NHS Blood and Transplant

NHSBT Board

Clinical Governance Report
01 December 2016 – 31st January 2017

1. Status – Public

2. Executive Summary

- Both previously reported Serious Incidents (SI) (INC1840, 71660) have been closed.
- Diagnostic and Therapeutic Services - Retrieval of heart tissue which was required for hospital post mortem (INC 1726). The hospital post-mortem was delayed and did not have access to the heart. Consent for tissue donation was collected by the National Referral Centre and this has been confirmed from the recorded conversation. The Trust are investigating this incident as serious and NHSBT are working with the Trust.
- As previoiusly noted the Advisory Committee on the Safety of Blood Tissues and Organs (SaBTO) recommended Hepatitis E virus (HEV) screening of all blood donations and donors of stem cells, tissues and organs. NHSBT will commence screening of all blood donations from mid-April 2017. Work on the implementation plan for stem cells, tissue and organs is ongoing.
- As requested at the January 2017 Board meeting, support for staff dealing with legal claims is detailed in section 13.

Subsequent to this reporting period the following incidents have occurred.

- A near miss Information Governance incident was escalated (INC 69937) regarding the transfer of microfilmed Blood Donor Health Check forms. All files have now been located confirming no loss of data.
- INC 2278 On the 2 February 2017 the Organ Donor Register (ODR) team were alerted to an error in reporting preferences on the ODR. The error was within the NHS Digital service, not the ODR. The ODR team and NHS Digital met on 16th February 2017, immediate action to stop this error occurring was taken and a series of actions have been agreed to rectify this.
- Serious incident INC2293: ODT - Information communicated to Transplant Centre. This incident resulted in a patient having a liver transplant process halted when anaesthetised in theatre.
- Serious incident INC 2306 ODT - Kidney graft removal following lymphoma diagnosis in donor. This has resulted in two patients having their kidney transplants removed and requiring prophylactic treatment.

3. Action Requested

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

4. Serious Incidents (SI)

The two previously reported Serious Incidents have been closed:

4.1 ODT Cytomegalovirus (CMV) incident (INC1840). A patient died from CMV disease after receiving an organ where the CMV status was reported incorrectly. The inquest is scheduled for May 2017. The joint PHE & NHSBT meeting to look at joint learning from the incident was held on the 9th March 2017. A report detailing this is in preparation. All NHSBT actions have been completed and the incident closed.

4.2 Manufacturing & Logistics National Transfusion Microbiology Reference laboratory (NTMRL) incident (INC 71660). The testing of blood samples occurred outside the manufacturers' recommended timeframes and storage conditions. The validation and testing of samples has been completed, all validation results from samples with the longer storage times were reliable and correct. The incident has been closed.

Although outside the formal timeframe of the report two other incidents in ODT have been classified as SIs.

4.3 INC2293: ODT - Information communicated to Transplant Centre. On the 10th February 2017, a donor proceeded to organ donation after circulatory death (DCD). The liver, kidneys, pancreas, lungs, and heart were offered for transplant. The kidneys, liver and heart were initially accepted however only the heart was subsequently transplanted. The lungs were left insitu following assessment. Following completion of the retrieval, a lung nodule was noted by the abdominal team and a biopsy of the nodule for frozen section sent for histology. Both kidneys were subsequently declined due to verbal biopsy report of the nodule suggesting a possible carcinoma. The liver was accepted for transplantation. Prior to the verbal histopathology results, the recipient coordinator 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 liver recipient had been transferred to theatres and their procedure commenced. 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, that processes were not correctly followed. All SNODs have been reminded of this responsibility. The incident has been reported to the HTA.

