NHS Blood and Transplant (NHSBT) Board
29 March 2018

Clinical Governance Report
01 December 2017 – 31 January 2018

1. Status – Public

2. Executive Summary

- There were no new Serious Incidents (SIs) in this reporting period. Two SIs have now been closed: ODT INC 2306: Removal of two kidney grafts following histology results in donor indicating lymphoma, and DTS QI4492: the removal of ocular tissue in error without consent.
- Despite the recent extreme weather conditions (outside the reporting period) NHSBT did not fail to deliver blood to any hospital. During the worst of the weather, ODT operations in Scotland were stood down, but recovered quickly. DTS services (including TAS) were maintained throughout. The week following the snow an amber alert for platelets was called due to collection difficulties during the weather. This was despite platelet stock being healthy before the snow started. It had the effect of reducing demand immediately. The lessons learned exercise will be completed by May 2018.
- NHSBT will provide information for three upcoming inquests; two relating to incidents QI1697 and QI6552 in DTS. In both cases the patients died despite interventions and blood components from NHSBT, rather than as a result of them. QII697 concerns the death of a patient following a thyroid operation. The death is associated with low blood pressure during the operation, significant bleeding, and multiple organ failure post operatively. QI6552 concerns the death of a patient with Thrombotic Thrombocytopenic Purpura (TTP). The third is a Coroner's inquest concerning the recent patient death, which is reviewing the possibility of the transmission of Hepatitis C via a blood transfusion from transfusions received before 1997.
- Within the reporting period Organ Donation and Transplantation (ODT) had the first case of a donor positive for Hepatitis E Virus (HEV). The Advisory Committee on the Safety of Blood Tissues and Organs (SaBTO) expects 2-3 cases per annum, so this isn't unexpected. Two kidneys and the liver were transplanted, the liver donor seroconverted and has been given ribavirin. NHSBT will continue to monitor the recipient's clinical outcome.
- The findings of Blood Supply AUD3208: Audit of Donor Carer Acceptance of Tattoos and Skin Piercings provided evidence that extending the Donor Carer (DC) selection criteria is safe, working, and being followed. CARE praised the quality of the audit and supported the development of the findings of this and previous audits into a transfusion paper to share with other blood services.
- The Chair of the Infected Blood Inquiry has been announced as Mr Justice Langstaff, who will commence the role following his retirement from the High Court on 1st May 2018. The Terms of Reference (ToR) for the Inquiry have not yet been announced.

3. Action Requested

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

4. Serious Incidents (SI)

The following SI are now closed

- ODT INC 2306: Removal of two kidney grafts following histology results in donor indicating lymphoma.
- DTS QI4492, the removal of ocular tissue in error without consent.

In addition

- ODT INC 2273: Disseminated Herpes Simplex Virus (HSV) infection. It has been agreed that this report can now be closed and the final draft is in preparation.

5. Risk

There are currently 21 risks within the risk management system which have the risk impact area recorded as clinical; this is a decrease of five from the previous reporting period. One risk with the primary impact area recorded as clinical has been removed from the risk register: CLIN- 10: There is a risk that NHSBT will be unable to appoint to two Microbiology Services Medical Consultant posts following retirement. These posts have now been recruited to. For four additional risks, the primary impact area has changed following risk reviews:

- CLIN-12: there is a risk that NHSBT cannot retrieve records archived with Iron Mountain promptly – changed to Information Governance
- ODT – 02: there is a risk of causing donor family distress or harm – changed to Reputational
- ODT – 05: there is a risk that ODT is unable to continue Business as Usual – changed to Business Continuity
- ODT – 06: there is a risk affecting ODT staff well-being – changed to Health and Safety

No new risks have been added since the last report.

6. Complaints and Commendations

Compliments were received across most services in DTS with a significant increase in compliments received in January in Therapeutic Apheresis Services (TAS). Complaints are monitored at DTS CARE, and there have been no upward trends reported in this period.

