NHS Blood and Transplant (NHSBT) Board
29 November 2018

Clinical Governance Report
01 August – 30 September 2018

1. Status – Official

2. Executive Summary

- In April 2017, Patient Blood Management (PBM) launched an Indications Code App. The app guides clinical staff in the appropriate indications for the use of blood. Since its launch it has had over 7000 users; 60% of users have returned to the app and pages on the app have been viewed more than 83,000 times.
- All current Information Asset Owners (IAOs) have now completed their information asset training.
- The Randomised Controlled Trial CRYOSTAT-2 recruited ten patients from one site without following proper emergency consent procedures. Recruitment has been temporarily halted whilst the Trust employed research nurses are re-trained. Please see section 12 for further details.
- The new Leicester Donor Centre was successfully registered with the Care Quality Commission (CQC) and was opened and collecting blood to planned timescales.
- NHSBT has responded to a further Rule 9 request from the Infected Blood Inquiry (IBI). The DHSC have agreed to take primary responsibility for representing aspects relating to BioProducts Laboratory in the past.
- The Executive Team (ET) approved work to address the longstanding issue of the 14,797 unclaimed/untraced boxes.

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 and there are currently no SIs open within NHSBT.

5. Risk

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

6. Complaints, and compliments

Within Organ Donation and Transplantation (ODT) a total of 15 compliments were received in this reporting period. There were five complaints; three clinical complaints

related to service delivery, and two non-clinical complaints related to the website and Hub Operations.

Compliments were received across most services in Diagnostic and Therapeutic Services (DTS). A six-monthly customer satisfaction survey was undertaken with Hospital Transfusion Laboratory Managers, and with the exception of component availability (which had a top box score of 59% and is the lowest score for 2 years), all indicators demonstrated a positive trend, with customers responding 99% satisfied or very satisfied with service received.

In this reporting period a total of 74 complaints were raised relating to DTS and 84 raised relating to Manufacturing and Logistics (M&L). There was no discernible trend in DTS related complaints.

7. Blood Supply (BS)

Three Serious Adverse Events of Donation (SAEDs) were reported in August and three in September, an increase of two from the last reporting period. Four of the SAEDs related to needle insertion, one was a fracture and one related to a hospital admission following a faint and head injury, and the donor was discharged the following day.

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

A National Quality Incident (QI) has been raised to investigate that during the last 6 months there have been 56 incidents in Blood Donation (BD) (<0.01% donations) where legal consent has not been obtained from donors. A Root Cause Analysis (RCA) will be done and measures put in place to reduce occurrence. A training video has been created for collection teams and a revised training package will be available on-line.

8. Diagnostic and Therapeutic Services (DTS)

In April 2017, PBM launched an Indications Code App. The app guides clinical staff in the appropriate indications for the use of blood. Since its launch it has had over 7000 users; 60% of users have returned to the app and pages on the app have been viewed more than 83,000 times.

Sixteen events (thirteen in Cellular and Molecular Therapies (CMT), two in Tissue and Eye Services (TES) and one in Stem Cell Donation and Transplantation (SCDT)) 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)

Whilst there is no further decision in relation to pregnancy testing and organ donation, it was referred to the British Medical Association's (BMA) ethics committee, at the request of the Department of Health and Social Care (DHSC). ODT await the outcome of the October meeting.

10. Information Governance (IG)

No incidents were reported to the Information Commissioner's Office (ICO) in this reporting period. However, two cases remain open with the ICO from previous reports.

All current IAOs have now completed their information asset training.

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 three have already reported, and a further ten are on track to be completed and report within 2018/19. Two DTS audits; Audit of Serum eyedrops in TES, and audit of Bacteriology Positive Donations in CMT will not report in 2018/19 as planned. The data collection periods for these two audits have been altered, to allow sufficient time following service process changes. These two audits will now report in 2019/20. This was approved at October DTS CARE and supported at November National CARE.

