NHS
Blood and Transplant

Board Meeting in Public
Tuesday, 28 November 2023

Title of Report	Clinical Governance Report	**Agenda No.**	4.1.2
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 28th of September 2023. Key issues:

- One new SI was recorded in NHSBT: This was previously reported and concerned a patient receiving a red cell exchange who received air into their circulation (air embolism). This incident has been investigated and closed and all necessary actions taken. The report will be presented at the next meeting.
- Two further SI's occurred outside of the reporting period. This first incident related to a patient who had a transfusion reaction following receiving incompatible blood. NHSBT Consultant advice on the appropriate blood was recorded on paper but was not transcribed into our electronic system Hematos leading to a wrong selection of blood on two occasions. Investigation ongoing. The second incident related to malaria testing whereby the testing machine developed a fault that went unnoticed for an undetermined period of time and unreliable results were issued leading to risk of transmission. Lookback and Investigation ongoing.
- Following the verdict in the case against Lucy Letby NHS England wrote to NHS organisations. CGC discussed immediate actions and agreed; including ensuring a communication to the organisation reiterating the importance of raising concerns and ways in which to do this, circulating the Patient Safety related questions from the NHS staff survey to all staff and ensuring that the board are sighted on concerns raised via relevant reports.
- A deep dive into Principal Risk 01 - Harm to a Donor or Patient was presented. The risk has been further developed with five strategic risks contributing to patient and donor safety identified. The five risks are effectively controlled and tolerated within NHSBT risk appetite. It has been agreed that a clinical risk review group will be formed with subject matter experts from across all clinical directorates to improve the understanding and definition of Principal Risks 01 and 06.

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)

1.1 Summary

There are five open SIs in NHSBT; one new SI recorded in NHSBT during this period **(QI35832)**; two SIs reported outside this reporting period **(QI36772 and QI36303)**; and two previously reported SIs, for which joint closure reports are being finalised (**QI33203 and INC6524)**.

1.2 *New SIs during this reporting period*

1.2.1 Clinical Services **SI QI35832** – This SI was discussed in the previous report. It is in relation to a sickle cell patient who received 10-15 ml air into their circulation (an air embolism) during Red Cell Exchange due to error in setting up the apheresis machine. The patient experienced shortness of breath and chest pain but recovered and completed treatment. The investigation has completed, and the closure report will be submitted to the next CGC meeting.

1.3 *New SIs outside of this reporting period*

1.3.1 Clinical Services **SI QI36772** – This is in relation to a patient who experienced a transfusion reaction following receiving incompatible blood. NHSBT Consultant advice on the appropriate blood was recorded on paper but was not transcribed into our electronic system Hematos leading to a wrong selection of blood in two occasions. The investigation is ongoing, and details will be included in the next report.

1.3.2 Blood Supply **SI QI36303** – this is in relation to a Malaria antibody screen machine (DS2) in Testing was found to be faulty. The device was returning lower than expected 'cut off' values, although positive and negative controls were shown to be returning the correct results.

A lookback exercise, to assess the impact of the fault, identified 20 samples which could be viewed as being close enough to the expected cut off value as warranting retest by MSL. Subsequent analysis of these samples, along with a review of the donor history, has found that three donations have inconclusive results associated with red cell units that have been released to hospitals. The risk of patient or donor harm is very low, however NHSBT has issued products that would not have issued, if its normal processes were followed and hence this incident classed as a SI.

The DS2 affected by this problem has been out of use since the error was detected. The affected hospitals have been asked to review their patients.

1.4 Outstanding SI closure reports:

Due to the involvement of external organisations, there are two SIs closure reports that are still outstanding and currently in the approval process. These are:

1.4.1 Clinical Services **SI QI33203** - This SI is regarding a patient who developed sepsis after receiving Plasma Exchanges (PEX) treatment via a central line in one of the Therapeutic Apheresis Units. The investigation has been completed and the improvement plan is being implemented.

1.4.2 Organ and Tissue Donation and Transplantation (OTDT) **SI INC6524**: NHSBT is still awaiting the external, and NHS England led, closure report regarding this Never Event incident, where unintentional ABO-mismatched solid organ transplantation occurred.

1.5 Closed SIs and shared learning

There are two Blood Supply SIs have been closed:

1.5.1 **SI QI 35370** – This SI is regarding a blood donor who experienced an anaphylactic reaction during blood donation session. It was recommended that further work to be undertaken to ascertain whether Blood donation teams should carry Adrenaline/ EpiPens for use during an anaphylactic reaction at sessions.

1.5.2 **SI QI34949** – This SI is relating to a blood donor who become unwell and received blood transfusion after donation. This incident raised questions on the appropriateness of the use of copper sulphate in the estimation of Haemoglobin on sessions prior blood donation. A working group has been set up to review and make recommendations about future testing of Haemoglobin during blood donation.

2. Verdict in the trial of Lucy Letby

2.1 Olive McGowan presented a paper for discussion on actions associated with the verdict in the trial of Lucy Letby. NHS England have announced an independent inquiry by the Department of Health and Social Care into the events at the Countess of Chester.

