NHS Blood and Transplant

NHSBT Board Meeting

Clinical Governance Report

29th March 2022

Status: Official

1. Summary and Purpose of Paper

This paper summarises the clinical governance issues discussed at the March NHSBT CARE meeting.

1.1 There were no new serious incidents reported during the reporting period. One previously reported SI related to a cornea issued for training purposes without appropriate family consent has now been closed. The second SI also reported previously and related to a death of a patient with a diagnosis of sickle cell disease following a Red Cell Exchange is still open.

1.2 FAIR was successfully implemented for blood and component donation by NHSBT in June 2021. Post-implementation, a range of outcomes have been monitored including stakeholder feedback, mainstream and social media, complaints, epidemiology of infection and ongoing qualitative and virological research. The six month post FAIR implementation assessment showed an overall positive stakeholders and media feedback, low complaints, and an increase in new blood donation registrations. More importantly, there has been no increase in recently acquired infections and no evidence of an increase in higher risk behaviours. The results provide assurance that the implementation was successful. A further report will be prepared 12 months post implementation for presentation to SaBTO.

1.3 The Therapeutic Products Safety Group (TPSG) carried out an annual review of the Alliance of Blood Operators (ABO) Risk-based Framework for Blood Safety and recommended its continuous use in NHSBT.

2. Action Requested

The Board is requested to note the contents of the report and seek assurance where required.

3. Serious Incidents (SIs)

3.1 There were no new serious incidents reported during the reporting period.

3.2 Two previously reported SIs have been closed. One related to a cornea issued for training purposes without appropriate family consent (OTDT-QI28175) and the second one related to a pre-cut cornea which was not acceptable for transplant (OTDT-QI25942).
One SI also reported previously and related to a death of a patient with a diagnosis of sickle cell disease following a Red Cell Exchange is still open (BS-INC83041).

3.3 **Open SI**

3.3.1 Blood Supply: INC83041 - Supply of incompatible blood

A patient with sickle cell disease sadly died within 24 hours of receiving a Red Cell Exchange. The patient was admitted to an NHS hospital with COVID-19 and Pulmonary Embolism. This incident was classified as a 'near miss' event as although incompatible red blood cell units were issued, they were not transfused and therefore the error in itself did not cause patient harm. The cause of death was reported to be related to COVID-19. Due to similarity with two other incidents reported previously and the potential to cause harm, this 'near miss' was investigated as a SI.

Following the completion of RCA related to the incident, a Process Deviation to SOP4146 has been created and gone live to ensure critical substitutions for RBCs are carried out according to a new process (as per new DAT4111). This includes the information around how we are managing critical substitutions for RBC orders and the order amendment process for hospitals. The newly created DAT4111 flow chart provides the correct actions to take in the different substitution scenarios.

A workshop was also held with the PULSE group to look at longer term IT options to support the reduction of errors related to supply of blood which identified several ideas for consideration. A follow up system user workshop took place in January 2022 to discuss the options. A follow up SI call is scheduled in March 2022 to discuss options and close the SI.

3.4 **Closed Serious Incidents and Shared Learning**

3.4.1 OTDT: QI28175 – Cornea issued for training purposes without appropriate family consent

Consent for corneal donation for clinical use was undertaken by the National Referral Centre (NRC) and taken from the Next-of-Kin (NOK). The left cornea was incorrectly issued for Training and Development (T&D) to the Royal College of Ophthalmologists without consent from the NOK. The NOK has been contacted and an apology given.

The Root Cause Analysis (RCA) showed that this SI was regarded as an isolated incident, but further checks have been carried out to review if there were other incidents of this nature. The checks did not identify more incidents of similar nature. Actions put in place have included reviewing of related documents to ensure robust checks are routinely completed, and retraining teams with regards to the requirements for non-clinical tissue to improve knowledge within the department.

3.4.2 OTDT SI QI25942 - Pre-cut cornea was not acceptable for transplant

This incident was reported previously, but now has been closed with shared learning discussed at CARE. Key Points for Shared Learning include:

- Ensuring that the right people/ those involved can attend any RCA scheduling to ensure effective learning
- Ensuring that the necessary checks are in place when orders are received and dispatched to ensure the right product is sent to the right person/ designation
- Ensuring effective documentation of procedures
- Consider international best practice/ benchmarking to ensure best practice is followed

4. Risk Management

4.1 The strategic level (parent) risk: NHSBT-01, Safety and Quality of Clinical Care, currently has 54 recorded functional (child) level risks (compared to 54 in the previous report), with no high scoring, priority 1 risks (risks with a residual score =/>15). The current 'worst child' score is moderate, with a score of 12.

4.2 Teams across all directorates continue to review and update risks and actions. For this reporting period, there are no risks or actions which are overdue for assessment.

5. Clinical Audit

5.1 Clinical Audit schedule for 2022/23 was presented at CARE for approval. The revised schedule will be presented to CARE in April for approval to ensure that the priorities are aligned with Strategic internal audit and based on plan, themes and trends from risks, incidents, complaints, and patient and donor feedback.

5.2 One Blood Supply clinical audit report was approved in February 2022:

Audit of Prescription Writing for Platelet Donation (AUD4054)

Session Nurses in blood donation centres prescribe the appropriate target yield of platelets that can be collected from donors based on pre-set criteria. A triple dose, which could provide three Adult Therapeutic Doses (ATD) for transfusion to patients is considered 'optimal' and the national minimum is two doses. This audit was undertaken to determine if efforts to achieve optimisation are being undertaken as per guidelines.

