NHS
Blood and Transplant

Board in Public
Tuesday, 25 July 2023

Title of Report	Clinical Governance Report	**Agenda No.**	3.5.2
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 meeting discussed at The Clinical Governance Committee (CGC) held on the 14th of July 2023. Key issues:

- Two new SIs were recorded in NHSBT: one previously reported and concerning a blood donor who became unwell post donation due to pre donation screening issues resulted in donor hospitalisation and requiring blood transfusions; the second SI is regarding a blood donor who experienced an anaphylactic shock potentially attributed to the arm cleansing solution used.
- Another SI occurred outside of this reporting period involving a sickle cell patient who received air into their circulation (air embolism) during Red Cell Exchange due to error in setting up the apheresis machine.
- A key area of concern was raised regarding the interface between NHSBT email and other NHS Trusts' emails where important clinical information is delayed and potentially causing delayed patients' care and/or treatment. It was suggested that NHSBT should investigate this issue to identify any system problems and work with relevant NHS Trusts to address the concerns.
- Unlike other NHS trusts, Our Voice Survey does not include specific questions regarding assessing clinical patient/donor safety and safety culture. The wider NHS Staff Survey contains seven questions relate to patient safety. It was recommended that similar questions be included in Our Voice Survey to obtain a benchmark against the wider NHS. Meanwhile, a proposal to send out a separate survey across relevant directorates is being considered.
- A quinquennial review of the National Liver Offering Scheme (NLOS) has been proposed. The scheme is maintained by NHSBT and aims to reduce the number of patients on the liver transplant waiting list and increase the life expectancy of recipients. It was agreed that a risk assessment should also accompany any proposed changes and to be reviewed and agreed by the committee.
- There has been a significant increase in Safeguarding notifications being reported during the last financial year (78 reports compared to 30 in 2021/22), which correlates with both the introduction of the National Safeguarding Lead and an electronic Safeguarding Notification system. The majority of these (52/78) were related to NHSBT staff with mental health being the most common theme (39/52). Actions are being taken along with People directorate to align safeguarding/mental health policies.

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; two new SIs recorded in NHSBT during this period (**QI34949 and SI QI35370)**; one SI reported outside this reporting period (**QI35832)**; and two previously reported SIs joined closure report are being finalised (**QI33203 and INC6524)**.

1.2 *New SIs during this reporting period*

1.2.1 Blood Supply **SI QI34949** - this SI was previously reported to the Board regarding a blood donor who become unwell after donation and was admitted to hospital with severe anaemia and received blood transfusions. It was suspected that the Hb (haemoglobin) screening might not have been performed appropriately.

The investigation has completed, and the closure report is being finalised. The possible contributary factors identified include: the donor likely had an undetected infection, at the time of the test, which may have impacted the Hb test; and the nurse who performed the Hb screening may have turned the tube slightly during the test, but it is unknown if this movement would be sufficient to affect the result of the test.

Key actions identified include improving the governance process around nurses undertaking copper sulphate testing, and reviewing NHSBT pre-screening blood donation testing approach, including whether copper sulphate testing is still appropriate and safe.

1.2.2 Blood Supply **SI QI35370 –** this is concerning a blood donor; known to have allergy to celery and was carrying an EpiPen (an adrenaline auto-injector for self-administration in emergency treatment of severe allergic reactions). During the donation, the donor experienced an anaphylactic shock (cough, arm swelling and redness, and throat swelling causing difficulty breathing). The donor refused to allow staff to administer adrenaline using their EpiPen. The donor was immediately transferred and treated in the accident and Emergency (A&E) department. Following discharge, the donor had two further recurrences of anaphylaxis and required emergency treatment.

The root cause was a probable unknown allergy to chlorhexidine (donor arm cleansing solution). The investigation found no fault identified with the NHSBT practice. However, the investigation team will review and improve NHSBT's management of anaphylaxis and donor consent process.

1.3 *SI outside of this reporting period*

1.3.1 Clinical Services **SI QI35832** – this 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 root cause identified was an inconsistency in the training received by the two nurses involved in the incident. It was also noted that the manufacturer had already raised a field notice alert (in 2018) about this risk, but this was not issued to the UK.

Actions identified are already being addressed including reviewing and standardising our training, alerting other UK organisation using this machine of the risk, discussing the risk with the manufacturer and informing the MHRA (The Medicines and Healthcare products Regulatory Agency) through the medical device incidents system.

1.4 *Closed SIs and shared learning*

1.4.1 Clinical Services **SI QI33203** joint closure report has been completed and it is currently in the approval process. This SI is regarding a patient who experienced sepsis originated from the central line following Plasma Exchanges (PEX) treatment.

1.4.2 Additionally, NHSBT is still awaiting the external, and NHS England led, closure report regarding the Never Event incident **(INC6524),** where unintentional ABO-mismatched solid organ transplantation occurred. Shared learning will be disseminated once the report is completed and shared.

2. Information Governance

2.1 Data Security Protection Tool Kit (DSPT) audit - The DSPT allows organisations to measure their performance against the National Data Guardian's 10 data security standards. Within these standards, 134 assertions that are grouped into their corresponding areas. This year, NHSBT was audited by the Government Internal Audit Agency (GIAA) against 44 assertions. Despite considerable progress that has been made over the last two years to improve and mature NHSBT's security position, the report resulted in an Unsatisfactory result.

