NHS Blood and Transplant (NHSBT) Board
25 January 2018

Clinical Governance Report
01 October – 30 November 2017

1. Status – Public

2. Executive Summary

- There were two new Serious Incidents (SIs) in the reporting period. An SI occurred in Organ Donation and Transplantation (ODT), ODT-INC-2273 was reported to the November Board and relates to the death of a lung recipient from possible disseminated Herpes Simplex Virus (HSV) infection. Viral typing to ascertain if we can confirm the source of the viral transmission was the donor is underway. In DTS a new SI has occurred (QI5762) which relates to the release of ocular tissues without complete information. This SI encompasses three incidents and remains under investigation.

- An incident occurred in Blood Donation (BD) outside of the reporting period in which a female donor was found to be very anaemic following donation. At the donation, the donor failed the copper sulphate test twice, but passed on the third attempt. It is suggested it was indicated to the donor that she had been accepted for donation because she was O negative. The message that donor safety is always paramount has been communicated across blood donor teams. The method used for the copper sulphate test is already being reviewed in the light of the INTERVAL trial results.

- NHSBT provided a report and attended a coroner's inquest in Manchester in December 2017 following the death of a patient with sickle cell disease. The coroner recorded a narrative conclusion that the death was due to a sickle cell crisis contributed to by blood transfusion reactions in 2011 and 2016. The patient's husband has been reported in the national press, highlighting the transfusion needs of patients with sickle cell disease.

- There is an on-going issue for Specialist Nurses in Organ Donation (SNODs) accessing electronic patient records in Hospitals to undertake donor characterisation. The main challenges are in gaining access to and maintaining training / familiarity with the necessary IT systems.

3. Action Requested

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

4. Serious Incidents (SI)

ODT INC 2273: was reported to the November Board and relates to the death of a lung recipient from possible disseminated Herpes Simplex Virus (HSV) infection. There is currently no indication that there were any omissions in the donor characterisation that would have been of clinical significance. Further testing is ongoing and final sequencing results to confirm if the HSV was donor derived is underway.

In DTS a new SI has occurred (QI5762) which relates to the release of ocular tissues. This SI encompasses three separate incidents. Root cause analyses (RCAs) have been performed. The preventative actions are the centralisation of ocular tissue records, training

of additional nurses, and computer control requiring complete and satisfactory microbiology results before ocular tissue can be issued for transplantation. An audit of effectiveness will be performed once these actions have been implemented.

Updates on SIs previously reported:

- ODT INC 2306: 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 received.
- DTS QI4492, the removal of ocular tissue in error without consent. The report is currently being finalised.
- ODT INC 2273: as above.

5. Risk

There are currently 25 risks within the risk management system which have the risk impact area recorded as clinical; this is a decrease of three from the previous reporting period. The three risks removed from the risk register were: ICT-11: There is a risk in Data Security that Third-party's actions or inactions may lead to data loss. ICT – 38: There is a risk that ICT does not have the right skill mix to carry out its functions. ICT – 47: There is a risk that current infrastructure (especially network and internet access) and desktop environment is not sufficient to rollout cloud based (or internal) solutions.

6. Complaints and Commendations

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

In DTS during the reporting period compliments were received across most services with Red Cell Immunohaematology (RCI) receiving a marked increase in compliments in November. RCI and RCI reagents saw an increase in complaints in October which they did reduce again in November.

In ODT during October and November ten complaints were noted, eight were clinical in nature, and the remaining two were in relation to the possible change in legislation. There were 17 compliments received nationally.

7. Blood Supply (BS)

An incident occurred in Blood Donation, outside of the reporting period, which was deemed significant enough to warrant inclusion in this report. A female donor was found to be very anaemic following donation. The Haemoglobin (Hb) was recorded as 50g/L when the donor went to the GP. At the donation, the donor failed the copper sulphate test twice, but passed on the third attempt. It is suggested it was indicated to the donor that she had been accepted for donation because she was O negative. The message that donor safety is always paramount will be communicated across blood donor teams. This event will be considered as part of the ongoing project for Hb screening. Immediate action has been taken to ensure that only a single copper sulphate test is performed

One Serious Adverse Event of Donation (SAED) was reported in October and five in November. One donor died 11 days after donating, three donors reported problems with needle insertion which remained more than one year's duration, and two were admitted to hospital within 24 hours.

No cases of bacterial transmission to patients have been confirmed.

Work is currently on-going regarding the new irradiation labels; both with the manufacturer and internally. The work includes commissioning some Human Factors work in conjunction with the Serious Hazards of Transfusion (SHOT) team to ensure that any labels utilised for this purpose are clear and understandable. During training, members of staff in hospitals had complained about the risk of error with labels that involve multiple shades of blue being difficult to interpret, together with the word 'IRRADIATION' always present on the label irrespective of whether the product is irradiated, being suggestive of an irradiated product.

A review is being undertaken of the gamma irradiation process in use across NHSBT. The irradiator in Southampton is nearing the end of its operational life and there has been a Home Office instruction to move away from gamma irradiation due to the security risk posed. X-rays devices used previously were unreliable but it is anticipated that technology has improved to make them now a viable alternative. The Executive Team agreed a pilot of x-ray at Southampton. A paper will be presented to M&L Senior Management Team with a proposal.

8. Diagnostic and Therapeutic Services (DTS)

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

Seven events (one in Therapeutic Apheresis Services, two in Cellular and Molecular Therapies, four in Tissue and Eye Services) were reportable to the Human Tissue Authority (HTA) as Serious Adverse Events and Reactions (SAEARs).