The audit found that 93% (212/228) of donors were optimised for their procedure. In 95% of donors, the prescription was deemed to be appropriate. The prescription was deemed to be complete in 68% of donations, with 81% of incomplete prescriptions lacking a predicted duration for the procedure. 17% of incomplete prescriptions lacked a rationale, whilst 3% of incomplete prescriptions were unsigned. In cases where the nurse prescription did not correspond with the optimal target yield offered by the apheresis device, a rationale for using a different calculation was not recorded in 32% of donors. This lack of a documented rationale for deviation resulted in an overall moderate risk assessment for the audit.

Actions recommended include disseminating the results to all Donor Centre Nurses with a reminder to document rationale for clinical decisions. E-learning prescription writing training will also be rolled out in 2022.

6. Directorate CARE updates

6.1 Blood Supply- A Clinical Complaints and Compliments multidisciplinary subgroup has been formed, led by the Deputy Chief Nurse. The group will determine the priority area(s) of focus on an ongoing basis, considering factors such as the Blood Supply risk register, current / planned work, opportunities for service improvement, and opportunities to provide better support for staff responding to complaints.

6.2 OTDT - The Quality in Organ Donation (QUOD) biobank – OTDT CARE have agreed that the kidney biopsy size to be increased from 2mm to 3mm of which Kidney Advisory Group (KAG) are supportive. Details of this change will be communicated to all teams, and they will be provided with a training video, new biopsy needles and changed QUOD kit boxes. The new process will be monitored closely.

6.3 Clinical Services- Workforce related concerns have been reported across the directorate attributed to vacancies and staff sickness particularly in Yorkshire and London regions. Cross cover arrangements have been put in place where possible. Recruitment initiatives have remained ongoing to cover the gaps.

7. Information Governance (IG)

Nothing to note during this period.

8. Safety Policy Update

8.1 Infectious Blood Infection (IBI) update

All the IBI related evidence from NHSBT has now been provided and currently hearing evidence regarding plasma fractionation. Additional evidence from DHSC is yet to be heard.

The next steps involve invitation for submissions for recommendations to the IBI Chair and the Legal team. This is an opportunity to suggest any areas that may have been missed and give time for any additional witnesses to be called.
The initial submissions and recommendations are due in June 2022 and will be discussed by the IBI steering Group. The hearing is expected to complete by Christmas with the final report published by the Spring 2023.

8.2 CQC well-led inspection preparedness

A program of work remains ongoing in preparation for the expected CQC inspection of the Well led Domain sometime this year led by Director of Quality. CQC preparedness project group established in October last year undertook a gap analysis and reviewed evidence to support compliance with the Framework.

Additionally, the recommendations from the **Good Governance Institute (GGI) Report** following our governance review have also provided valuable insight for the CQC project team on how we can use available information to support our improvement journey and culture. The project is compiling a “Book of Great” which will include a collection of case studies/stories to support CQC inspection preparations.

The findings from both the CQC gap analysis and recommendations from GGI review have now been consolidated into one overarching action plan overseen by the project and will form the basis for the actions required to ensure we are meeting the Well Led Domain standards.

8.3 Patient / Donor Safety Group

Following on from the Paterson / Cumberledge reports and recommendations shared previously, a patient/donor safety group is being established to strengthen the management of serious incidents and complaints, with a focus on learning and shared learning. The group will also review and maintain oversight of other patient/donor safety related concerns, risks, and alerts. This group will be a subgroup to Corporate CARE. Terms of Reference are in development and will be presented to the next CARE meeting for approval.

8.4 Formal review of FAIR (For the Assessment of Individualised Risk)

FAIR was successfully implemented for blood and component donation by NHSBT in June 2021. Post-implementation, a range of outcomes have been monitored including stakeholder feedback, mainstream and social media, complaints, epidemiology of infection and ongoing qualitative and virological research.

Following implementation, there was a doubling in registrations in the first week of FAIR. In addition, during June there was a 5% increase in people saying that they would be willing to donate blood, with a 10% increase in 15–44-year-olds. Very few complaints were received from donors with overall feedback being positive.

These changes were seen as part of a wider piece of work within NHSBT to improve the diversity of our donor pool. As expected, there has been a small number of new donors who had a previously undiagnosed infection. However, there has been no increase in recently acquired infection and no evidence of an increase in higher risk behaviours. An updated 12-month post-implementation report will be submitted to SaBTO.

8.5 Infection Prevention and Control (IP&C)

The planning for implementation of the new Standards for Healthcare Cleanliness remains ongoing led by IP&C lead Nurse and supported by Facilities and Estates. NHSBT approach to implementation was presented to ET in February 2022.

8.6 Safety Framework Review

The Therapeutic Products Safety Group (TPSG) has recently reviewed the Alliance of Blood Operators (ABO) risk-based framework for Blood Safety Framework. This was a planned annual review to ensure that the Framework was still fit for purpose. Following further considerations, it was agreed that the Framework will continue to be used in NHSBT.

8.7 Occult hepatitis B testing

The SaBTO recommendations on the introduction of anti- Hepatitis B core (anti-HBc) testing to reduce the risk of donations from donors with occult hepatitis B reaching the blood supply, is still awaiting ministerial instructions to implement the changes. A joint Clinical Microbiology and Communications group has met to prepare for the implementation of OBI screening.

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