4.4 INC 2306: ODT - Kidney graft removal following lymphoma diagnosis in donor. On the 17th February 2017, two kidneys were accepted for transplantation, on the preparation of the kidneys an enlarged lymph node was found on the left kidney. Full clinical information was given to two centres who declined the organs. It is thought that full information was not given to a third centre who accepted and transplanted both organs into two recipients. There were several conversations between the transplant centre and our teams and between the retrieval and implanting surgeons. Initial analysis suggests that full details were transmitted with the first two offers to two centres but not on the third occasion two pieces of information were omitted. The accepting surgeon states that the decision would have been different had this information been included. The lymph node was sent for histology; these histology results were received 48 hours later and showed a low-grade follicular lymphoma in the lymph node and infiltrating lymphoma cells within the kidney. Both recipients of the kidneys elected to have the grafts removed and will need prophylactic treatment. ODT are conducting a full investigation, information to date suggests that there four opportunities to prevent this incident including making the diagnosis in the Trust prior to the donation procedure starting. A date for the RCA is being set and will address these. This has been reported to the HTA as two Serious Adverse Reactions (SARs).

5. Donor adverse events/reactions

Three Serious Adverse Events of Donation (SAEDs) were recorded in December 2016 and six in January 2017.

6. Clinical risks

There are 49 risks on the corporate risk register for which the dominant risk is clinical. One new risk has been added in ODT as detailed in paragraph 10.3

7. Complaints and Commendations

DTS: Histocompatibility and Immunogenetics (H&I) Voice of the Customer report. Customer Services undertook a bespoke survey for key H&I haematopoietic stem cell transplant customers whose feedback is not captured through the quarterly NHSBT customer satisfaction survey. All customers were positive with 100% customer satisfaction.

8. Blood supply

One event was reported to the Serious Adverse Blood Reactions and Events (SABRE) system in December 2016 and one in January 2017.

- Hospital Services labeling error at validation (INC 876). The wrong group label had been attached to the wrong platelet pack. No harm occurred; the unit was identified within NHSBT and not issued. This was due to operator error.
- Blood Donation (INC1439). Confusion between Dominican Republic and Dominica led to incorrect acceptance and transfusion of a donation without a malaria test. This was subsequently negative. The documentation of implicated countries has been clarified.

There were no transfusion transmitted infections confirmed during this period.

9. Diagnostic and Therapeutic Services (DTS)

9.1 Retrieval of heart tissue which was subsequently required for a hospital post mortem (INC 1726). Consent for tissue donation was taken via telephone by National Referral Centre (NRC) staff and full tissue retrieval followed. Our processes confirm that no coroner's post-mortem is required. The possibility of a hospital post mortem (PM) was discussed with family at the time of death by local hospital staff however their consent for this was not taken at that time. Subsequently the family attended the hospital to give consent for hospital PM and the family were informed that the heart had been retrieved for tissue donation. The family stated they had not consented for heart tissue retrieval. Recordings of the consent conversation with the family have been reviewed by the NRC and it is confirmed that appropriate consent had been received. The local NHS Trust have raised an incident which is being investigated, NHSBT is contributing to the investigation.

9.2 INC 67183: The Associate Medical Director (DTS) has 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 an urgent red cell exchange was required made obtaining compatible blood a challenge. There was no error on the part of NHSBT. NHSBT is working with the local Trust.

10.0 Organ Donation and Transplantation (ODT)

10.1 Three additional incidents in ODT have been considered as serious incidents (SI). Two have been classified as SI (detailed in section 4 above) and one detailed below. All three incidents were reported in February outside the time period for this report.

10.2 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). In 2010 the Open Exeter system was introduced at GP practices in England. Unfortunately, the system contained a software error which has recently been discovered. The error means that when someone ticks 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 difference between these is the use of tissues (other than corneas), small bowel, or any future organs (e.g. stomach); therefore this preference is being sent to, and recorded, incorrectly on the ODR. The 'any organs and tissue' button is functioning correctly. The Organ Donor Register team and NHS Digital met on 16th February 2017, immediate action to prevent the error occurring further was taken and a series of longer team actions agreed to rectify the problem.

