NHS
Blood and Transplant

NHSBT Board

Clinical Governance Report

25th March 2021

Status: Official

1. Summary and Purpose of Paper

This paper summarises the NHSBT CARE meeting held 1st March 2021.

1.1 During December 2020 and January 2021, no new Serious Incidents (SIs) were reported, one SI was closed,

1.2 The safety framework was reviewed, and CARE recommended to continue to use the ABO Risk-Based Decision-Making Framework for any significant safety decisions.

1.3 As we move to collect plasma for fractionation, we are reviewing the clinical governance for this.

2. Action Requested

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

3. General updates

3.1 The implications of the new announcement to lift the ban on the use of UK plasma to produce immunoglobulins have been discussed. As decisions are made regarding collection of sourced plasma, CARE will review how incidents and clinical governance work with respect to this and this may be dependent on our model of provision. Currently incidents in CVP are discussed in Blood Supply CARE and SMT.

4. Serious Incidents (SI)

4.1 During December 2020 and January 2021, no new SIs were reported. All SIs are closed.

4.2 Two initial SI calls were held during this period, but these were downgraded and managed as Major Quality incidents:

- ***QI19194*** - ***Coroner's Schedule 5 Request*** *(from CSO)*
  A Schedule 5 communication was received from the Coroner with respect to this incident. There had been multiple contacts with the coroner who had requested a report relating to recalled platelets administered to the deceased. NHSBT has investigated the donation implicated in the recall and no component fault has been identified. Preventable donor/donation associated issues which could have resulted in the deterioration in the recipient's condition had therefore been excluded but this had not been communicated to the coroner. The process of communication with coroners has been investigated and improved.

- ***ODT INC 5249 - Transport failure (from OTDT)***
  A donation after circulatory death (DCD) donor liver was accepted by a centre in January 2021 but was later declined. Due to the late decline, the liver was fast-tracked and accepted by another liver centre for a patient who had been previously called in for transplant. Due to travel times, it would be blue-lighted to ensure a timely transplantation. The liver however was dispatched to the incorrect centre, the error was made by the driver. All escalation processes were followed correctly. A possible

SI call was held but agreement that this although a serious incident for the intended patient, it was not an SI for OTDT. A root-cause analysis (RCA) has been carried out with the transport provider to ensure that a recurrence does not occur and to ensure that the transport provider checks in regularly with their drivers.

Whilst the patient may have missed this opportunity for transplant, it is not definite that they would have been able to have this transplant until the liver had been looked at by the recipient centre. Given the ischaemic times for transplant of DCD livers, there is no guarantee this would have gone ahead.

5. Clinical Governance

5.1 *Blood Supply (BS)*

- The Donor Health Check and donor consent statement are being revised. Interim consent is being agreed to support the collection of plasma for fractionation.
- A fault was identified with a PK7300 blood group analyser in Filton Testing, which could have led to false-negative syphilis results being generated. The machine has been repaired and revalidated. The clinical risk of this is extremely small, a letter will be sent to hospitals but was deliberately postponed for a few weeks due to the pandemic.

5.2 *Clinical Services Operations (CSO)*

- The fetal *RHD* screening customer survey showed a Net Promoter Score of 96%. The "Voice of the Customer" survey in Cellular Molecular Therapies (CMT) has also indicated 100% customers satisfaction.
- NHSBT have been asked to provide short term, out of hours therapeutic apheresis support for patients with thrombotic thrombocytopenic purpura (TTP) cared for at University Hospitals Birmingham NHS Foundation Trust.

5.3 *Organ and Tissue Donation and Transplantation (OTDT)*

- Three recent incidents involving COVID 19 infection within days of transplantation have been reported to us:
  - Liver recipient –The patient subsequently died of COVID19. The infection was found to have come from the city of origin of the recipient rather than the donor. The other recipients from the donor concerned were informed of the outcome and all are currently well.
  - Bilateral lung recipient - The recipient was asymptomatic and remained so following transplantation. It is thought that the recipient received lungs from someone who had already had COVID19 infection. This case is highlighted to illustrate the importance of follow up of patients.
  - Heart recipient – It is thought the infection is due to a chain of transmission due to the patient being in hospital for some months prior to transplantation. Despite doing well initially, the patient subsequently died due to COVID19.

6. Information Governance (IG)

6.1 The Data Security and Protection Toolkit (DSPT) baseline was submitted end of February 2021.

6.2 Correspondence is continuing with the Information Commissioner's Office (ICO) regarding the ongoing incident in OTDT. A new incident has been raised by a staff member, which relates to a dignity at work complaint. The ICO are happy with the way this latter incident was managed and have closed this case.

7. Risk Management

7.1 One risk has been closed and three new risks have been recorded, all residual risks for these are 6 or lower.

8. Clinical Audit

8.1 The Internal Audit, Quality Audit and Clinical Audit plans were submitted to and reviewed by ARGC this month. Leads from these areas will continue to work to align these so that the Board can view audits across the organisation and how they relate to risks and incidents.

9. Therapeutic Products Safety Group (TPSG)

9.1 The safety framework was reviewed, we have continued to use the ABO Risk-Based Decision-Making Framework for any significant safety decisions. This was used this year to decide on safety assessment to inform the procurement of arm wipes used in cleansing of blood donors' arms. This framework is widely used across international blood services in addition to JPAC and SaBTO. Blood services not using this tend to use internal frameworks as we previously did. CARE do not recommend moving from this framework.

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