NHS Blood and Transplant (NHSBT) Board
26 July 2018

Clinical Governance Report
01 April – 31 May 2018

1. Status – Official

2. Executive Summary

- There was one new Serious Incident (SI) in Diagnostic and Therapeutic Services (DTS) in this reporting period: INC76020, this related to the delayed delivery of cardiac tissue and was verbally reported at the last Board meeting. The investigation is completed for this incident.
- Two Information Governance (IG) incidents of IG severity score level two were reported to the Information Commissioner's Office (ICO), an additional incident did not meet the threshold to be reportable, but the decision was made to inform the ICO to seek advice and guidance:

    - The first related to the UK Serious Hazard of Transfusion (SHOT) team whose governance is the responsibility of NHSBT. SHOT use an online platform called TOAST Digital to securely share data including minutes of meetings, CVs of potential members and other administrative documentation. A member of SHOT discovered personal information had become available on Google through a search. At this stage we believe 30 CVs have been made publicly available. Immediate actions have been undertaken to ensure that this documentation is no longer public as well as a formal request to TOAST to rectify this issue.
    - The second incident reported to the ICO was an email sent from a donor centre, inviting potential new whole blood and platelet donors to a session; the email contained the personal email addresses of the 160+ plus recipients. Whilst no formal complaints were received, numerous complaints or replies were received by the sender and donor centre.
    - The last incident, which was not ICO reportable, relates to an email sent to just under 500,000 blood donors about Britain's Got Talent. Changes to processes have been made to prevent this event occurring again in the future.

Following these recent IG incidents, an email was sent from NHSBT's Data Protection Officer (DPO), to the senior leadership team reminding all of our data protection responsibilities and the need to be mindful regarding how we communicate with, and share data donor/patient data.

3. Action Requested

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

4. Serious Incidents (SI)

There was one new SI within this reporting period:

- DTS INC76020: Delayed Delivery of Cardiac Tissue. Cardiac surgery on a 2-month-old boy was brought forward to the 14/5/18 from 15/5/18 as he was unwell. The tissue required for the operation was booked to be collected at 03:00 from Tissue Eye Services (TES) in Liverpool on 14 May. At 08:00 on 14/5/18 TES were informed the valve had not been collected. The surgery was cancelled and was subsequently carried out successfully 15 May. The surgeon confirmed that there was no deterioration in the boy's condition between the 14 and 15 May as a result of the delay. NHSBT has undertaken a joint investigation with the courier TNT who did not collect the tissue at the allotted time. Both organisations have strengthened their processes to ensure orders do not get missed in this manner.

5. Risk

There are currently sixteen risks recorded within Pentana at a divisional risk level, which have the primary risk impact area recorded as clinical. This comprises one high scoring risk (=/>15), fourteen moderate / low risks and one very low scoring risk. The high scoring risk relates to the risk that collections of whole blood and platelets are inadequate to meet the demand; scored 16 (4x4).

6. Complaints, compliments, and commendations

In Organ Donation and Transplantation (ODT) ten complaints were noted within this reporting period; eight clinical and two non- clinical. The two non-clinical complaints were relating to social media. Closure timescales have been reduced from 20 days to 18 days and this has resulted in some overdue complaints. Some of these are out of NHSBT's control, due to the complexity and involvement of Trusts, and arranging face-to-face meetings with complainants.

Compliments were received across most services in DTS. A customer feedback survey has been performed by the International Blood Group Reference Laboratory (IBGRL) relating to non-invasive fetal *RHD* blood group: 100% of customers would recommend the service and 82.5% of the survey questions scored "top box" responses (9 or 10) out of 10. Complaints are monitored at DTS Clinical Audit, Risk and Effectiveness (CARE) Group, and there have been no upward trends reported in this period.

The Blood Donation (BD) teams were commended for their early management of vasovagal events, thereby preventing the events from becoming more severe.

7. Blood Supply (BS)

Six Serious Adverse Events of Donation (SAEDs) were reported in April; one was a hospital admission (24 hours), two involved a fracture (24 hours), two were coincidental events and one was a death (7 days). Three SAEDs were reported in May; the first was a hospital admission (24 hours), the second was related to needle insertion (1 year) and the third was a fracture (24 hours). The death related to a 65-year-old male who had a Myocardial Infarction (MI) four days after donating platelets. He was a regular platelet donor with over 200 previous donations. The post mortem report identified coronary artery atherosclerosis as a cause of death resulting in a severe MI. There is no reported link or association with blood donation.

There were no confirmed reports of Transfusion-Transmitted Infections (TTIs) in this reporting period.

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.

Eighteen events; nine in Cellular and Molecular Therapies (CMT), four in TES and five in Therapeutic Apheresis Services (TAS), were reportable to the Human Tissue Authority (HTA) as Serious Adverse Events and Reactions (SAEARs). With the exception of the aforementioned SI, there was no evidence of an error by NHSBT resulting in harm to a patient.

There was loss of access to the TAS unit in Bristol (QI8056) due to a fire in the host Trust building. The emergency plan was successfully invoked, and all patients were successfully treated. This was reported to the HTA and the Care Quality Commission (CQC).

