NHS Blood and Transplant

NHSBT Board

Clinical Governance Report

November 2020

1. Status – Official

2. Executive Summary

Within the reporting period of August and September 2020, one SI was closed, and there were no other open SI's recorded.

Four additional incidents were escalated to directors as requiring formal assessment calls. These are now all being managed as either Major Quality or Near Miss incidents.

Two incidents of probable workplace transmission of COVID-19 have been actively managed involving stake holders to ensure colleague wellbeing and business continuity.

The Advisory Committee for the Safety of Blood, Tissues and Organs (SaBTO) met in October, receiving reports which included For the Assessment of Individualised Risk (FAIR), Occult Hepatitis B working group and Hepatitis E screening updates and revised Patient Consent for Blood Transfusion recommendations.

3. Action Requested

The Board is requested to note the contents of the paper and discuss where relevant.

4. Overview of events in this reporting period

One SI (INC 4791) was closed during the reporting period

Four additional incidents were escalated to directors as requiring formal SI assessment. These are now all being managed as major Quality Incidents:

- ODTD INC 4994: A patient was registered on the transplant waiting list by Centre A for a routine liver on 7th February 2020 and subsequently registered for a routine lung on 13th February 2020. As of 13th February 2020, the patient was registered for a routine lung/liver transplant. On 11th March 2020 it was noted by Hub Operations that they only make offers to a centre for a specific named lung/liver patient if they appear on both the liver and lung Matching Runs (MR) for a donor. The current allocation process does not allow for this to happen. Currently routine listed liver patients appear on the MR as a named patient, but only urgent lung patients are listed as named patients. This patient would not be listed as a named patient on any lung MRs as they were registered as routine.

  The Chair of CTAG was contacted for advice and it was agreed on 12th March 2020 that if the intended recipient appeared on the liver MR, Hub Operations were to offer to the lung-liver patient after all urgent named patient lung offers, but before centre group offering where the patient was at the zonal centre (i.e. first centre on the group offering list). It was also agreed that the patient did not miss any organ offers and should be managed as a near miss.

- OTDT INC 4995 - On 2nd September 2020, following a review of suspended cardiac patients within Hub Operations, it was identified that a patient registered for an urgent heart and routine lungs had been registered on the 18th July 2020 and did not seem to be appearing on any MRs despite donors being blood group compatible and within the height and weight restrictions of the recipient.

The patient was discussed with the Stats department who agreed that the patient was not appearing on MRs and since listing had not appeared on any Urgent Heart MR where they were compatible. The patient was registered as requiring Urgent Heart and Routine Lungs and was active for both organs on the waiting list. The offering scheme is currently being reviewed in collaboration with Digital, Data and Technology Services (DDTS) with updates planned early December 2020.

- OTDT INC 4943 – On the 10th December 2019 consent was obtained for organ donation to proceed from a donation after brain death (DBD) donor, cause of death Intra-Cranial Haemorrhage. Following donor characterisation and organ offering, the kidneys, and pancreas were accepted for transplantation.

  In August 2020 (eight months later), we received a report regarding a likely donor derived malignancy as the recipient of the pancreas islet transplant had developed a melanotic liver cancer. A review of the medical records has found that the medical history of malignant melanoma was clearly documented on the Electronic Offering System (EOS). This melanoma was excised 9 years prior to donation and there was no lymph node involvement. All information available was documented on EOS.

  Sadly, both kidney transplant recipients have died after developing metastatic disease, whilst the pancreas recipient is under the care of the oncology team.

  Due to the complexity of grading and reporting on this type of cancer it has been decided that Malignant melanoma will now be classed as an absolute contra-indication to organ donation. Following this incident, the SaBTO Donor Organ Risk Assessment (DoRA) group are reviewing their guidance regarding the transplantation of organs from donors with cancer or a history of cancer.

- Clinical Services QI 20506 - On Sunday 13th September, a call was taken regarding an urgent referral for plasma exchange (PEX) treatment for a patient who had initially declined treatment but subsequently consented. Sadly, twenty minutes after the second PEX had been completed, the patient suffered several cardiac arrests and despite attempted cardiopulmonary resuscitation, died. Following an incident call and discussions with clinicians at the hospital, it was agreed that the patient had died despite NHSBT's intervention. No error on the part of NHSBT was identified by the investigation.

5. Infected Blood Inquiry Update

Regular meetings are ongoing both internally and with the IBI so any issues regarding processes/procedures etc can be discussed in a constructive manner.

NHSBT continues to provide boxes of documents to the IBI. The IBI are sending documents, from the earlier box deliveries, for review. The rate of provision of documents is slower than originally anticipated and it is likely to take many months before this part of the process is completed.

NHSBT continues to receive Rule 9 Requests for information from the IBI. We understand that a further eight Rule 9 Requests may be sent out to retired staff in the coming months.

The witness hearings recommenced on 22 September 2020 with Lord David Owen giving evidence, followed by a presentation by Counsel to the Inquiry of medical and scientific material relating to the development of knowledge of risk of infection from blood and blood products, subsequent witnesses were previous Haemophilia Centre Directors.

6. Care Quality Commission (CQC)

A joint NHSBT and CQC meeting has been held which included NHSBT Board representation. In light of the pandemic, the CQC are reviewing future inspection plans.

7. Clinical Audit

Previously it has been reported that the planned Clinical Audit programme for 2020/21 has been revised due to COVID-19. We are currently on track to deliver against this plan. Fourteen audits are currently in progress. Three completed audit reports were approved by CARE this month.

8. Risk Management

The strategic risk *NHSBT01: Safety and Quality of Clinical Care* was presented to the ARGC, with consideration being given to the definition and scope of this risk in relation to wider patient outcomes.

Blood Supply are actively monitoring donor adverse events associated with donating Convalescent Plasma. A working group has been set up to monitor these events. There were no concerns in discussion at CARE.

The Infection Prevention and Control (IPC) lead has provided advice and support to the ongoing COVID-19 pandemic. There have been two incidents of probable workplace transmission of COVID-19. Incident teams were convened involving stake holders to ensure colleague wellbeing and business continuity, with Test and Trace support and advice. These incidents have been RIDDOR reported to the Health and Safety Executive and lessons learned from these incidents will be shared with colleagues across NHSBT.

9. Information Governance

Nothing new to report.

10. Safety Policy Update

SaBTO met during October. The following discussions were of note:

- The committee received an update on the For the Assessment of Individualised Risk (FAIR) report, considering whether donor selection policy can move from a population-based donor selection policy to one based on a more individualised risk assessment.
- The committee received updates from the Occult Hepatitis B working group and Hepatitis E screening.
- The revised SaBTO Patient Consent for Blood Transfusion recommendations were approved.

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