In ODT there were seven complaints during the reporting period; two were clinical and related to follow up post donation; five were non-clinical and related to the ODR website/ disputed registrations. A total of 18 compliments were received in ODT.

7. Blood Supply (BS)

BS CARE agreed a new clinical risk will be added to the Blood Donation (BD) risk register regarding the potential loss of donors due to the development and introduction of genetic testing of donors. An example is donors found to have pseudohyperkalaemia. This is a genetic mutation that causes increased potassium leakage on storing red cells which could potentially cause harm to neonatal and infant recipients.

Two Serious Adverse Event of Donation (SAED) were reported in December 2017 and two in January 2018. One donor died within 7 days of donation, two donors were admitted to hospital within 24 hours of donation, and one donor had a fracture within 24 hours of donation.

No confirmed cases of bacterial transmission to patients have occurred.

Lidocaine was removed from blood donation sessions almost a year ago and has led to a financial saving of £32,000. Out of approximately 10,000 donors, NHSBT received 126 complaints and 136 of these donors have been withdrawn during the past year; equating to a loss of 0.01% of the 10,000 donors. CARE congratulated the operational teams on how they made this change.

A Coroner's inquest has been listed 5th April in Birmingham concerning the death of a female in January 2018, and is reviewing the possibility of the transmission of Hepatitis C via a blood transfusion. A Transfusion Microbiology consultant will attend as a witness for NHSBT and communications will attend also.

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.

DTS will provide information for two Coroner's inquests: In both cases the patients died despite intervention or blood components from NHSBT, rather than as a result of them. QI6552: A patient suffered a cardiac arrest and died during a plasma exchange being undertaken by NHSBT for TTP. QI6971: A patient died following a thyroid operation associated with low blood pressure during the operation, significant bleeding requiring transfusion and multiple organ failure post operatively.

From 1st April 2018, NHSBT will no longer provide apheresis granulocytes as part of its portfolio. We have only received requests from one Trust in England in recent years and the number of requests have been diminishing. There have been a number of QIs relating to the provision of these components. In addition, we can no longer source the hydroxyethyl starch preparation used for this procedure, as supply to the UK has been discontinued. The Trust that orders these components has been informed.

Issues affecting the performance of Haematos, particularly the log-on process, are being resolved following the clarification of the root cause, which is a discrepancy between the versions of software on the new desktop and Haematos.

9. Organ Donation and Transplantation (ODT)

Following engagement with microbiologists a revised process for the reporting of positive transport fluid results was introduced in January 2018. Initial feedback has been positive.

The previous report flagged a query raised by the Human Tissue Authority (HTA) in relation to Quality in Organ Donation initiatives (QUOD), and our processes in relation to taking specimens from patient's pre-mortem. ODT have written to the HTA to inform that we are in the process of preparing our annual submission to the March Research Ethics Committee (REC) for the QUOD bio resource. Particular emphasis, as we have previously done, will be on the Organ Donation after Cardiac Death (DCD) element of the donation pathway. In addition, we will approach the Scottish authorities to ensure full transparency and ensure correct processes are in place in Scotland. The HTA are content with this approach.

Since the previous report two Serious Adverse Events (SAEs) and one Serious Adverse Reaction (SAR) were reported to the HTA under NHSBT's Assisted Function.

Within the reporting period ODT had the first case of a donor testing positive for HEV. SaBTO expects 2-3 cases per annum, so this was not unexpected. Two kidneys and the liver were transplanted, the liver donor seroconverted and has been given ribavirin. NHSBT will continue to monitor the recipient's clinical outcome.

10. Information Governance (IG)

The management of the General Data Protection Regulation (GDPR) action plan was approved as a project at January Transformation Programme Board (TPB).

A consent working group has been established and has a broader remit than just GDPR; encompassing the new HTA Code of Practice (CoP), research requirements, and application of the Montgomery ruling in BD sessions. The working group is being led by the Assistant Director, Governance and Clinical Effectiveness, and includes representation from each of the operational business units, IG, Research and Development (R&D), Information Security, contracts, and Quality Assurance (QA).