NHSBT provided a report and attended a coroner's inquest in Manchester on 11 December 17 following the death of a patient with sickle cell disease. The coroner recorded a narrative conclusion that the death was due to a sickle cell crisis contributed to by blood transfusion reactions in 2011 and 2016. The patient's husband has been reported in the national press, highlighting the transfusion needs of patients with sickle cell disease.

9. Organ Donation and Transplantation (ODT)

It has been agreed that the process of reporting Transport Fluid results needs to be re-reviewed. ODT will issue a list of positive cultures that require reporting after engagement with microbiologists. The new process will go live in January 2018.

In December 2016, a query was raised in relation to Quality in Organ Donation initiatives (QUOD), and our processes in relation to taking specimens from patient's pre-mortem. The concern was in relation to consent/authorisation in donors after circulatory death (DCD) in relation to taking blood samples pre-mortem. NHSBT ODT and QUOD reviewed the processes and Research Ethics Committee (REC) approvals in accordance with the appropriate legislation and sought legal advice. The REC approval letter included reference to the Mental Capacity Act (2005) but was not explicit in mentioning The Adults with Incapacity (Scotland) Act 2000.

A paper was written in March 2017 outlining the position and was shared with the HTA. QUOD have since been following up the REC for confirmation of whether the Scottish Act was considered when REC approval was granted. The HTA have recently written a formal letter to NHSBT outlining concerns about the initial REC decision. ODT will respond to the

HTA advising that QUOD is in the process of applying for renewed REC approval and the original REC have advised to submit the resubmission to the England and Scotland REC.

During the period between October – November there were three Serious Adverse Reactions (SARs) and one Serious Adverse Event (SAE) reported to the HTA under NHSBT's Assisted Function. Of these 2 SARs were related to the same incident (relating to ODT INC 2773 above).

10. Information Governance

NHSBT's process to ensure compliance with the new General Data Protection Regulations (GDPR) will be managed as a change project. The formal request will be submitted to the Transformation Programme Board (TPB) on the 17 January 2018.

There is an on-going issue for Specialist Nurses in Organ Donation (SNODs) accessing electronic patient records in Hospitals to undertake donor characterisation. The main challenges are in gaining access to and maintaining training / familiarity with the necessary IT systems. A view has been sought from the UK Council of Caldicott Guardians.

11. Clinical Audit

A total of three clinical audit reports or protocols were approved in this reporting period:

- DTS: AUD 3588 Heart Valve Audit. The audit identified 42 donors who donated heart valves from 105 potential donors, a conversion rate of 40%. This compares with data from the Barcelona Tissue Bank who report a conversion rate of 64%. It is worth noting that presumed consent has existed in Spain for a number of years. Where potential missed opportunities were identified in the audit these donor files will be further scrutinised. A system of ongoing regular monitoring will be undertaken with a standardised list of options for the reason for heart valves not being utilised. A re-audit will be performed to assess the impact of this detailed monitoring.

- DTS: AUD 3833 Alerting the Duty Consultant. An inspection by the United Kingdom Accreditation Service (UKAS) prompted re-auditing this area. Data was gathered regarding calls to medical staff during the period 1st January to 31st March 2017. 90% of calls were appropriately logged. Rates of formal handover were lower at 73% but not all require formal handover. The audit recommended that SOP4743 and all forms relating to it are reviewed along with the mechanisms of handover to ensure they meet the needs of patient safety, the team and UKAS.

- DTS: AUD 3319 Cord Blood (CB) File Authorisation. The audit was carried out as part of the change control process to enable the authorisation of donor files by Health Care Scientists (HCS) rather than a doctor. The audit demonstrated that a proportion of CB donor files can be safely reviewed and the CB donations listed by HCSs. It evidenced that the new process has reduced the time taken to appropriately release cord blood units for listing for search. More staff have been trained, they are accumulating experience so it is anticipated that there will be further improvement when the process is re-audited. It was not stated in the audit report, however, the speed at which cords are listed by NHSBT compares favourably with peer registries. The controlled documents underpinning the new process will be developed further to address specific areas that have been identified as needing further clarification. The need for regular refresher training of all members of staff involved with cord blood donor authorisation will also be addressed.

12. Nursing Leadership Team

Dr Sarah Morley, Associate Medical Director, Manufacturing and Logistics, is the new Safeguarding Medical Lead.

12. Research update

Dr Lise Escourt has been appointed as Interim Director of the Clinical Trials Unit.

The **Pla**telets for **Ne**onatal **T**ransfusion - 2 (PlaNeT-2) study of pre-term newborn babies with low platelet counts has been completed ahead of time. The study randomised newborns (neonates) to prophylactic platelet transfusion at a platelet count of either a liberal $50x10^9$/L or conservative $25x10^9$/L. The outcomes of the two groups will be compared in the analysis that is now underway.

No research governance issues were reported.

13. Safety Policy Matters

The pre-donation arm cleansing review continues, and has two main aims 1) achieve cost savings against current product and 2) review current venepuncture practice to reduce donor arm injury rates. Maintaining donor safety remains paramount when choosing a new product. Specification is currently in draft for a supplier event to identify possible alternative preparation(s). FREPP implementation remains a short term option to achieve some cost savings, any other new product will require a medium to long term plan to validate and implement.

The UK Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) paediatric components working group 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 and will report to SaBTO in May 2018. The review aims to use a revised risk assessment for the transmission of variant Creutzfeldt-Jakob Disease (vCJD) from blood, which the Advisory Committee for Dangerous Pathogens Transmissible Spongiform Encephalopathies (TSE) subgroup if this is agreed in February.

The SaBTO microbiological safety guidelines have been published this month.

JPAC will review the donor selection criteria for travellers returning from malarial affected countries. It will use the ABO risk-based decision-making framework to review the current guidelines.

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