

NHSBT Board

**Clinical Governance Report
01 February 2017 – 31 March 2017**

1. Status – Public

2. Executive Summary

Two previously reported Serious Incidents (SI) occurred during this reporting period

- ODT INC2293: Information communicated to Transplant Centre incident resulting in halted liver transplant surgery. The investigation into this incident is ongoing. A root cause analysis (RCA) has taken place.
- ODT Removal of two kidney grafts following histology results in donor indicating lymphoma. This has been reported to the HTA. An RCA has taken place.

Subsequent to this reporting period the following two further SIs have been declared:

- QI2669/ ODT INC 2432: Diagnostic and Therapeutic Service (DTS) Tissue and Eye Services (TES) and ODT. Tissue removed after withdrawal of consent. This incident has been reported to the Human Tissue Authority (HTA). On the 12th April 2017 consent was obtained for donation after circulatory death (DCD) and for heart valve retrieval. Unfortunately, the patient did not die within the time frame to allow organ donation to proceed and the patient's husband then changed his mind and withdrew consent for heart valve donation. This was documented in the medical notes and on, but there is no documented record of this decision having been communicated and received by TES. On the 15th April 2017 the National Referral Centre (NRC) contacted the hospital to ascertain if the patient had died and the tissue retrieval team attended the hospital and retrieved the heart for valves. Four days later the SNOD was informed by the NRC that the heart valves failed processing and were not suitable for transplantation. At this point it was recognised that the family had withdrawn consent but the retrieval had proceeded.
- QI2408: DTS. The death of a fetus in a mother with anti-Kell red cell antibodies. A sample for non-invasive fetal K genotyping was sent by a hospital from a woman who was 20 weeks pregnant for testing by IBGRL, the results predicted that the fetus was K antigen negative and requested a repeat sample at 28 weeks. The baby subsequently died prior to NHSBT receiving the repeat sample. Genotyping of post mortem fetal genetic material has confirmed the fetus to be K positive. The original assay was performed correctly, the false negative rate for this assay is approximately 1:100-1:1000 cases. National guidance is not clear that the baby should continue to be monitored until a second test confirms negativity. Monitoring was not undertaken. The AMD for DTS has met with clinicians at the Trust and a joint meeting with the family will be arranged. This was declared an SI on reputational grounds.

3. Action Requested

The Board is asked to note the contents of the paper.

4. Serious Incidents (SI)

- 4.1.1 ODT INC2293: Information communicated to the transplant team resulting in aborted liver transplant surgery. On the 10th February 2017, a donor proceeded to organ donation after circulatory death (DCD). The organs were offered for transplant however only the heart was transplanted. The lungs were left insitu. Following completion of the retrieval, a lung nodule was noted by the abdominal National Organ

Retrieval Service (NORS) team and a biopsy was sent of the nodule for frozen section histology at the NORS base. The liver was accepted for transplant. Prior to the verbal histopathology results, the recipient centre point of contact raised queries that they had not been informed of the concerns around the lung nodule and subsequent frozen section. At the point that this concern was raised, the patient due to receive the liver transplant had been transferred to theatres and their procedure commenced. The preliminary result on the night was reported as a possible lung carcinoma. Following the verbal results the procedure was halted prior to hepatectomy. The heart was accepted and transplanted and the formal histology showed no malignancy. The responsibility for communicating, and documenting, this information lies primarily with the SNOD and NHSBT. The member of staff has recognised that, on this occasion processes were not correctly followed. All SNODs have been reminded of this responsibility. The incident has been reported to the HTA. The RCA has been completed.

- 4.2 ODT INC 2306: Removal of two kidney grafts following histology results in donor indicating lymphoma. On the 14th February 2017 two kidneys were accepted for transplantation. On preparation of the kidneys, by the Consultant Renal Transplant Surgeon, an enlarged lymph node was noted on the left kidney and sent for histology. The kidneys were implanted into two recipients and the preliminary histology results received 48 hours later. The histology showed a low-grade follicular lymphoma in the lymph node and infiltrating lymphoma cells within the kidneys. Following discussion with both recipients at the transplant centre the two recipients elected to have their grafts removed and received prophylactic treatment. This has been reported to the HTA. The investigation is ongoing and a RCA has been completed.