Work has begun, for example in Tissue and Eye Services, to pro-actively write to Hospital Trusts to outline the basis on which they can continue to share information with NHSBT under GDPR.

The previous report highlighted the range of issues experienced by Specialist Nurses – Organ Donation (SNODs) in accessing electronic records in Hospitals. There is no simple solution to this complex issue; the issue will be considered as part of the GDPR action plan and ODT will review all the Memorandums of Understanding (MOU) held with all Trusts to establish if NHSBT's position can be strengthened.

11. Clinical Audit

Two clinical audit reports were approved in this reporting period:

- BS AUD3208: Audit of Donor Carer Acceptance of Tattoos and Skin Piercings. At the time of this audit, a Discretionary Test (DT) for Hepatitis B must be taken with a donation between four and 12 months after a donor has had a skin piercing or tattoo event, to ensure the safety of blood supply to patients. Previously, these tests could only be signed off by nurses. In 2016 the acceptance and deferral criteria was expanded to allow DCs to request DTs for skin piercings or tattoos. The audit found the decision-making process was regarded as correct in 98% of cases. This is now the second audit to demonstrate that extending the DC selection criteria is safe, working, and being followed. CARE praised the quality of the audit and supported the development of the findings of this and previous audits into a transfusion paper to share with other blood services.

- BS AUD3546: SAED communication audit. In 2016, Donor Consultants were asked to change their practice by commencing to write a letter of apology to each donor who experienced an SAED. This audit was undertaken to ascertain if this change in practice was embedded. The audit found; all donors who experienced an SAED were communicated with verbally by the Donor Consultants/Clinical Support Team, apart from one, who was appropriately dealt with verbally on session; and a total of 63.8% of the donors were sent a letter from the organisation relating to their SAED. It should

be noted, that compliance improved over the course of the financial year, from 41.7% for SAEDs raised in Quarter 1 to 81.3% in Quarter 4.

CARE approved the 2018/19 Clinical Audit Programme, which included a total of 27 clinical audits across all the operational business units; 15 will complete and report in 2018/19, 10 will complete and report in 2019/20, and two are rolling programmes of audits.

12. Research update

There were no research governance issues reported.

13. Safety Policy Matters

NHSBT will continue to use the ABO risk based decision making framework as its safety framework. Work continues with the ABO to gain international experience in using the framework, particularly using it for rapid decision making.

At the beginning of February, it was announced that Mr Justice Langstaff will chair the public Inquiry into the infected blood scandal. Mr Justice Langstaff will be the full time Chair of the Inquiry from 1 May 2018 following his retirement from the High Court. Once further consultation on the ToR has taken place, the Minister for the Cabinet Office will confirm the final terms to the House of Commons.

The SaBTO review of the provision of non-UK sourced Fresh Frozen Plasma (FFP) and cryoprecipitate for individuals born after 1995 or with TTP, and the provision of apheresis platelets to individuals born post 1995 has been using the ABO risk based decision making framework to support the process, to look at ethical and contextual issues, and to identify key stakeholders and develop a communications plan. Hospitals and trauma centres have been surveyed to provide information on the current usage of imported plasma. The blood transmission risk assessment for variant Creutzfeldt-Jakob Disease (vCJD) is currently being revised by the Advisory Committee on Dangerous Pathogens' Transmissible Spongiform Encephalopathy **(**ACDP TSE**)** subgroup, and will be used by the SaBTO review for a revised cost/benefit analysis of the current measures. A consultation plan for patient groups is being developed which will take place prior to any recommendations to SaBTO. The review will report in May/June 2018.

A new version of the SaBTO microbiological safety guidelines was published in January.

Improved testing timelines means that Nucleic Acid Amplification Testing (NAT) results for Hepatitis B Virus (HBV), Hepatitis C Virus (HCV) and Human Immunodeficiency Virus (HIV) can be made mandatory for the release of all granulocyte products.

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