NHS Blood and Transplant

NHSBT Board

Clinical Governance Report
July 2020

1. Status – Official

2. Executive Summary

During this reporting period of April and May 2020 there were no new serious incidents (SI) recorded within NHSBT, however one has subsequently occurred outside the reporting period. All previous SIs had been closed. Five incidents were escalated to directors as requiring formal assessment calls. These all now continue to be investigated as major incidents.

INC 4791 – OTDT has subsequently been reported to the Board in June as a serious incident. In December 2019, a patient proceeded to organ donation. Following 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 valve donation. Subsequently the coroner reported that the heart was not present in the body at post-mortem. Further investigation continues.

3. Action Requested

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

4. Overview of events.

During this reporting period of April and May 2020 there were no new serious incidents (SI) recorded within NHSBT. All SIs had been closed.

INC 4791 – OTDT has subsequently been reported to the Board in June as a serious incident, and further investigations continue.

On 4th December 2019, 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 valve donation.

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.

On the 28th April 2020, the Specialist Nurse Organ Donation (SNOD) received an email from the Donor Records Department 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.

Upon receipt of this information the Organ Donation Services Team management team were informed, and a detailed review of the case began.

OTDT contacted the family who appreciated us contacting them and were very understanding of the situation and asked to be made aware of the outcome of the internal investigation.

We have as yet been unable to definitively confirm what happened to the heart, and we are continuing our investigation into this incident.

Five incidents were escalated to directors as requiring formal assessment calls. These all now continue to be managed as major incidents. Three (INC79914, QI18406, QI 18462) were included in the last report and are not included here.

In addition, the following occurred during the reporting period;

QI18802 - Clinical Services - On Saturday 16 May 2020, an urgent referral was received by Therapeutic Apheresis Services for plasma exchange treatment for a 20-year-old female who had overdosed on paracetamol. Full personal protective equipment (PPE) was required as her COVID-19 status was not known. Prior to commencing treatment, she had a low blood pressure. After the procedure commenced her blood pressure fell further requiring the procedure to be stopped. The patient lost cardiac output and cardiopulmonary resuscitation (CPR) was commenced but proved unsuccessful and she did not survive. There were no procedural errors on the part of NHSBT and the patient died despite our support and that of the Trust team. The patient was very unwell with a guarded prognosis when referred. This event is being managed as a major quality incident.

INC80357 – Blood Supply - On 12th April 2020 at 23:41 Manchester Hospital Services received an emergency delivery request for two units of platelets with a requested time of 01.00. The platelets were for a child with neutropenic sepsis who at around 23:00 had become severely unwell with a low platelet count of 5x109/l. The hospital informed Manchester Hospital Services that they would be requesting an emergency delivery and asked how long it would be. The answer was one hour. However, the hospital emergency delivery SLA is one hour 25 minutes. The platelets were received late at 01.18 (12 minutes over the SLA time and 42 minutes past the one hour quoted time). The child suffered cardiac arrest and passed away around one hour after receiving transfusion of platelets due to sepsis. The hospital has reported that whilst this delay did not contribute to the death of the patient, it delayed the management of the patient's serious condition. Additional to this the emergency delivery SLA was also not met. Both these factors are being investigated as a major quality incident and CAPA is ongoing.

During June and July, outside of the reporting period, five additional incidents were escalated to Directors as requiring formal assessment. Three of these are being managed as major incidents. Two continue to be investigated as SI.

5. Clinical Audit

Previously it has been reported that the planned Clinical Audit programme for 2020/21 has been revised due to COVID-19. This revised timetable is being reviewed via the Directorate CARE groups on a regular basis. Currently seven of the 28 planned clinical audits are continuing, and one new audit report has been approved.

6. Risk Management

The strategic level (parent) risk: NHSBT-01, Safety and Quality of Clinical Care has 39 recorded functional (child) level risks. There are currently no high scoring, priority 1 risks (risks with a residual score =/>15). The risk team continue to work with business areas to review scores, descriptors, controls, and review dates. This will be presented to GAC in an upcoming meeting.

7. Information Governance

There has been one Information Governance incident reported to the Information Commissioners Office in this period. This is being investigated.

The deadline for submissions to the new Data Security and Protection Toolkit (DSPT) has been extended to September 2020 due to COVID-19. Reminders are being sent to ensure mandatory training requirements for this submission are met.

8. Research

The 6-monthly report form the Clinical Trials Unit highlighted that due to COVID-19, most of the trials that were in recruitment in March were paused, and one was terminated early. There has subsequently been a reduction in the number of serious adverse events and incidents. Any adverse events in patients receiving convalescent plasma are being monitored in collaboration with the Serious Hazards of Transfusion (SHOT). To date there has been one suspected Transfusion Related Acute Lung Injury (TRALI) in the RECOVERY trial, which remains under investigation.

9. Safety Policy Update

Nothing new to report.

Author: Andrea Harris, Clinical/DTS Professional Nursing Lead

Responsible Director: Dr Gail Miflin, Director of Clinical Services