Two further incidents were discussed at CARE. Both occurred outside the reporting period for the report. Following the CARE meeting the incidents were classified as SIs.

- 4.3 QI266: TES/ODT. Tissue removed after withdrawal of consent. On the 12th April 2017 consent was obtained for donation after circulatory death (DCD). Consent was also obtained by the Specialist Nurse Organ Donation (SNOD) for heart valve retrieval. Unfortunately, the patient did not die within the time frame to allow organ donation to proceed. Following this the SNOD discussed again the option of heart valve donation with the family and at this point the patient's husband changed his mind and withdrew consent. This was documented in the medical notes and on donorpath as per ODT processes, but there is no documented record of this decision having been communicated and received by TES. On the 15th April 2017 the National Referral Centre (NRC) contacted the hospital to ascertain if the patient had died. They were informed they had and the tissue retrieval team attended the hospital and retrieved the heart for valves. On the 19th April the SNOD was informed by the NRC that the heart valves failed processing and were not suitable for transplantation. At this point it was noted that the family had stated they did not want to proceed with heart valve donation however the retrieval had proceeded. It has been agreed that this incident will be managed jointly by TES and ODT and has been reported to the HTA.
- 4.4 QI2408: DTS (IBGRL) The death of a fetus in a mother with anti-Kell red cell antibodies. A sample for non-invasive fetal K genotyping was sent by a hospital from a woman who was 20 weeks pregnant for testing by IBGRL, the results predicted that the fetus was K antigen negative and requested a repeat sample at 28 weeks. The baby subsequently died prior to NHSBT receiving the repeat sample. Genotyping of post mortem fetal genetic material has confirmed the fetus to be K positive. The original assay was performed correctly, the false negative rate for this assay is approximately 1:100-1:1000 cases. National guidance is not clear that the baby

should continue to be monitored until a second test confirms negativity. Monitoring was not undertaken. The AMD for DTS has met with clinicians at the Trust and a joint meeting with the family will be arranged. This was declared an SI on reputational grounds.

- 4.5 The annual SI report was presented to CARE. Five incidents, classified as SIs were reported in 2016/17. Four out of the five SIs are now closed. The Annual SI report will be presented to the Governance and Assurance Committee (GAC) in June 2017. The GAC will then identify a SI from those that has been closed for further scrutiny.

5. Clinical risks

There are 49 risks on the corporate risk register for which the dominant risk is clinical. One new clinical risk has been added by ODT in relation to Hepatitis E (HEV) testing. Scotland has commenced HEV testing of all blood and organ donors. An NHSBT cross directorate working group to implement the SaBTO requirements for HEV testing is in progress.

6. Complaints and Commendations

There have been no serious clinical complaints specifically reported to CARE during February and March.

The Patient Experience Survey in Therapeutic Apheresis Services demonstrated positive results from all locations. Top box scores were given of 93%. The target for 2017/18 is 90%. The report will be circulated to key stakeholders.

7. Blood Supply (BS)

7.1 A total of ten Serious Adverse Events of Donation (SAEDs) were recorded in February and March 2017. Three donors suffered a fracture, five donors reported problems related to the venepuncture lasting more than 12 months, one donor was admitted to hospital within 24 hours and one donor had an 'other' event. This patient was admitted to hospital 9 days after the donation with staphylococcal septicaemia. No corrective actions were identified at the RCAs as it was found that all NHSBT processes had been followed correctly. It was also noted that there has been an increase from 33 to 53 annually in the number of SAEDs. BS CARE will consider further analysis of trends and categorisation over the past three year period and report to CARE.

7.2 BS CARE will consider the impact of consent for research in Blood Donation from the updated HTA Codes of Practice. Although Blood donation for therapeutic purposes is not covered by this, the HTA codes apply to consent for blood donated for research purposes.

