NHS Blood and Transplant (NHSBT) Board
28 March 2019

Clinical Governance Report
01 December 2018 – 31 January 2019

1. Status – Official

2. Executive Summary

- There was one new Serious Incident (SI) in Organ, Donation and Transplantation (ODT) outside the current reporting period (ODT-INC-3840). On 23 February a heart was accepted for transplant. The Heart Transplant Centre was informed the heart was retrieved and leaving Theatre. The transplant centre anaesthetised the intended recipient. Unfortunately, the heart was delayed leaving theatre and due to the geographical location of the donor and transplant centre, and the new estimated Cold Ischaemic Time (CIT), the transplant centre made the decision to stand down the transplant. The intended recipient remains on the urgent heart transplant list.
- The SI in Diagnostic and Therapeutic Services (DTS): QI10809 - Discrepancies in Blood Donors – The British Bone Marrow Registry Database (BBMR) has now been closed.
- There has been a confirmed case of Hepatitis E Virus (HEV) transmission which was detected during a lookback investigation after an apheresis donor tested positive for HEV RNA. The recipient is in remission after chemotherapy and is currently well and being monitored.
- There was a delayed detection of *Staphylococcus Aureus* in a pooled platelet donation. The recipient did not show symptoms or signs of a transfusion reaction and they remained well without the need for antibiotics. They have been discharged from Hospital.
- There has been a possible transmission of *Staphylococcus epidermidis.* A young child, under 2yrs old, received one unit of seven-day old apheresis platelets which did not alert on bacterial screening. Within five minutes of the transfusion commencing the child experienced a high temperature and was unwell. *Staphylococcus epidermidis* was cultured from the pack and from blood cultures from the child. The patient recovered and has been discharged. The investigation is ongoing, the donor has been contacted.
- One Blood Donation (BD) incident previously reported to the Information Commissioner's Office (ICO) has now been closed with no regulatory action being taken.
- The clinical audit report 2019/20 programme was approved.

3. Action Requested

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

4. Serious Incidents (SI)

There was one new SI in ODT (ODT-INC-3840) outside the current reporting period. On 23 February a heart was accepted for transplant from a multi-organ donor following Donation after Brain Stem Death (DBD). The heart transplant centre was informed that the heart was retrieved and was leaving the operating theatre. Based

on this information the heart transplant centre anaesthetised their intended recipient and invasive monitoring was undertaken as per usual protocol. Unfortunately, the heart did not actually leave theatre until 26 minutes after the call to the heart transplant centre. Due to the geographical location of both the donor and transplant hospital, the heart was to be sent via both road and air. Due to this delay the heart transplant centre team deemed that the new estimated CIT (time between retrieval and transplantation) was unacceptably long and therefore they decided to stand down so as to not expose their patient to undue risk. Their patient remains on the urgent heart transplant list. A Root Cause Analysis (RCA) is planned for the 22 March 2019.

Update on previous SIs:

- DTS: QI10809 - Discrepancies in Blood Donors – The BBMR. A donor wrote to NHSBT in September to check their details on the BBMR. This SI has now been closed.

5. Risk

There are currently fifteen risks with the primary risk impact area recorded as clinical. One new risk has been added to the risk register; BD-08, Horizon Scanning – Residual risk score 12. There remains one P1 risk - ODT-003 - Affecting organ donation and transplantation facilitation – Residual risk score 15.

6. Complaints, and compliments

Within ODT a total of eleven compliments and four complaints were received in this reporting period, three of which were clinical and one non-clinical.

In this reporting period a total of 66 complaints were raised relating to DTS and 61 raised relating to Manufacturing and Logistics (M&L) which is a total reduction of nearly 50 from the last reporting period.

7. Blood Supply (BS)

Five Serious Adverse Events of Donation (SAEDs) were reported in December and none in January. One SAED related to needle insertion, one related to a hospital admission following a pain in the donor's jaw following a second platelet donation, and one event related to an air embolism detected in the return line and observed entering the donor's arm before the donor carer was able to clamp the line, there was no error on the part of NHSBT. The donor remained asymptomatic throughout.

There has been a confirmed case of HEV transmission which was detected during a lookback investigation following a positive result from an apheresis donor with acute Hepatitis E. The previous donation has tested negative but on repeat individual testing was positive. This was not detected because of the low viral load. There were no errors in testing. The previous apheresis donation was a double donation and was transfused to two people. The first sadly died 48 hours after transfusion from other causes, the second was being treated for lymphoma and is now in remission. On notification they were tested and proved positive for HEV RNA. Sequencing at Public Health England (PHE) confirmed the same virus and confirms the transmission. The patient is being monitored and is awaiting reconstitution of their immune system following

chemotherapy after which doctors will see if the patient is able to clear the virus. This is the first screen negative transmission of HEV since screening began in 2016 and was due to the timing of the infection and low viral load at that point.

There has been a possible transmission of *Staphylococcus epidermidis.* A young child, under 2yrs old, received one unit of seven-day old apheresis platelets which did not alert on bacterial screening. Within five minutes of the transfusion commencing the child experienced a high temperature and was unwell. *Staphylococcus epidermidis* was cultured from the pack and from blood cultures from the child. The patient recovered and been discharged. No error was made by NHSBT. The investigation is ongoing, the donor has been contacted.

There was a delayed detection of *Staphylococcus Aureus* in a pooled platelet donation. There was no reaction in the recipient post transfusion, and they remained well without the need for antibiotics. They have been discharged from Hospital. It is suspected the contamination came from the one donor who did not provide a sample for testing. Donors do not always respond well to requests for additional testing. Due to having no sample and not being able to eliminate that donor as the source of the infection that donor has now been withdrawn. No error was made in processes.