NHS leaders and Boards must ensure proper implementation and oversight. Specifically, they must urgently ensure:

1. All staff have easy access to information on how to speak up.
2. Relevant departments, such as Human Resources, and Freedom to Speak Up Guardians are aware of the national Speaking Up Support Scheme and actively refer individuals to the scheme.
3. Approaches or mechanisms are put in place to support those members of staff who may have cultural barriers to speaking up or who are in lower paid roles and may be less confident to do so, and also those who work unsociable hours and may not always be aware of or have access to the policy or processes supporting speaking up. Methods for communicating with staff to build healthy and supporting cultures where everyone feels safe to speak up should also be put in place.
4. Boards seek assurance that staff can speak up with confidence and whistleblowers are treated well.
5. Boards are regularly reporting, reviewing and acting upon available data.

OTDT have circulated the NHS Patient Safety questions to all staff. The report from OTDT will be shared with the CGC and ET for discussion regarding wider utilisation and it was suggested that the safety scorecard be re-developed and re-introduced.

Work should be undertaken with the Freedom to speak up Guardian to develop a confidential report on F2SU activity and themes for review at CGC.

3. Directorate CARE updates

3.1 A national Re-audit of Blood Sample Collection & Labelling was completed. It aimed to assess the quality of practice of labelling transfusion samples; determine whether bedside electronic identification systems had an impact on mislabelling; assess the incidence of Wrong Blood in Tube (WBIT); explore reasons for sample rejection; and provide information for targeted review and improvements. The findings indicated a generally worsening results compared to the 2012

audit results. The National Clinical Audit team will be working with key hospitals to address the issues using human factors and system-based approaches.

3.2 There has been a trend in cases reported regarding delays in hearts for transplantation leaving theatre post retrieval. In all cases, the hearts have been successfully transplanted despite the delay. There is a clear time standard for placing the heart in the ice box following cross clamp, however, there is no clarity regarding the time the heart should leave the theatre. The Clinical Governance team are working with Commissioning and the Statistical Team to review details and timings to ascertain whether this is wider concern.

3.3 A case was brought to CARE for discussion where a kidney patient developed TB. The other kidney went into research and the liver recipient remains well and has been fully assessed by a TB specialist. The team are not able to exclude the possibility of TB being transmitted from the donor. Urine and tissue samples have been sent for further culture analysis, but the results are not expected for three weeks. It is classed as a possible donor derived; however, the laboratory is not able to confirm. The recipient is responding to prolonged treatment.

3.4 The wider review of donor consent/information is underway. The first stage is to agree the requirements for specific consent for non-clinical/research use of donated material. The Non-Clinical Issue (NCI) department has been collating responses from departments across NHSBT, as well as the collection teams to ensure that appropriate governance is in place for the material that they are collecting/providing for non-clinical use. A paper on Montgomery and donor consent has been finalised for presentation to the Executive team.

4. Principal Risk 01 Harm to a Donor Or Patient - Deep Dive

The Bi-annual Deep dive into the principal risk has been undertaken and presented to CGC

4.1 A The Principal risk evaluation has changed since the last deep dive, with operational risk no longer informing the risk score.

4.2 Five strategic risks contributing to patient and donor safety have been identified.

- 4.2.1 CLIN-01 Application of Learning to Clinical Safety
- 4.2.2 CLIN-02 Manual processes & paper-based systems
- 4.2.3 CLIN-03 Transmission of disease by a previously unidentified agent
- 4.2.4 CLIN-04 Known complications of transfusion or transplantation
- 4.2.5 CLIN-05 Advice & Education provided by NHSBT

4.3 The five risk are effectively controlled and tolerated within NHSBT risk appetite.

4.4 Actions to improve the effectiveness of control of two of the risks have been identified; actions identified for the other 3 risks will maintain the effectiveness of the controls but are not anticipated to reduce the overall risk level.

4.5 It has been agreed that a clinical risk review group will be formed with subject matter experts from across all clinical directorates to improve the understanding and definition of Principal Risks 01 and 06. This will add greater assurance that the risks to patient and donor safety are defined and managed effectively.

5. Clinical Audit

5.1 Two further audits have been completed.

- 5.1.1 Re-audit of the national frozen blood bank demonstrated some improvements since the last audit however areas for improvement were noted and an action plan developed accordingly including a redesign of the process for obtaining outcome information from hospitals, which would improve the ability to understand ordering behaviours.

5.1.2 Re-audit of the appropriateness and accuracy of RCI antenatal reporting demonstrated a moderate assurance as evidenced by compliance and adherence to process across much of the criteria for this clinical audit. Actions include investigation of standardising and reducing copy reporting arrangements, provision of clearer explanations for application of charge codes and clarification of coded comments.

6. Data Security, Privacy and Records Management

6.1 NHSBT continues work on becoming compliant with two NHS Digital standards for clinical risk management of IT systems used in healthcare, DCB0129 and DCB060. This prevents NHSBT's email tenant from having 'trusted' status, which requires mitigating actions to enable effective communication with other NHS organisations due to being unable to comply with DCB1596 (the secure email standard for NHS). Gail Miflin reported that Andrew Broderick will undertake the Clinical Safety Officer role in the interim and Andrew outlined the work that was underway to meet the standard.

7. Terms of Reference

7.1 The Committee approved the Terms of Reference for both the Infection Prevention and Control (IPC) Committee and the Therapeutic Product Safety Group which had been updated to reflect current arrangements.