8. Diagnostic and Therapeutic Services (DTS)

8.1 INC 67183: The Associate Medical Director (DTS) previously provided a report on behalf of NHSBT for a coroner's inquest relating to a patient with sickle cell disease who died in Sheffield. Additional red cell antibodies identified on the day a red cell exchange was required made obtaining compatible blood a challenge. A nurse and medical consultant from NHSBT gave evidence at inquest in April 2017. Obtaining compatible blood was a challenge, however there does not appear to have been any error on the part of NHSBT. The coroner will present a summary report on 17th May in the presence of family members, representatives from NHSBT and from the Trust.

- 8.2 Two incidents relating to two fetal deaths where the mothers of the babies had anti-K red cell antibodies- International Blood Group Reference Laboratory (IBGRL) and Red Cell Immunohaematology (RCI). One has been declared an SI as detailed above. In the other (Q12316) where a fetus died the results of the test were reported correctly and there appears to have been no error on NHSBT's part. The report was received in a timely manner but not acted on by medical staff at the Trust. The baby developed severe anaemia and died.

9.0 Organ Donation and Transplantation (ODT)

Three incidents in ODT are being managed as SIs (as detailed in section 4).

Two further ODT incidents of note:

- ODT INC 2278: On the 2 February 2017, the Organ Donor Register team were alerted to an incident relating to Open Exeter and the Organ Donor Register (ODR). Unfortunately, the system contained a software error meaning that when someone ticks all of the six individual organ and tissue boxes, the record is incorrectly sent to the ODR as 'all organs and tissues'. This indicates the individual has stated yes to any organs and tissues rather than just yes for the individual organs and tissue ticked. The Organ Donor Register team and NHS Digital met on 16th February 2017 and a series of actions were agreed. The script that the statistics team are creating to support this is complex and has taken longer to construct than the original estimate.
- ODT INC 2391: It was reported that a change to the banner on the Organ Donor Register webpage was requested by the NHSBT digital team (NHSBT Comms Directorate) and subsequently delivered by NHSBT's third party provider. The ODR team were unaware of the change and therefore appropriate test scripts were not completed to confirm the safety of the change. The website amendment unintentionally created a fault with the address look-up application in the ODR Web forms. The fault resulted in the corruption of house numbers provided by registrations made through the English and Welsh ODR Website forms. A fix has now been deployed. This has been reported as an information governance incident to the Information Commissioner's Office as a level 2 incident.

10. Information Governance (IG)

- 10.1 NHSBT's 2017 submission of the NHS IG Toolkit was completed and submitted as required by the 31st March 2017. The overall rating was 'Satisfactory' (green) with a percentage score of 82%. Price Waterhouse Cooper (PwC) Audit of the IG tool kit was received in May 2017 with a rating of moderate assurance.
- 10.2 Big Data Projects are in the process of approval. These projects are where NHSBT is working in partnership with commercial sector organisations on big data trials/experiments to test whether their data analytics and machine learning algorithms can provide insights for NHSBT.

11. Clinical Audit

Two clinical audit reports were discussed and approved at directorate CARE groups, there are currently a total of 29 clinical audits in progress.

12. Clinical Claims

Changes to the Discount Rate. The Lord Chancellor reduced the discount rate to -0.75%. This new rate came into force on 20 March 2017. The discount rate calibrates the level of discount to be applied so it reflects the level of return that an individual can reasonably expect to achieve through investment of their damages fund. This will significantly increase the value of claims.

13. Nursing Leadership Team

There were two safeguarding cases reported via the ODR, both have been managed and closed.

14. Safety policy matters

- 14.1 The SaBTO Donor Selection working group recommendations are expected be approved at the SaBTO June 2017 meeting. These will be presented to health ministers following the general election. The NHSBT communications team have been working closely with SaBTO.
- 14.2 JPAC approved the use of first time donors for the production of cryoprecipitate and fresh frozen plasma (FFP) as the additional risk of transmission of blood-borne infections was assessed as very small. This change will not apply to products supplied to neonates and infants.

Authors

Ella Poppitt
AD Governance and Clinical Effectiveness
Gary Mallinson, Safety Co-ordinator

Responsible Director

Gail Miflin
Medical and Research Director.