One clinical audit report was approved, BS (AUD3205): Re-audit of Medical Referral and Deferral codes. The key findings regarding coding were; medical coding was applied correctly in 99% of cases, an improvement of 9.8% compared to the previous audits, and deferral coding was applied correctly in 96.5% of cases, an improvement of 7.4% from the previous audits. The one area for improvement was compliance with Good Documentation Practice (GDP) which was 56.3%. The nurse training plan will be updated to pick up the issues identified as part of this audit.

12. Research update

CRYOSTAT – 2 is a multi-centre, Randomised Controlled Trial evaluating the effects of early high-dose cryoprecipitate in adult patients with major trauma haemorrhage. Due to the clinical scenario patients are treated on a consent waiver (as per ethical approval) and this is retrospectively obtained. Ten patients did not have retrospective consent obtained. This has now been rectified, an RCA has been held and more training completed in the centre where this happened. No harm has occurred.

The CTU commissioned a mock MHRA Good Clinical Practice (GCP) audit of the TREATT Trial (trial to evaluate antifibrinolytic therapy in thrombocytopenia). The audit was undertaken in April – June 2018 and identified a number of learning points and improvements. The audit identified three major findings which were predominantly as a result of the processes and knowledge at the time of the trial set up. Actions have been put into place to address all the issues raised, and a GCP Quality Assurance Specialist is being recruited who will be dedicated to the CTU.

13. Infected Blood Inquiry (IBI)

NHSBT has responded to a further rule 9 request from the Inquiry Team. A rule 9 request refers to a written request from an inquiry team regarding the collection of evidence as part of that inquiry. This request is for some clarification around information already provided on our records.

The current elements of the 'heritage' IT systems containing pre-Pulse donor records have been reviewed and a recommendation that a database is created from the back-ups of the Heritage PCs currently held on the G Drive. The objective is to create a single source for all look-back requests that pre-date Pulse. A proposal to proceed with this work will be presented to the Transformation Programme Board (TPB) following consideration through the ICT demand management process.

Currently Iron Mountain (IM) hold 14,797 unclaimed/untraced boxes of NHSBT data, the content of which is unknown, this equates to 17% of all data held by IM. The ET approved a recommendation to commission IM to conduct a full box review including allocating to department and providing a description of box content on the IM Connect system. This will enable NHSBT to respond to the inquiry team comprehensively. We are liaising with the IBI team about how best to view around 2500 boxes that they wish to see.

Following discussions with the DHSC they have agreed to represent BPL and its witnesses.

14. Care Quality Commission (CQC)

NHSBT liaised with the CQC to trial a revised registration process for new donor centres which reduces the likelihood of service disruption. The new process was used to successfully register the Leicester Donor Centre, which was opened and collecting blood to planned timescales.

15. Clinical Claims

ODT has no new claims this year to date, and currently has two on-going claims.

DTS has one active claim from 2010, which is a long-standing claim regarding a baby born with severe anaemia due to Haemolytic Disease of the New-born (HDN) and is awaiting more time to assess the impact on the child. Both NHSBT and the Trust have admitted liability on a 50/50 basis.

M&L have one existing (HIV) and one new (Hepatitis C) claim, both of which have been accepted by NHS Resolution (NHSR).

At the start of 2018/19 BD had seven active claims; three have been settled, and one has been withdrawn, with one new claim.

16. Safety Policy Matters

The Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) reviewed the regulation on Advanced Cellular Therapies (ACT) beginning with an overview of developments in ACT since the last SaBTO review in 2014. A time-limited working group will consider updating guidance on the impact of the General Data Protection Regulations (GDPR) and the potential for transmission of neuroproteinopathies such as prion disease, Alzheimer's and Parkinson's disease from cell cultivation & propagation.

The SaBTO paediatric components working group to assess the importation of plasma is ongoing. The blood safety risk assessment is to be endorsed by the full ACDP committee before the stakeholder consultation. The report will now go to SaBTO in April/May 2019.

Authors
Louise Cheung, Assistant Director,
Governance and Clinical Effectiveness

Gary Mallinson, Safety Coordinator

Responsible Director
Dr Gail Miflin
Medical and Research Director

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