An action plan is being developed to improve NHSBT's DSPT standing for the 2024 submission. Many improvement activities are already progressing to address the deficiencies in the systems and business continuity.

2.2 Uncompliant with NHS Digital standards for clinical risk management - There are two NHS Digital standards for clinical risk management of IT systems used in healthcare that NHSBT is found to be incompliant with; DCB0129 and DCB0160. These standards were incorporated into English law through the Health and Social Care Act 2012. DCB0129 is relevant to the Manufacture of Health IT Systems, whereas DCB0160 is relevant to the Deployment and Use of Health IT Systems.

The standards mandate a Clinical Safety Officer role and describe the documentation and repositories required to demonstrate that all clinical risks associated with the manufacture and use of IT systems are being appropriately managed. Although NHSBT has a documented approach to risk management, it does not currently recognise the Clinical Safety Officer role, nor does it formalise all of the artefacts mandated by the standards. This means that NHSBT is non-compliant and in breach of English law.

This non-compliance is preventing NHSBT's email tenant from being 'trusted' by the system, which in turn forces NHSBT to use several hundred NHSmail accounts to interact effectively with other NHS organisations. However, the level of this use is also in breach of the national tenancy agreement, which stipulates that organisations can operate either the national email tenant, or their own, but not both. NHS Digital had requested that we stop using NHSmail but agreed to pause this request on the basis that NHSBT is working towards trusted status. Compliance with DCB0129 and DCB0160 is the last remaining criterion for NHSBT to achieve this status. A plan is being developed to address compliance with these standards by September 2023.

2.3 A key area of concern was raised regarding the interface between NHSBT email and other NHS Trusts' emails where important clinical information is delayed and potentially causing delayed patients' care and/or treatment. It was suggested that NHSBT should investigate this issue to identify any system problems and work with relevant NHS Trusts to address the concerns.

3. Directorate CARE updates

3.1 Measuring Safety Culture – it was highlighted that unlike other NHS trusts, Our Voice Survey does not include specific questions regarding patient/donor safety and raising concerns regarding clinical safety. Therefore, we do not have a baseline measurement for clinical safety culture within NHSBT. The wider NHS Staff Survey contains seven questions relating to patient safety. It was recommended that the same questions be included in Our Voice Survey to obtain a benchmark against the wider NHS. Currently this is being considered and meanwhile, a proposal to send out a separate survey across relevant directorates to assess clinical safety culture is being discussed.

3.2 Incidental finding policy - It was highlighted that NHSBT does not currently have a policy in relation to incidental findings **-** observations/results of potential clinical significance unexpectedly discovered and unrelated to the purpose of the original test/service **-** as a result of our testing (particularly genetic testing) or services. It was agreed to explore further whether we need a wider NHSBT policy.

3.3 Quinquennial review of the National Liver Offering Scheme (NLOS) - A proposal was submitted for undertaking a quinquennial review of the NLOS. This national scheme was introduced by NHSBT in 2018, providing a new way of matching livers from deceased donors to adult patients on the liver transplant waiting list. The scheme is also maintained by NHSBT and aims to reduce the number of patients on the liver transplant waiting list and increase the life expectancy of recipients. The proposal highlighted various IT changes that are required to enhance the scheme further. It was agreed that a risk assessment should also accompany any proposed changes as a result of the review, which will require review and agreement by the committee.

3.4 Welsh Duty of Candour (DoC) policy – Following changes to the Welsh DoC policy, it is now required from relevant organisations to produce a DoC annual report. It was agreed that NHSBT will provide a DoC annual report for its Welsh patients/donors and submit to Wales NHS. NHSBT will continue to capture DoC reporting within England in its SI annual report and successive policies.

3.5 COVID-19 Lessons Learnt exercise – an organisation wide COVID-19 lessons learnt exercise has started, which is being led by the Business Continuity team. It was agreed that clinical input and insights should be integral to this exercise. In addition to considering what the organisation

should do in case of another pandemic, the committee suggested to also explore how can we work more efficiently and transform the organisation.

4. Safeguarding Annual Report 2022/2023

The Safeguarding Annual Report was discussed, and key highlights included:

4.1 A National Safeguarding Lead (NSL) was appointed in October 2022. The NSL supports staff managing safeguarding concerns and leads on the development and delivery of Safeguarding policies, training and supervision.

4.2 An updated electronic Safeguarding Notification system was launched in December 2022, which provides an instant, confidential method for internal reporting.

4.3 There has been a significant increase in Safeguarding reports, which correlates with both the introduction of the NSL and the electronic Safeguarding Notification system.

4.4 A total of 78 safeguarding cases (previous year = 30) were reported during the past financial year. Of these, 52 were NHSBT staff related cases (previous year = 10).

4.5 The most common theme within staff cases is related to mental health (39/52), followed by concerns relating to domestic abuse (11/52). The NSL has been closely working with HR and the Health and Wellbeing teams to evaluate current practice and resource availability. A quick-reference flowchart to guide colleagues in supporting each other when there are mental health concerns has been created and the safeguarding/mental health policies are being aligned.

4.6 Adult mental health was also the most common reason for notifications received about the public, accounting for 18 out of the 26 reports.

4.7 Overall, there has been significant improvements in the training provision and compliance across NHSBT. The only exception is compliance for Level 3 face-to-face Workshop, which remains low at 54%. This has been impacted by the uplift of the TAS Nurses to complete this level of training. Areas of low compliance is being monitored and addressed at the Safeguarding oversight group (SOG) meetings.