NHS Blood and Transplant

NHSBT Board Meeting

Clinical Governance Report

30th September 2021

Status: Official

1. Summary and Purpose of Paper

This paper summarises the clinical governance issues discussed at NHSBT Clinical Audit, Risk and Effectiveness Committee (CARE) meeting held 31st August 2021.

- There are two open Serious Incidents (SIs) that are currently being investigated, these have been reported to the Board. Two previously open incidents have been closed since the last report.
- A new probable case of occult Hepatitis B infection (OBI) transfusion transmission is reported in an individual who received 11 units of red cells in 2019.
- The SaBTO working group on OBI have recommended to SaBTO that an anti-Hepatitis B core antibody is performed once on all donors. The working group is still considering recommendations on a lookback process. An implementation group has been stood up to determine how this will be introduced in NHSBT.
- A Government Internal Audit Agency (GIAA) audit to review the adequacy and effectiveness of the current NHSBT process for horizon scanning for emerging infections, particularly following the EU Exit, has concluded that the current processes are operating effectively and are supported by proportionate governance arrangements. The audit conclusion is that a Substantial Assurance is appropriate. One recommendation has been made in line with good practice that NHSBT formalise and document a periodic internal review of the process.
- The Chief Medical Officer in England has approved the restart of the REMAP-CAP arm of COVID19 convalescent plasma to immunosuppressed patients in light of emerging evidence. A plan to restart is being agreed.

2. Action Requested

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

3. Serious Incidents (SIs)

Two previously open incidents have been closed since the last report. There are currently two open Serious Incidents (SIs) recorded within NHSBT during June and July 2021:

3.1 OTDT: QI25942 - Pre-cut cornea was not acceptable for transplant

A pre-cut cornea graft issued from the Filton eye bank to a hospital in England. The Pre-cut tissue supplied had a thickness that met NHSBT release criteria. However, during the surgery, the surgeon felt that the graft was not acceptable for transplant due to an uneven cut in the eye bank, and abandoned surgery after removal of the patient's cornea.

Although it is a usual practice for this hospital to request the tissue from NHSBT, the cut is usually requested to be done at another eye-bank. Additionally, this particular surgeon is not

part of the relaunch arrangements to be supplied with pre-cut cornea grafts and thus we should not have supplied a pre-cut cornea to this hospital.

A number of factors led to this happening which are being addressed via the action plan. Our processes currently only measure central thickness. An Optical Coherence Tomography (OCT) instrument is used in other eye-banks for measuring thicknesses across the entire corneal graft. An OCT machine is now on order so the thickness across the entire cornea will be measured prior to future dispatch. The cutting service remains paused until the machine has arrived, and staff are fully trained in its use.

3.2 BS: INC82403 - cytomegalovirus (CMV) positive granulocytes

A customer ordered some granulocytes but failed to add into the requirements on the Online Blood Ordering System (OBOS) that the patient (scheduled for Bone Marrow Transplant) required CMV negative granulocytes. The Consultant Approval form included the CMV negative requirement. This should have been checked against the OBOS order as part of our process, but this was not done and therefore the CMV neg requirement was missed and not supplied. The patient was CMV negative but was transfused with both CMV positive and negative granulocytes.

Both organisations have called this a serious incident and are communicating on this case. We have apologised to the patient and their family for our part in this incident, via the Consultant in charge of their care. The patient was given prophylactic treatment, they remained CMV negative throughout the post-transplant period. Unfortunately, unrelated to this error, the patient sadly recently died from complications of the transplant.

The Root Cause Analysis indicated that three steps of SOP4146 were not followed, and the Consultant form was not cross checked against OBOS order at different occasions. Training needs have also been highlighted to improve understanding of granulocyte transfusion and requirements for CMV negative units. Further actions are being completed to simplify the multiple manual processes involved in the granulocytes ordering process.

A communication to all hospitals has been sent out regarding the importance of ensuring that this specification is requested accurately on OBOS.

3.3 One additional initial SI call was held during this reporting period, but this was downgraded and managed as Major Quality incident, this related to delayed engraftment of frozen allogeneic stem cells during the pandemic (QI25847), the number of patients was small and many of them had other reasons for delayed engraftment. There were no errors in our processes.

4. Care Quality Commission (CQC) update

Following the “potential safety concern” raised anonymously to the CQC regarding the air in line incidents during donation of plasma, the CQC have now confirmed that they do not require any further information from NHSBT.

