NHS Blood and Transplant (NHSBT) Board
30 November 2017

Clinical Governance Report
01 August – 30th September 2017

1. Status – Public

2. Executive Summary

- There were no new Serious Incidents (SI) in the reporting period of this report. However, since the previous report there has been one new SI in Organ Donation and Transplantation (ODT), ODT-INC-2273. Following the brain stem death of an adult donor, five patients received organs from the deceased; two of those received a split liver. On the 4 October 2017, ODT were made aware of the death of the adult lung recipient due to suspected disseminated Herpes Simplex Virus (HSV) infection. A child liver recipient has also died, although this is suspected to be due to the underlying metabolic condition. Immediate action was taken to inform all the relevant transplant centres to commence the other three recipients on anti-viral treatment. This SI has been reported to the Human Tissue Authority (HTA) as a serious adverse event.

- There was a major Quality Incident (QI) in Manufacturing and Logistics (M&L) in Manchester. It was identified that around13,000 donations were at risk of having exceeded the acceptable time limit before being transferred to a temperature controlled environment. A review of the microbiological and component quality implications was undertaken and established that clinical risk was very low and these units did not require a recall. A substantial number of these units had already been transfused and there had been no unexpected reports or incidents.

- A Coroner's inquest will be held in Manchester on 11 December 17 into the death of a patient with sickle cell disease.

- In the previous report an identified issue in complying with the new HTA Code of Practice (CoP) was raised. Changes continue to be made within both Blood Donation (BD) and Non-Clinical Issue (NCI) to accommodate the changes to the CoP. The Executive Team (ET) has been briefed and agreed the approach. A group has been formed to undertake the gap analysis and will now implement the changes required to address the shortfalls identified. The HTA has been briefed on the issues identified and NHSBT are keeping them informed of progress.

- A gap analysis to the requirements of GDPR has been undertaken and is reported in a separate paper to this meeting.

3. Action Requested

The Board is asked to:

- Note the contents of the paper.
- Approve any recommendations/actions outlined in the paper.

4. Serious Incidents (SI)

ODT INC 2273: Since the previous report there has been one new SI in ODT, albeit it subsequent to this reporting period. Following the brain stem death of an adult donor, five patients received organs from the deceased; two of those received a split liver. On the 4 October 2017, ODT were made aware of the death of the adult lung recipient due to suspected disseminated Herpes Simplex Virus (HSV) infection. A child liver recipient also died, this is suspected to be due to the underlying metabolic condition. Immediate action was taken to inform all the relevant transplant centres to commence the other three recipients on anti-viral treatment. This SI has been reported to the HTA as a serious adverse event.

Updates on SIs previously reported:

- ODT INC2293: Information communicated to the transplant team resulting in halted liver transplant surgery. The final report has been written and the SI is now closed. ODT Directorate Clinical Audit, Risk, and Effectiveness (CARE) group will manage completion of the action plan.
- ODT INC 2306: ODT Removal of two kidney grafts following histology results in donor indicating lymphoma. This SI remains open, but will be closed once the haematology review report is completed.
- ODT INC 2495: Organ donation in Wales with subsequent known registered ODR opt out. The final report has been written and the SI is now closed.
- DTS QI4492, the removal of ocular tissue in error without consent. A multi-organisation closure meeting has been arranged for 15 November 2017 and the final report will be produced after the closure meeting.

5. Risk

There are currently 28 risks within the risk management system which have the risk impact area recorded as clinical; this is an increase of one from the previous reporting period.

The new risk added was QA-025: There is a risk that NHSBT IT systems and other data recording systems are not compliant with the Medicines and Healthcare Products Regulatory Agency (MHRA) expectations for data integrity. Causes for this risk are due to some systems having generic logins that do not allow attributable changes to be recorded.

6. Complaints and Commendations

No complaints or commendations were reported to Blood Supply (BS) CARE.

In Diagnostic and Therapeutic Services (DTS) there was a continuing decreasing trend in complaints in Red Cell Immunohaematology (RCI) – reagents. RCI, Histocompatibility and Immunogenetics (H&I), and Customer Services all experienced a slight increase in complaints in August. During the reporting period compliments were received across most services in DTS.

Since the start of the 2017/18 ODT have received a total of 18 complaints. ODT continue to receive positive feedback from donating families. A total of 55 compliments have been received in 2017/18 to date regarding care provided by the Senior Nurses Organ-Donation (SNODs).

7. Blood Supply (BS)

There was a major QI in M&L in Manchester. It was identified that up to 13,000 donations were at risk of having exceeded the acceptable time limit before being transferred to a temperature controlled environment. The proportion of these units that were affected was felt to be low, but could not be accurately quantified. A careful review of the microbiological and quality implications was undertaken and established that clinical risk was very low. A substantial number of these units had already been transfused and there had been no unexpected reports of quality concerns or patient related incidents. The risk assessment determined that recall of these units was not required. This has been reported as a Serious Adverse Blood Reactions and Events (SABRE) to the MHRA. The root cause relates to a relatively new workforce not working at the appropriate speeds to meet the processing timeframes and increased throughput.

