NHS
Blood and Transplant

NHSBT Board Meeting
27th May 2021
Clinical Governance Report

Status: Official

Summary and Purpose of Paper

This paper summarises the clinical governance issues discussed at NHSBT CARE meeting held 4th May 2021. There are two new SIs which have been reported to the Board. These both involve different aspects of consent in OTDT and are detailed below.

An anonymous whistle blower to the CQC alleged a poor clinical practice at one of the donor centres. The incident was investigated by the Chief Nurse in Blood Supply and no grounds for concern were found. A response was sent to CQC who were satisfied, with no further actions required.

The 'For the Assessment of Individualised Risk' (FAIR) group changes to eligibility criteria for MSM will be implemented on 14th June.

Significant business critical supplier issues affecting primarily Diagnostic Functions (pipette tips) were reported which have potential for direct clinical impact. Affected departments are liaising directly with procurement and DHSC. Currently there is sufficient supply to maintain our operations, but multiple actions are in progress to address this and minimise clinical risk.

A cluster of donors whose cause of death was a rare cerebral venous sinus thrombosis (CVST) combined with low platelets occurring a few days after vaccination for COVID was identified. Clinical leads for organ donation have been informed of the British Society of Haematology (BSH) guidelines as well as guidance on assessing potential donors. Work on the implications of this syndrome for organ donation and transplantation are being considered and, as always, we will monitor outcomes on those who have received a transplant to determine whether special follow up is required.

Action Requested

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

1. Serious Incidents (SI)

1.1 During February and March 2021, no new Serious Incidents (SIs) were reported. Subsequent to this reporting period, two new SIs have been reported to the Board:

- *OTDT: INC5466 – A heart was retrieved without the donor family's agreement*

A family were approached for deemed consent for donation after brain stem death. Due to the geographical location of the donor hospital and transportation logistics, the family approach and consent conversation with the Specialist Requestor (SR) took place via Zoom. The family were told that the heart may not be suitable for donation and following further discussion the family decided they did not wish for the heart to be donated for heart valves either.

There were three Nurses involved in the donation process; the SR carried out the consent conversation and SNODs 2 and 3 were mobilised to the hospital to facilitate donation. The

SR emailed the consent form to SNOD 2 but there was no verbal handover. SNODs 2 and 3 did not review the consent form. On initial investigation it appeared that the retrieval team only looked at the front sheet of the consent form and did not go through which organs had been consented.

As requested by the SNODs on-site, another member of the Organ Donation Services Team (ODST) contacted the external heart valve bank to assess the suitability of the heart for valves who advised that the pulmonary valve could potentially be used. The abdominal NORS team were mobilised and the heart was retrieved for heart valve donation.

The SR that established consent reviewed DonorPath and noted that the heart had been retrieved. SNOD 2 contacted the donor family to discuss. The family initially gave retrospective consent for the heart to be retrieved for heart valves, however, later the family informed the SNOD that a family member was very distressed and requested that the heart be returned to the body. The heart was repatriated to the donor hospital and returned to the body. The RCA is planned for the end of May 2021.

- *OTDT: INC5477 – Eye tissue was retrieved despite Coroner's restriction to the retrieval of corneas*

Consent was obtained from a potential donor family for solid organ, tissue and eye donation. The patient was subsequently discussed with the Coroner who gave 'restricted' permission to donation stating 'no' to corneas due to the cause of death. The family were informed that eye tissue would not proceed due to the Coroner restriction.

A referral was made to the National Referral Centre (NRC) and the SNOD verbally informed the NRC that the Coroner had stated 'no' to eye donation. It was later noted by the SNOD on DonorPath that an entry had been made stating 'Tissue retrieved – eyes'. It was subsequently confirmed that eye donation had taken place.

Initial investigation has confirmed that a verbal discussion between the SNOD and Tissue and Eye Services (TES) regarding 'restricted' permission was not noted on the documentation. A paper form is used to aid the NRC in acquiring all relevant information from DonorPath succinctly. The conversation had by the SNOD informing that there was no permission from the Coroner for eye tissue should have been noted on this form, but this did not occur.

