NHS Blood and Transplant (NHSBT) Board
27 September 2018

Clinical Governance Report
01 June – 31 July 2018

1. Status – Official

2. Executive Summary

- There were no new Serious Incidents (SI) within this reporting period.
- The Infected Blood Inquiry (IBI) announced in July 2017 has now commenced with publication of the terms of reference. The Inquiry will hold a preliminary hearing in London on 24-26 September, commencing with a service of commemoration.
- An immediate Central Alerting System (CAS) alert was received from the Chief Medical Officer on the evening of the 2 August (outside this reporting period). This pertained to a number of unsolicited packages with accompanying literature requesting testing. Details on precautionary measures required for dealing with these packages were given. The alert was managed well however issues with our management of out of hours immediate CAS alerts were picked up and are being resolved.

3. Action Requested

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

4. Serious Incidents (SI)

There have been no new SIs within this reporting period. Updates on previous SIs.

- Diagnostic Therapeutic Services (DTS) INC76020: Delayed Delivery of Cardiac Tissue. This SI has now been closed.

There are currently no SIs open within NHSBT.

5. Risk

There are currently fourteen risks recorded within Pentana at a divisional risk level, which have the primary risk impact area recorded as clinical, this is a reduction of two from the previous report. This comprises no high scoring risks (=/>15), thirteen moderate / low risks and one very low scoring risk.

6. Complaints, and compliments

There has been an increase in the number of compliments received from across ODT, with 15 compliments being received in the reporting period. There were seven complaints noted within this reporting period. Five clinical complaints related to service delivery, two non-clinical complaints related to the website.

A total of 56 complaints were raised across DTS and 73 relating to Manufacturing and Logistics (M&L) in this reporting period, this was generally consistent with previous reporting periods. Compliments were received across most services in DTS.

7. Blood Supply (BS)

One Serious Adverse Event of Donation (SAED) was reported in June (road traffic collision – 24 hours), Four SAEDs were reported in July. Two were fractures (24 hours), one was a coincidental event and one was a hospital admission (24 hours).

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

Following a review by staff in Blood Donation (BD) and Quality Assurance (QA) there is a plan to pilot a new algorithm that will support staff in decision making around the process to be undertaken for events relating to arm pain, the aim of this is to reduce the number of nerve injuries.

8. Diagnostic and Therapeutic Services (DTS)

One event was reported to the Medicines and Healthcare Products Regulatory Agency's (MHRA) in August and related to the failure of an automated analyser (IH1000) to detect plasma dispensing errors. A manual checking process has been put in place and the error has not since been duplicated.

Eighteen events (seventeen in Cellular and Molecular Therapies (CMT), one in Tissue and Eye Services (TES)) were reportable to the Human Tissue Authority (HTA) as Serious Adverse Events and Reactions (SAEARs). There was no evidence of an error by NHSBT resulting in harm to a patient.

9. Organ Donation and Transplantation (ODT)

There has recently been an audit of offers and allocations by the chair of Liver Advisory Group (LAG). This was triggered by a specific concern raised that the allocation process was being possibly manipulated by centres. The chair of LAG has confirmed that the audit did not identify any conduct that was a clear breach of allocation. A policy on audit and governance of the allocation process is being developed and a paper should be ready for discussion at LAG in November. This will also address the actions to be taken in the event of such a breach of allocation rules.

EU legislation enshrined in UK law requires that donor information is kept for 30 years after donation and that such data may be stored in electronic form. Currently donor files are part electronic only (information entered directly into DonorPath) and part electronic and paper (all the supplementary information documented on paper is scanned into DonorPath as well as being retained in paper form). Consideration was given to a proposal to move to an electronic only filing system and to destroy the paper copies. It was agreed that this would be considered and agreed as part of a wider consideration of NHSBT's approach to digitisation of records. It was also agreed that ODT would seek the view of NHS Digital and NHS Improvement on this matter

10. Information Governance (IG)

NHSBT currently has 14,500 unclaimed/untraced boxes of paper records stored at Iron Mountain. The issue of the unclaimed boxes poses a number of risks for NHSBT including; regulatory, statutory, reputational and financial risks. As part of the legacy records pilot work an NHSBT team reviewed 100 boxes of archived records stored at Iron Mountain to ascertain: the owning department, the type and volume of records contained in each box, whether or not the records had reached or exceeded their retention period and could be destroyed or had to be retained for longer for traceability. Just over 50% of the boxes (52/100) could be destroyed due to exceeding their retention period, of those boxes 11 were kept for further review in relation to the IBI. A proposal of how to resolve the issue of the legacy boxes will be presented to November ET in conjunction with reporting of progress on the IBI.

11. Clinical Audit

Two clinical audit reports were approved:

- DTS AUD2611: Referrals to Red Cell Immunohaematology (RCI) Laboratories Outside of Core Hours. The audit highlighted issues regarding the completeness of data provided by hospitals to RCI, along with a number of referrals where red blood cell units were issued but not subsequently transfused within three hours (an indicator that the referral could possibly have been evaluated within the core-hour period). Internal communication processes between Duty Consultants and Biomedical Scientists (BMS) were followed in the majority of cases, demonstrating that the RCI BMS staff who are working on-call understand the scope of their practice and have a clear understanding of the nature of cases that require the input of the Duty Consultant.

- BD AUD3503: Management of Arterial Punctures. This audit was as a result of a previous audit (AUD2352) regarding the Management of Donation related Adverse events which highlighted specific issues in arterial punctures in donors. Arterial punctures are important to avoid as they may, rarely, result in severe damage within the arm if bleeding is not controlled. The audit identified 121 arterial punctures across a seven-month period and, in nine of those cases, arterial punctures were not diagnosed until after the session based on the clinical picture reported by the donor to the Clinical Services Team (CST). Although these were managed well clinically, several gaps in documentation were also found, with errors including transcription errors which have the potential to impact on donor safety significantly through mismanagement following donation or putting donor safety at risk. The need for this to be re-audited again to ensure practice has improved was agreed. The audit recommended refresher training for all staff involved in the management of arterial punctures; an electronic donor clinical referral form be designed for submission directly to the CST inbox; and that in future IT systems more than one permanent donor instruction be allowed on a Donor's record rather than just one as currently allowed.

12. Research update

No research governance issues were reported.

13. Infected Blood Inquiry

The IBI announced in July 2017 has now commenced with publication of the terms of reference.

NHSBT, the Department of Health and Social Care (DHSC), and four other UK Blood Services and Health Departments are all designated core participants. JPAC is not a core participant but will be involved through NHSBT.

The Inquiry will hold a preliminary hearing in London on 24-26 September, commencing with a service of commemoration. The Chair of, and Counsel to, the inquiry will outline the way in which the Inquiry proposes to carry out its work. Core participants or their legal representatives can then make opening statements.

Further details are outlined in the separate paper submitted to this Board meeting.

14. Central Alerting System (CAS) Alert

An immediate CAS was received by QA from the Chief Medical Officer on evening of the 2 August (outside this reporting period). This pertained to a number of unsolicited packages with accompanying literature requesting testing. Details on precautionary measures required for dealing with these packages were given. Whilst the alert was managed well and distributed across NHSBT, issues were identified in how NHSBT manages and urgency CAS alert out of hours immediate CAS alerts were picked up. Immediate actions have been put into place to address this, and further actions agreed to test this change.

14. Safety Policy Matters

There have been no meetings of the Advisory Committee on the Safety of Blood**,** Tissues and Organs (SaBTO), the Joint UK Professional Advisory Committee (JPAC) or the Therapeutic Products Safety Group (TPSG), in this reporting period, and therefore no updates for this report.

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