There is an ongoing review of the non-touch technique for venepuncture as part of the actions to reduce the number of venepuncture Serious Adverse Events of Donation (SAEDs). This will be run in parallel with the project to source an alternative and more cost-effective arm cleaning product.

Four SAEDs were reported in August and three in September. There was one fracture, and one hospital admission. Three SAEDs related to venepuncture, one was a co-incidental event and one was acute coronary syndrome.

No cases of bacterial transmission to patients have occurred. There is an ongoing investigation of a probable transmission of Hepatitis E Virus (HEV); so far one HEV positive donor has been identified.

8. Diagnostic and Therapeutic Services (DTS)

There have been no new cases of Transfusion Related Acute Lung Injury (TRALI) in this reporting period, with one to date this year.

A Coroner's inquest will be held on 11 December 17 into the death of a patient with sickle cell disease. The Associate Medical Director (AMD) DTS has provided a report for the inquest.

9.0 Organ Donation and Transplantation (ODT)

A short video has been produced demonstrating best practice for the diagnosis and confirmation of brain stem death.

The process of reporting Transport Perfusion Fluid microbiology results is to be re-reviewed. ODT will issue a list of positive cultures that require reporting after engagement with microbiologists.

Currently National Organ Retrieval Service (NORS) teams are not licensed to remove tissue for any other purpose other than to support organ transplantation. The HTA are aware and are in support that current practice may continue whilst this is reviewed. NHSBT will continue to work with the HTA to develop a process that enables teams to meet the Regulatory requirements without impacting on urgent clinical need.

10. HTA Code of Practice (CoP)

In the previous report an identified issue in complying with the new HTA CoP was raised. Changes continue to be made to both Blood Donation and Non-Clinical Issue processes to accommodate the changes to the CoP. The ET has been briefed and agreed the approach. A group has been formed to undertake the gap analysis and will now implement the changes required to address the shortfalls identified. The HTA has been briefed on the issues identified and NHSBT are keeping them informed of progress.

11. Information Governance (IG)

The GDPR gap analysis has now been completed and a separate paper has been submitted to the Board for discussion and approval. A particular focus will need to be on consent, a group will be established. A new Head of IG will start in January 2018.

12. Clinical Audit

No clinical audit reports or protocols were approved in this reporting period. A mid-year review of the 2017/18 Clinical Audit Programme is underway, and through discussions with Directorate CARE Groups has resulted in some clinical audits being removed from the programme with others reprioritised and/or allocated to the 2018/19 programme.

13. Clinical Claims/legal issues

CARE received a six-monthly update report regarding clinical claims. There are currently twelve open clinical claims across NHSBT; one in ODT, one in DTS and ten in BD. In 2017/18 to date, NHSBT has received ten new clinical claims and settled nine claims.

In 2017/18 two Coroner's inquests have been held in which NHSBT was involved in the care of the individual; one related to ODT and one to DTS. A further inquest is listed for December relating to DTS and was (referred to above).

14. Nursing Leadership Team

DTS and the Clinical Directorate Nurses came together on 28 September 2017 for a conference focusing on 'Developing Knowledge, Developing Networks'. A total of 40 nurses attended the day and feedback from the event was 97% excellent or good.

There has been one safeguarding incident identified during the reporting period which was related a member of staff. This incident has raised a number of issues related to how concerns regarding a member of staff are categorised and dealt with and subsequently how they are documented. These issues will be raised with the Nursing Leadership Team for review and action.

The Professional Nursing Lead in DTS, Andrea Harris has been appointed to the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO).

15. Safety Policy Matters

The SaBTO Blood Donor eligibility report will be implemented on 28 November 2017. Acupuncture has not been included in the changes to implement from the Department of Health (DH) and will remain as a four-month deferral.

Post donation HEV testing of all deceased organ donors and for all tissues and stem cells processed in DTS commenced on 2 October 2017. This recommendation is now fully implemented in NHSBT.

SaBTO is reviewing the provision of non-UK sourced Fresh Frozen Plasma (FFP) and cryoprecipitate for individuals born after 1995 or with Thrombotic Thrombocytopenia Purpura (TTP), and the provision of apheresis platelets to individuals born post 1995. Both are risk reduction measures for variant Creutzfeldt-Jakob Disease (vCJD). A working group will review the options using a new blood risk assessment model and will use the ABO risk based decision making framework. Workstreams will include blood and patient safety, health economic, operational and contextual assessments.

The SaBTO microbiological safety guidelines are awaiting approval from DH ministers. This is expected in mid-November.

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November 2017