The Coroner has been contacted and eye retrieval did not impact on the post-mortem findings. The family have been contacted and have requested that the eye tissue is returned to the body which was facilitated. A full RCA is to be arranged.

2. Care Quality Commission (CQC) update

2.1 The CQC are currently reviewing what is within or out of registration based on the review of 2014 regulations. The outcome of this review may have some implication on NHSBT in terms of what is inspected. This is also being discussed with the DHSC.

2.2 An anonymous whistle blower to the CQC alleged a poor clinical practice at one of the donor centres. The incident was investigated by the Chief Nurse in Blood Supply and no grounds for concern or poor practice were found. A response was sent to CQC who were satisfied, and no further actions were required.

3. Risk Management

3.1 The strategic level (parent) risk: NHSBT-01, Safety and Quality of Clinical Care, currently has 48 recorded functional (child) level risks, with no high scoring, priority 1 risks (risks with a residual score =/>15). The current 'worst child' score is moderate, with a score of 10. Since the previous risk report, no new risks have been recorded and one risk has been closed.

4. Clinical Governance

4.1 The new Donation Safety Check and Consent Information Leaflets are being finalised ready for the implementation of the 'For the Assessment of Individualised Risk' (FAIR) group changes on 14th June.

4.2 Following a recent independent review, a project is underway, led by Donor Experience to improve the management of the donor complaint process. It will focus on developing staff to effectively manage dissatisfied donors, and it will be supported by a new complaints management system.

4.3 Significant business critical supplier and procurement issues affecting primarily Diagnostic Functions (pipette tips) were reported which have potential for direct clinical impact. All affected departments (IBGRL and CMT) are liaising directly with procurement and DHSC. Currently there is sufficient supply to maintain our operations, but multiple actions are in progress to help address this and to minimise future clinical risk.

4.4 A draft policy 'NHSBT Divergent Outcomes Policy' prepared in consultation with, and supported by, the Royal College of Ophthalmologists was submitted and discussed. The aim of this paper is to outline the response when underperformance is suspected or divergent outcomes for corneal transplantation have been indicated by NHSBT. The paper describes the methods used to identify potential surgeon outliers, as well as detailing the subsequent actions following a signal of divergence including, where necessary, suggesting further clinical or analytical support.

4.5 A cluster of donors whose cause of death was a rare cerebral venous sinus thrombosis (CVST) combined with low platelets occurring a few days after vaccination for COVID. An urgent group has been set up by the British Society of Haematology (BSH) to develop guidelines for this group of patients/donors. The recommendation is not to give heparin or platelet therapy to this group of patients. Clinical leads for organ donation in all major ICU departments in the UK have been informed of these guidelines. There is now a need to examine detailed information from donors, testing for potential recipients or those who have received a transplant to monitor outcomes and to decide whether special follow up is required. Work is ongoing in this area and the Vaccine induced thrombocytopenia and thrombosis (VITTs) guidance has been updated and will continue to be updated based on emerging information.

5. Clinical Audit

5.1 An audit of the effectiveness of convalescent plasma donors has been removed from the programme as no longer applicable, leaving a total of twelve audits due for completion within 2020/21.

6. Information Governance (IG)

6.1 The IG team have begun a dedicated project to streamline a variety of processes and procedures including the Freedom of Information, Subject Access Request, and Data Privacy Impact Assessment processes. This involves working closely with Customer Service and Corporate Communications Teams as well as relevant lines of business

to ensure that each process is customer-centric while maintaining adherence to compliance obligations.

6.2 The Information Commissioner's Office (ICO) closed, in April 2021, the ongoing complaint regarding a FOI request for ‘all internal NHS guidelines currently in force, relating to the Organ Donation (Deemed Consent) Act 2019”.

7. Safety and Policy

7.1 A collaboration between SaBTO and NHSBT has led to the development of a rapid reference guide for transplant clinicians to help decision-making when considering the use of organs for transplantation from donors with infection, malignancy and other potentially transmissible diseases. This is a web app hosted on the ODT website: https://www.odt.nhs.uk/transplantation/tools-policies-and-guidance/donor-transmissible-disease-reference-guide/