8. Diagnostic and Therapeutic Services (DTS)

Eighteen events were reportable to the Human Tissue Authority (HTA) as Serious Adverse Events and Reactions (SAEARs). There was no evidence of any errors by NHSBT resulting in harm to patients.

Clean room infrastructure: stem cell laboratories in three locations were without clean rooms at the time of DTS CARE. This has been affecting operational capacity supporting patients, internal research and development projects and future contracts. A clean room advisory group has been reconstituted and the scope of this group is being reviewed to improve internal expertise in clean room infrastructure.

9. Organ Donation and Transplantation (ODT)

ODT received advice from The Department of Health and Social care (DHSC) in relation to organ retrieval from pregnant patients in 2017. Following receipt of this advice and given its importance to the wider NHS, NHSBT obtained the opinions of Leading Counsel. Further correspondence with the DHSC resulted in engaging with the BMA Ethics Committee in relation to pregnancy in donation.

The BMA focused their discussions on cases where the fetus is not viable (i.e. not capable of being born alive) because where the fetus is viable, consideration would be given to delivering the fetus prior to withdrawing treatment. A key focus of their advice was regards to withdrawing life-prolonging treatment. The committee was clear that the best interests of the woman is the sole consideration when deciding whether life-prolonging treatment should be continued or withdrawn from a pregnant woman. A thorough best interests' assessment should be undertaken, considering a range of factors including the gestational age of the fetus, and the woman's own views about the pregnancy. If there is agreement between the treating team and those close to the patient that it is not in the woman's best interests to continue treatment, there would be no legal justification for continuing to provide it and it should be withdrawn. The BMA outlined that in situations where a woman is pregnant

with a viable fetus, and it is proposed to withdraw life-prolonging treatment then legal advice should be sought.

In February 2019, the DHSC endorsed the recommendations of the BMA and have written to ODT confirming they are very content for us to continue to work with relevant stakeholder to operationalise the recommendations. This is a very positive step forward for ODT.

At the SXSW event in Texas, Dr Tim Brown, a Transplant Surgeon from Belfast, presented how a 3D printed kidney was used to aid a world-first, life-saving operation. He explained how a 3D printed replica of a patient's kidney was created to allow the surgical team to safely plan an operation to extract the kidney with a tumour, remove the benign tumour, & transplant the tumour-free kidney to the patient's 22-year-old daughter. The technology is as a result of a collaboration between Dr Tim Brown and a medical 3D printing firm and was a world-first operation

10. Information Governance (IG)

One BD incident was reported to the ICO in this reporting period as documented previously. The ICO have now closed this incident and confirmed no regulatory action will be taken. In addition, the ICO have been made aware of one complaint received relating to Cookies on the blood donor website.

11. Clinical Audit

The 2018/19 clinical audit annual programme included fifteen audits which were scheduled to be completed and report within 2018/19. Of those fifteen, eleven have now reported. Three DTS audits will now report in 2019/20. ODT CARE approved the removal of an audit of SI action plans from the 2018/19 programme due to no related SIs within the directorate.

The 2019/20 clinical audit annual programme was approved by CARE. The programme consists of a total of 30 clinical audits; with 18 scheduled for completing and reporting completion in 2019/20. There are seven audits within BS, 20 audits within DTS and three audits within ODT.

One clinical audit report was approved within this reporting period:

- BS AUD3789: Re-audit of Infection Prevention and Control (IPC) Procedures on Blood Collection Teams. The re-audit reviewing effectiveness and current compliance with current IPC guidelines. Every blood collection team completed observations of staff hand and donation arm hygiene and donor arm disinfection, as well as a survey. Results were positive; 99.1% events observed were compliant with hand hygiene and 94.4% venues fully supported IPC measures. It was recommended that all staff be reminded of the seven-step technique for hand washing.

12. Research update

No research governance issues were raised.

13. Infected Blood Inquiry (IBI)

The IBI team visit to Filton, to include the Chair and lead Counsel to the Inquiry, has been arranged for 2 April 2019. We are still finalising the position regarding Legal Professional Privilege (LPP). The IBI hearings, where evidence is heard from the infected and affected, will commence in London 30 April 2019.

14. Non-Clinical Issues (NCI)

All actions required to close the findings from the July 2017 Audit (including findings against compliance with the Human Tissue Act 2004 and associated Codes of Practice) have been completed. Following discussions with the Human Tissue Authority and agreement by CARE of a definition for genetic testing, NCI will shortly be able to consider applications requesting samples for RNA sequence analysis. Operationally, NCI continues to grow its business, largely driven by sales of discard plasma and white cell cones.

15. Safety Policy Matters

The Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) paediatric components working group, looking at the importation of plasma and provision of apheresis platelets for individuals born on or after 1st January 1996 as risk reduction measures for Variant Creutzfeldt-Jakob disease (vCJD), has now concluded stakeholder engagement on the potential withdrawal of these measures. The final report will go to SaBTO on the 19th March and then a recommendation made to ministers at the UK Departments of Health.

SaBTO has requested an update from NHSBT/Public Health England (PHE) on HEV testing since the start of universal testing in 2017 to review if the current measures remain cost effective. This will go to a SaBTO meeting later in the year.

The Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee (JPAC) have produced a paper on derogations for UK blood microbiological screening in the event of disruption to supply of testing kits.

JPAC, NHSBT and the Medicines and Healthcare products Regulatory Agency (MHRA) are participating in an EU Joint Action “Facilitating the Authorisation of Preparation Processes for blood, tissues and cells (GAPP)”. The purpose of this work is to provide standardised protocols for authorisation changes in donation, procurement and collection, processing, preservation, storage and distribution of blood, tissues and cells.

JPAC recommended that individuals identified with familial hypokalaemia should not be used for large volume neonatal and infant transfusions, including intrauterine and neonatal exchange transfusions.

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