9. Organ Donation and Transplantation (ODT)

ODT have yet to receive an update from the Department of Health and Social Care regarding the retrieval of organs from pregnant females. It was agreed by the National Donation Committee that ODT should commence pregnancy testing of all women of child bearing age, defined by National Patient Safety Agency (NPSA) Public Health England (PHE) as aged 12-55yrs, will be rolled out nationally.

10. Information Governance (IG)

Two incidents of IG severity score level two, the levels go up to five, were reported to the ICO, an additional incident did not meet the threshold to be reportable, but the decision was made to inform the ICO to seek advice and guidance. Level two incidents, and above, are reportable to the ICO. All occurred in June 2018 outside the reporting period of this paper:

- The first related to the Serious Hazard of Transfusion (SHOT) team, whose governance is the responsibility of NHSBT. SHOT use an online platform called TOAST Digital to securely share data including minutes of meetings, CVs of potential members and other administrative documentation. A member of SHOT discovered that a CV containing their name, home address and date of birth, which they had shared through this platform, had become available on Google through a search. At this stage we believe 30 CVs have been breached. Immediate actions have been undertaken to ensure that this documentation is no longer available via google search, and formal request has been put to google to remove this functionality as well as a formal request to TOAST to rectify this issue.
- The second incident, which was not ICO reportable, relates to the Britain's Got Talent email sent to just under 500,000 blood donors, suggesting they may wish to vote for the B positive choir. Five donors complained and have received an apology. This has been investigated as a major Quality

Incident (QI) and a number of processes have been amended to prevent this occurring again.

- The third incident relates to an email sent from a donor centre, inviting potential new whole blood and platelet donors to a session; the email contained the personal email addresses of the 160+ plus recipients. Whilst no formal complaints were received, numerous complaints were made directly to the sender and/or the centre.

Following these recent IG incidents, an email was sent from NHSBT's Data Protection Officer (DPO), to the senior leadership team reminding all of our data protection responsibilities and the need to be mindful regarding how we communicate with and share donor/patient data.

11. Clinical Audit

The 2018/19 Clinical Audit Annual Report was approved. A total of ten clinical audits were completed in 2017/18 from a programme of 40. Fifteen were started and will progress into 2018/19, whilst the remaining fifteen were not started. CARE agreed that the already approved new structured clinical audit plan for 2019/20, better reflects the work and approach required regarding clinical audit in NHSBT.

One clinical audit report was approved; DTS: Follow on Audit of Fetal Genotyping for *KEL* in IBGRL (AUD3547). This highlighted the need to increase the awareness in Hospitals about the importance of follow samples as only 22% patients had a follow up sample tested where this should have occurred Similarly only 4% babies had a confirmatory test at birth on cord blood.

12. Research update

12.1 One Suspected Unexpected Serious Adverse Event (SUSAR) occurred in the TREATT trial in a patient recruited to the trial in Oxford and was reported to the MHRA. The patient died suddenly unexpectedly, and as it was not clear why they died, the site Principal Investigator (PI) deemed the event to be unexpected and possibly related to the investigational product (tranexamic acid). The CI/sponsor assessment of this event is that there is no reasonable possibility of the event being related to the tranexamic acid. The case has been referred to the Coroner, and NHSBT awaits the results of the post mortem.

12.2 NHSBT is uniquely positioned to support UK research establishments with the provision of Leukapheresis collections from healthy donor volunteers to support pre-clinical trial research projects. By establishing these services, NHSBT will be setting the foundations in positioning itself to support phase 1 and 2 clinical trials in the future. CARE supported the provision of Leukapheresis collection services from healthy donor volunteers.

12.3 CARE was asked to consider the level of consent required from donors and donor families before donated material can be used to create cell lines; and whilst not a regulatory requirement, specific consent is considered to be best practice and CARE were asked to support the request. The proposal, was in principle supported, but outlined the delivery of this for each study needs to be addressed and consideration as to if and how NHSBT will support will be

study specific. It was agreed the governance and oversight would be through ODT CARE.

13. Safeguarding

The safeguarding annual report was approved by CARE. During 2017/18, there was a total of 14 safeguarding incidents reported within NHSBT. Of these incidents, none required escalation to external agencies for further investigation.

14. Safety Policy Matters

There were no meetings of the Advisory Committee on the Safety of Blood, Tissues, and Organ (SaBTO) or its working groups in this reporting period. The SaBTO Paediatric components working group has had to delay making recommendations regarding the continued provision of imported plasma and apheresis platelets for individuals born after 1995, as the Advisory Committee on Dangerous Pathogens' Transmissible Spongiform Encephalopathy **(**ACDP TSE) subgroup's revised blood safety risk assessment has yet to be completed. This will be completed by the end of July and the working group will meet in September. After making recommendations there will be a consultation with stakeholders, including patient groups and the Creutzfeldt-Jakob disease (CJD) support network, in the Autumn with support from the NHSBT communications team.

Increased demand for imported plasma means that this cannot be met solely by male donors. Around 20% of demand will have to come from female donors who need to be screened for HLA & HNA antibodies to reduce the risk of TRALI. The testing regime will be audited to ensure it meets UK (Red Book) standards and has appropriate adequate regulatory oversight before female plasma donations are accepted. This was discussed at the Therapeutic Products Safety Group (TPSG).

Authors
Louise Cheung, Assistant Director,
Governance and Clinical Effectiveness

Gary Mallinson, Safety Coordinator

Responsible Director
Dr Gail Miflin
Medical and Research Director