NHS
Blood and Transplant

Board Meeting in Public
Tuesday, 28 March 2023

Title of Report	Clinical Governance Report	**Agenda No.**	3.3.2
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 discussions at the Clinical Governance Committee (CGC) meeting held on 7 March 2023.

Key issues:

- One new Serious Incidents (SIs) was recorded in this reporting period within NHSBT. This was 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 strategic risk 'Donor and Patient Safety (Board Assurance Framework (BAF) - 01) has been conducted and reviewed at CGC. Key strategic elements, current and planned mitigations were highlighted. Although a child risk is now scored higher than the judgement zone, overall, the risk is deemed to still be within this zone.
- The need for a review of our business continuity action plan has been identified, this is to determine that the plan for a pandemic preparedness for an agent transmissible by blood and our other products is outlined.

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 Data Unavailable for 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)

One new SI was recorded within NHSBT during this period. Two previously reported SIs are still open as these are being investigated.

1.1 **New open SIs**

One new SI was recorded within NHSBT during this reporting period (the initial investigation was previously reported):

SI QI33517– this SI was in relation to a blood analyser 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 a serious blood transfusion reaction. Due to the timing of escalation of this incident, the 344 red cell and platelet shorter shelf-life components had already been either issued or discarded. Other potentially impacted units with a long shelf-life (260 Fresh Frozen Plasma (FFP)) that had been issued to hospitals were recalled. Another 190 FFP units in NHSBT were put in quarantine and will be used for non-clinical issues.

A lookback investigation is currently ongoing to ascertain the fate of the above blood products units and whether there has been any patient harm, if transfused. Additionally, the initial root cause analysis indicated that the blood analyser machines are old; meaning that they are more prone to wearing of parts leading to reduced functionality to detect error. Mitigating actions have been put in place whilst the machines are being replaced, including further layers of checks and testing.

1.2 **Two previously reported SIs are still open and currently being investigated:**

SI QI33203: This SI was regarding a patient who received Plasma Exchange (PEX) treatment via a central line in one of the Therapeutic Apheresis (TAS) Units. Due to a number of errors the line wasn't removed, and the patient developed an intracardiac blood clot. We continue to work with the hospitals to have a joint investigation meeting.

SI INC6524 (Never Event): NHS England are facilitating the investigation with all parties involved. NHSBT has been advised to wait for a joint closure report rather than completing its own. Further discussions are ongoing to confirm the appropriate way forward in completing and reporting the investigation to the affected parties.

2. Risk Management

A deep dive into the strategic risk 'Donor and Patient Safety (Board Assurance Framework (BAF) - 01) has been conducted and reviewed at CGC. Since the last deep dive, one risk (TAS-23 - Lack of digital systems) has an increased risk score from 'Judgement Zone' to 'Risk Limit'. The risk is currently being closely monitored and there are several controls and mitigations in place. The project to digitalise TAS managed services will eliminate this risk once implemented. The risk is also being evaluated as the risk of patient/donor harm is not thought to be as high as currently reported. Overall, the strategic risk remains in the judgement zone.

Key strategic elements were discussed including: failure of NHSBT processes to mitigate a known risk (a serious incident); failure to scan for emerging infections; a known complication of

transfusion or transplantation that we cannot currently mitigate; and complications occurring in the wider health system, where NHSBT is responsible for advice and education, resulting in a loss of confidence from our stakeholders and the wider public. The current and planned mitigations of these elements were highlighted, such as horizon scanning, audit and surveillance. The need for a business continuity action plan has been identified on what we would have done if COVID had been a substance of human origin (SoHO) transmissible (i.e., transmit through blood and blood components, organs and haematopoietic stem cells), to mitigate similar risks in the future.

3. Clinical Audit

3.1 Fourteen clinical audits have been planned for 2022/23. Form these, eight have been completed and two are currently in the approval process. The remaining two audits will be carried over to the next year's clinical audit programme.

3.2 The proposal for next year's clinical audit programme was discussed. It was agreed that in addition to the bottom-up approach in developing this programme, a top-down oversight is also required to ensure strategic risk issues and decisions are reflected within the programme. The revised proposal will be reviewed in the next meeting to be considered for approval.

4. The Patient Safety Incident Response Framework (PSIRF)

The PSIRF implementation plan is underway, and several workstreams have been established to move the work forward. Further engagement with NHS England and the Medicines and Healthcare products Regulatory Agency (MHRA) had taken place to provide further clarity and agree on the appropriate approach to investigate incidents that are reportable to the regulator and must meet certain regulatory requirements. NHS England has decided to produce a guidance document, in collaboration with MHRA, to address this issue, which will support NHSBT PSIRF policy.

5. Directorate CARE updates

5.1 The previously reported risk related to workforce challenges in TAS was still in the 'Risk Limit' zone. However, after the Clinical Services CARE meeting, this risk has been updated, and it has now decreased and moved into the 'Judgment Zone'. The risk is being appropriately managed.

5.2 Guidance, barcodes and webinar on the introduction of a new reduced-dose apheresis platelets component (2/3 of the standard dose) have been published and communicated to hospitals. The use of this component will be a temporary measure during a severe shortage, which will increase the platelet supply by approximately 18% and optimise the supply of available platelets for as many patients as possible.

5.3 A pilot trial using buccal swabs to test and recruit potential BBMR donors has gone live. The purpose of this pilot is to assess whether this testing approach would increase the number and diversity of British Bone Marrow Registry (BBMR) donors.

5.4 The OTDT team were made aware of seven reports regarding leaking/discolouration of the organ preservation solution submitted to the supplier (Bridge of Life). It is confirmed that 11 batches are implicated, and three further batches are potentially implicated. The supplier has reported this to the MHRA who are now leading the investigation.

NHSBT is investigating these issues. Teams with quarantined bags have been asked to send them to Colindale for testing. A contract is in place with another manufacturer for the use of an alternative fluid (HTK), and NHSBT advised the National Organ Retrieval Service (NORS) teams to use this product. NHSBT has issued some principles to the supplier about prioritising orders from the retrieval teams and limiting transplant only centres to 24 litres per order. There was no suitable alternative fluid for use in islet preservation. However, NHSBT has identified a new supplier and work is ongoing to source the new preservation solution.

5.5 A recent work on donor consent has highlighted the need to strengthening the governance process and improve transparency in relation to the collection and use of blood components and samples outside of the formal non-clinical issue (NCI) process. A stakeholder group has been formed to collate information on these issues and address the governance gaps.

5.6 A subgroup of Plasma for Medicine (PFM) CARE has been set up in support of managing plasma product pathways in the absence of Parvovirus B19 and hepatitis A virus testing. The subgroup aims to proactively risk assess and mitigate loss of plasma stockpile. Meanwhile, a formal project group has been established within the Testing Development Programme to manage the Parvovirus B19 and hepatitis A virus testing solution, with a recommendation to deliver an 'in-house' solution.

6. Safety Policy Update

6.1 In response to a request from the Chair of SaBTO on Hepatitis E virus (HEV) ongoing work, the TPSG recommended that NHSBT prioritise the pipeline project to resuspend apheresis platelets in Platelet Additive Solution (PAS). Further work is ongoing to understand the costs and implications of this. SaBTO are also reviewing their recommendations.

6.2 It was agreed to continue to use the Alliance of Blood Operators' (ABO) Risk-Based Decision-Making framework for safety policy assessments in NHSBT.