultures used to produce plasmids. Bacteriophages, also known as phages, are viruses that infect and replicate only in bacterial cells. This is very difficult to

eliminate and has never seen before within the CBC. NHSBT is working with Phage Consultants to understand the root cause and corrective actions required. Manufacturing is halted pending further advice on testing and cleaning of the environment. There have been no impacts on patients. The key risk is that the products may not be delivered on time to customers resulting in loss of income and reputation. The manufacturing of viral vectors is unaffected.

5.2 Progress is being made on most functions' risk registers to apply the new risk management framework and risk appetite.

5.3 A review of the current status of risk relating to Estates and Facilities highlighted that two thirds of child risks are outside of NHSBT's appetite for the primary risk area of Service Disruption. The CS Risk Lead is working with key stakeholders to address this issue.

5.4 There have been a small, but increasing, number of incidents reported in relation to travel for transplantation. NHSBT have two representatives on the National Focal Point Network that is part of a European wide initiative to focus on this concern and the Clinical Governance team link closely when any reports are received. The representatives are working closely with the HTA, and a multi-agency approach is agreed if any reports raised concerns.

5.5 A meeting is to be scheduled with the MHRA Scientific Advisory Group, with a view to considering requirement for mandatory HAV/B19 testing on current stockpile, and potential to extend sPFM shelf life from 3 years.

Other incidents of note

5.6 **QI33914** A request for a pre-cut cornea was received, a cornea was identified however during assessment it was deemed unsuitable. A second cornea was to be provided to the hospital on the day of surgery instead of the day before surgery, which is the usual practice. The pre-cut cornea was dispatched and transplanted that day. The microbiological samples were reviewed within NHSBT and displayed heavy growth / contamination. The Consultant Ophthalmologist was contacted and updated. The patient was immediately commenced on anti-fungal medication. Unfortunately, the patients graft had to be removed. Following treatment, the patient was re-grafted but is having an exceedingly difficult post-operative recovery due to infection, the original infection has affected the second graft. Investigation ongoing. Family have requested the investigation report.

5.7 **INC6916 –** The Incident relates to a DCD donation from a patient with complex medical history including MGUS (monoclonal gammopathy of uncertain significance), both kidneys and corneas were transplanted. Four weeks post-transplant, a histology result from a routine biopsy from one of the kidneys showed the presence of a low-grade B Cell lymphoma, this was an unexpected finding. There were no errors in the donor retrieval processes. This has been communicated to all centres and patients are being treated appropriately.

5.8 **QI34576 –** Air embolism**.** A male component donor with 275 previous donations was donating platelets when staff witnessed a small amount of air entering the circulation during the first return cycle of routine platelet donation (estimated to be less than 1 mL and below the dose reported to cause injury). The donor was transferred to A&E for observation and released after four hours. He has remained well throughout. The investigation to the cause is continuing.

6. Blood Donor Consent for Research

6.1 In July 2022 it was noted that following a change in the Donor Health Check consent wording that blood supplied for research through our Non-Clinical Issues (NCI) processes was not appropriately covered by the new wording. This was corrected in January 2023 and in the intervening period all issues were reviewed by a committee chaired by Director of Quality. The new wording on the consent was approved by the HTA prior to implementation.

6.2 Recently an anonymous complaint has questioned whether the consent given by blood donors is sufficient to allow the use of donated blood for specific research programmes without obtaining specific consent from donors. It was explained that this is covered by the HTA consent exemptions where consent is not required for research that NHSBT supports if the following three criteria are met: Samples are collected from live donors, supplied anonymously and to research projects approved by a Research Ethics Committee. NHSBT has processes to ensure these criteria are met. Furthermore, NHSBT processes are more stringent in requiring specific consent in these circumstances where the research involves animals or wide genomic testing which could result in de-anonymisation in any way. It was agreed that donated blood supplied to academic research studies through our NCI process has appropriate consent, in line with HTA requirements.

7. Safety Policy Update

The Therapeutic Products Safety Group (TPSG) Annual report was received and reviewed. There were no other items of blood policy to note.

8. Committee Review

The committee noted that there were a significant volume of papers to read and cover in the meetings to date. Members were asked to ensure papers were focused and brief to allow a fuller discussion of important issues brought to the committee, which will be identified by the secretariat.