10.3 Following the DH advice on not collection organs from women of childbearing age known to be pregnant, ODT has sought advice from Leading Counsel and following receipt of this have written to the DH, their response is awaited. In addition, the National Clinical Lead for Organ Donation in ODT is working with the Royal Colleges to progress the issue of routine pregnancy testing in all patients referred as organ donors. However, at present the risk remains that it may be discovered at the commencement of the organ retrieval procedure that a potential donor is pregnant. This risk has been added to the risk register

11. Information Governance (IG)

11.1 Four proposals of planned pilot studies using 'big data' have been agreed. These will use machine learning to interrogate anonymised patient and donor data. The aim of this work is to show proof-of-principle for a big data/machine learning approach to address key operational challenges in key areas - Donor Behaviour, Matching & Allocation, Genomics and Hospital Integration. For matching & allocation, anonymised data from the UK Transplant Registry will be used under the consent given by all patients who join the transplant waiting list. The donor behaviour and genomics projects will use anonymised NHSBT donor data under consent obtained when donors donate blood. Finally, the hospital integration project will use anonymised patient data from three NHS Trusts once permission is obtained from the Caldicott Guardian at each Trust. CARE approved in principle the release of data, which are in the process of being put together.

11.2 A near miss incident was escalated after the reporting period but should be noted. (INC 69937). This involved the transfer of microfilmed Blood Donor Health Check forms. In September 2014, an NHSBT quality audit was performed prior to the transfer of microfiche data files between storage suppliers. NHSBT confirmed all films were present. A change control was completed and closed at the time of records transfer. A further audit at the new supplier was completed some months later which identified 100 potential gaps in the sequential filing system used. All files have been located confirming no loss of data. An investigation and incident report is being written. There are lessons to be learned about our processes for records management and the classification and escalation of the incident.

12. Clinical Audit

The clinical audit workplans for 17/18 were approved at the directorate CARE groups. There are currently 23 clinical audits in progress.

13. Clinical Claims

13.1 An improved process for clinical claims has been approved by the Executive Team, which continues the principle of allowing reasonable compensation for injuries caused by donation but which also incorporates an early triage process with a set of criteria that signal the potential for higher value claims. If met, this will trigger early referral of the case to the NHS Litigation Authority (NHSLA).

13.2 Legal training has been provided by Weightmans to senior clinical staff on the process for clinical claims. This included an introduction to claims, the role of the NHSLA, claims history and patient safety, duty of candour and inquests. Staff involved in legal processes eg being required to attend inquests for a claim or coroner's investigation are supported by the NHSBT seconded solicitor. Weightmans have produced an inquest DVD which staff can view prior to attending inquest. In addition, bespoke briefings and support are provided to NHSBT staff prior to any inquest attendance.

13.3 There are at present two clinical blood donor claims of note that are being managed through the NHSLA. One is proceeding to court and is due to settle and another will proceed later in 2017. The latter is notable in that it is potentially first blood donation case to be reported to the NHSLA where breach of duty remains to be determined.

14. Safety policy matters

14.1 The Frepp™ arm cleansing trial in Blood Donation concluded in late January, The Therapeutic Products Safety Group (TPSG) has approved its use on safety grounds.

14.2 Implementation of universal HEV screening of blood will commence on 10th April 2017. Work on the implementation plan for stem cells, tissue and organs is ongoing.

14.3 Human T lymphotrophic virus (HTLV) testing is now performed only on donations from new donors and those donations being used to produce non-leucodepleted components (granulocytes). For this latter product the results may not be known prior to transfusion but will retrospectively be tested. The clinical need for these components usually far outweighs any risk of a transmissible HTLV infection and where required they will be issued through our established risk based decision and concessionary issue process.

14.4 There has not been a SaBTO meeting since the last report. The SaBTO Donor Selection working group is expected to report in June 2017. The working group recommendations, subject to SaBTO approval, will be presented to health ministers before the end of the current parliamentary session.

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