5. Risk Management

After approval by the Executive Team (ET), a Prevent training package will be provided to NHSBT staff by an external provider. No new clinical risks were added to the risk register

6. Clinical Governance

6.1 Probable Occult Hepatitis B transmission (QI21066) – A patient who had contracted Hepatitis B was reported to us in October 2020 as a potential transfusion transmitted infection following routine screening during dialysis treatment. He received 11 units of red cells in 2019. No other source or risk factors for HBV infection were identified. Public Health England (PHE) identified his HBV strain as genotype E. The patient originates from an HBV endemic area where this strain is prevalent, and reactivation cannot be completely excluded. Ten donors had their archives from subsequent donations tested and were negative for anti-HB core antibodies, thus excluding HBV infection in these donors. An archived sample of the remaining one donor tested positive for anti-HB core antibodies and HBV DNA was also detected at low level by an individual NAT. These results are consistent with an occult HBV infection. As this donor originated from the region where genotype E HBV infection is prevalent, further sampling was considered to allow genotyping. Four sample tubes were received for HBV testing, but HBV DNA was not detected in concentrated sample. Thus, we could not confirm transmission by sequence comparison, however on balance, the clinical team have determined the imputability to be probable. This has been reported to SHOT, MHRA and PHE.

6.2 The Government Internal Audit Agency (GIAA) has conducted an audit to review the adequacy and effectiveness of the current NHSBT process for horizon scanning for emerging infections, and to assess whether the implications of EU Exit has adversely impacted NHSBT's ability to perform the function in any way. The audit concluded that the current horizon scanning arrangements are operating effectively and are supported by proportionate governance arrangements which enable the process to identify emerging infections or highlight changes to existing mitigation actions in a timely manner. Therefore, the audit conclusion is that a Substantial Assurance is appropriate. One recommendation has been made that NHSBT formalise and document their periodic internal review activities in relation to identifying and assessing the sources of intelligence used to inform horizon scanning, and the overarching process itself. This would encourage ongoing refinement and improvement to the horizon scanning process and provide enhanced assurances that it was operating effectively.

6.3 The REMAP-CAP trial restart was approved by the England Chief Medical Officer. The trial will assess the effectiveness of COVID convalescent plasma with high titre antibodies for therapeutic use in immunosuppressed patients. The restart plan is being drawn together.

7. Clinical Audit

7.1 Two clinical audit reports were approved in August 2021: A re-audit of the clinical outcomes of pre-cut corneal grafts. Although there have been improvements, some issues with re-bubbling and graft failures remain and 10-13% of grafts were reported to be unevenly cut. In light of the current SI (QI25942) and re-suspension of the corneal cutting service, an action is being taken to implement OCT imaging to identify these problems.

7.2 An audit of urgent referrals to nurse within Therapeutic Apheresis Services provided assurance that changes to the referral process to allow Nurse Practitioners to accept patients referred for Thrombotic Thrombocytopenic Purpura, Sickle Cell Crisis and Hyperleukocytosis are being followed and working, with referrals to medical staff appropriately made where required. The audit highlighted the need for further minor improvements to the referral process.

8. Information Governance

The IG team launched IG and cyber security champions programme to raise awareness and to provide a collective understanding across the business on the importance of security both at work and at home.

9. Safety Policy Update

9.1 In 2019, following two incidents of transmission of occult Hepatitis B, the NHSBT Chief Medical Officer asked SaBTO to review the current processes and determine whether any changes to testing were required.

A SaBTO working group has been working through the pandemic to look at options. Following an initial assessment, two main options were considered. These were moving to individual donation testing for the triplex NAT (nucleic acid testing) for HBV, HCV and HIV. Or, alternatively, to keep the current process of pooled NAT testing and instead introduce an additional test (anti-hepatitis B core antibody testing) for all donors on a single occasion. That is all existing donors and all new donors. In March 2021, the working group recommended to SaBTO that anti-hepatitis B core antibody testing should be implemented on the basis that this was more cost-effective and reduced the risk to a lower absolute level. SaBTO accepted the recommendations, and this is noted in the public SaBTO minutes, but had also asked the working group to make recommendations for a lookback exercise. Recommendations to Ministers will be made once the SaBTO working party final report is complete. The principle of a lookback has been agreed; however the details and recommendations are expected in the full report at the October SaBTO meeting. The anticipated cost for this testing is £6m/10 years and the additional costs of lookback will depend on the extent of this.

In anticipation that recommendations will be accepted by Ministers, UK blood services have been considering potential implementation timescales and will want to introduce this concurrently. An operational group has been set up in NHSBT to explore options. Anti-hepatitis B core testing is already done in NHSBT on a small scale as a discretionary test, but the new increased volumes will require significant amendments to laboratories, contracts and personnel. The new microbiology serology contract is due to start in December 2022, but introduction cannot wait that long. Depending on the size of the lookback this could also require an increased clinical team.

9.2 SaBTO recommended that Human Herpes Virus 8 (HHV-8) testing be carried out for all solid organ donors. This is awaiting Ministerial approval. The plan is to test but not wait for results before transplantation, whilst also gathering data to inform patient monitoring and treatment strategies/interventions to assess outcomes.

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