NHSBT Board Meeting
September 2020

Clinical Governance Report

1. Status – Official

2. Executive Summary

During this reporting period of June and July 2020 there was one new serious incident (SI) recorded within NHSBT that was included in the last period's report.

Three additional incidents were escalated to directors as requiring formal assessment calls. These all now continue to be investigated as major incidents.

3. Action Requested

The Board is requested to note the contents of the paper and discuss where relevant.

4. Overview of incidents/events.

During this reporting period of June and July 2020 there was one new SI recorded within NHSBT.

OTDT INC 4791

A patient proceeded to organ donation after brain stem death. Following donor characterisation and organ offering, the lungs, kidneys, and liver were accepted and subsequently transplanted. The heart was unsuitable for solid organ transplant and there was no consent for heart donation for the purpose of heart valves. The family received a follow-up letter as per usual protocol informing them of the above and no further dialogue was had with the family after this.

Four months later the SNOD received an email from the Donor Records Department (DRD), informing them that the local coroner's officer had enquired if the heart from this donor was retrieved and transplanted, as during the Post-mortem (PM) it was documented that there was no heart present with the body. The donors Next-of-Kin had been informed of this by the Coroner. An immediate investigation was instigated.

As some time had passed from the day of donation to receiving new information from the Coroner about the heart not been present at the PM, it was not possible for those involved to recall precisely what happened, but the teams involved are confident that usual protocols were followed. There is no evidence to suggest that the heart was left outside of the body.

A face to face meeting was held with the family and whilst they understand we have been unable to reconcile events to know what precisely happened, they would like to request access to all the records we hold and also to the Trust's medical records.

Three additional incidents were escalated to directors during the reporting period as requiring formal assessment calls. These are all now being managed as Major Quality Incidents and are being managed via the respective Directorate CARE groups.

- Clinical Services QI 19016: During May 2020 the blood storage fridge in the Red Cell Immunohaematology (RCI) laboratory in Filton had broken down and the team had

been using blood transport boxes as an alternative. It was identified that this process deviation may potentially have led to red cell temperature excursions. This activity was stopped, and temperature validations were performed. A recall was initiated and continues. Hospital feedback has currently been received on fates of over 400 of the 728 units which were identified to have been potentially affected. No patient impact has been identified

- Clinical Services QI 19211: A Spanish transplant unit contacted the British Bone Marrow Registry (BBMR) to inform us that they were not going to use a bone marrow donation that had been harvested in the UK, frozen and shipped to the transplant facility in Spain where it was being stored. The tissue typing lab there had identified a mismatch between the donor and recipient which suggested that the patient's mother's type had been used to select the donor in error. It has been identified that pre-harvest only the confirmatory recipient typing had been undertaken, with the analysis having been performed after the donation had been made. The transplant centre in Spain has declared a serious incident and is undertaking an investigation. The donor has been contacted and offered an apology on behalf of the international transplant community. The donor did not report any major complications of the donation and is recovering in a satisfactory manner. No errors have been identified in NHSBT processes. The World Marrow Donor Association (WMDA) have since issued a Serious (Product) Events and Adverse Reactions (S(P)EARs) rapid alert which includes the statement *"(The) Transplant Centre must confirm the final donor selection and assess and confirm the recipient's eligibility for a scheduled transplant before the donor starts the donation procedure (i.e. start of mobilisation or hospital admission for bone marrow donation)".* This will reduce the risk of recurrence internationally.

- Clinical Services INC 80544: Following contact from the referring hospital, it became apparent that a potential sample switch had occurred in the International Blood Group Reference Laboratory (IBGRL) Molecular Diagnostics department in Filton. This has resulted in one false negative and one false positive non-invasive, high throughput fetal D screening type affecting two women who were receiving antenatal care. Two samples had been taken on the same day (02/12/19) and sent from the referring hospital. The samples were received and processed by IBGRL on 03/12/19 and reports were issued on 06/12/19.The referring hospital informed us on 22nd June 2020 that the baby predicted to be D negative by our fetal screening had proven to be D positive. The switch in samples resulted in incorrect predictions that one woman was carrying a D negative baby and the other a D positive baby.

  Following a previous incident (INC77867) changes to the process were implemented, there continues to be a very small error rate in the procedure that is consistent with this being a manual process. This event is within this error rate (<0.1%) which includes pre-analytical (wrong blood in tube and sample transposition), analytical and post-analytical errors. This is the level defined as cost effective by the National Institute of Health and Care Excellence (NICE). The operator had been trained and has a satisfactory performance record. The clinical risk to the mother of forming anti-D is an additional 0.7% over the baseline risk of 0.3%. Letters of apologies have been sent to hospitals. We continue to explore an automated solution and will be introducing standard sample tubes in anticipation of one becoming available in the medium-term future.

4. Infected Blood Inquiry (IBI)

A large number of documents continue to be reviewed and all requests for information are being managed. IBI hearings are due to recommence during September with representation from Lord Owen and Haemophilia Centre Directors.

5. Care Quality Commission (CQC) (Clinical Inspections)

Virtual relationships are being maintained with the CQC. An engagement meeting between NHSBT and CQC is planned for 1st October. The CQC are reviewing future inspection plans after suspending routine inspections at the start of the pandemic.

6. Clinical Audit

More clinical audits are being resumed following COVID-19 related pause and reprioritisation, with sixteen currently in progress. Three additional clinical audits have been added to the programme (Convalescent Plasma, Medical and Deferral Coding Received by Clinical Support Team, and NHS Bereavement Helpline). As priorities and resources available become clearer, it is anticipated that some audits originally planned to complete within 2020/21 will now complete in 2021/22. This is being actively managed by Directorate CARE groups.

A revised clinical audit risk assessment process was approved. Clinical audits will now report using a three-stage assessment of risk, and Directorate CARE groups will be required to review clinical audit risks against assessments listed in Pentana.

7. Risk Management

The strategic level (parent) risk: NHSBT-01, Safety and Quality of Clinical Care currently has 44 recorded functional (child) level risks, with no high scoring, priority 1 risks (risks with a residual score =/>15). The risk management team continue to work with business areas to review scores, descriptors, controls, and review dates.

Blood Supply are actively monitoring risks associated with donating Convalescent Plasma. Current figures indicate a higher faint rate. Associated factors are likely to be multi-factorial. A working group has been set up to monitor these events.

8. Information Governance

The Data Security and Protection Toolkit (DSPT) submission has been extended by NHS Digital until end of September 2020. The IG team are sending reminders to staff that are not compliant with IG Training.

No incidents were reported to the Information Commissioner's Office (ICO) during this reporting period.

9. Safety Policy Update

The NHSBT led group looking at the For Assessment of Individualised Risk (FAIR) study have completed their work for submission to SaBTO in October.

Author: Andrea Harris, Clinical/DTS Professional Nursing Lead

Responsible Director: Dr Gail Miflin, Medical and Research Director