NHS Blood and Transplant

NHSBT BOARD
Clinical Governance Report
16th September 2019

1. Status – Official

2. Executive Summary

- A new probable case of HBV was reported to CARE 2nd September. This is a second case of occult Hepatitis B (OBI) and was reported to the Board last week.
- Considerations of any changes to policy or testing regimens following our HEV transmission and our two probable HBV transmissions reported this year have both been referred to The Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO). Two papers have been submitted, one is a summary of OBI transmissions within UK Blood Services together with a review of the current knowledge as documented in the literature. We recommend that SaBTO consider this an emerging risk and consider if there need to be changes to policy in light of this. The second is on the prevalence of HEV testing and near miss events following the implementation of UK wide HEV testing in 2016.
- There were no new Serious Incidents (SIs) within this reporting period. All previous SIs are closed.

3. Action Requested

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

4. Overview of relevant events this reporting period

4.1 There were no new SIs within the reporting period, all previously reported incidents have been closed.

4.2 A new probable transmission of Hepatitis B was reported to CARE. We were contacted directly by a patient in January 2019. He had been advised by a hospital that he might have acquired his hepatitis B infection via blood transfusion as despite extensive investigations, no other sources for his infection were identified. He got our details through the Infected Blood Inquiry team, but they did not refer this case.

A patient had cardiac surgery in 2015 and received three units of red cells during that period. They were subsequently diagnosed as having chronic hepatitis B infection in 2016 and have been on treatment since. Investigations were done because their partner developed acute hepatitis B infection in 2016. Although they had not been tested previously for hepatitis B, it was expected that this infection was likely acquired via blood transfusion received in 2015. The hospital considered and excluded other sources of HBV, but blood transfusion was not considered at the time. Based on clinical evidence, it is likely that they had asymptomatic infection which then developed into chronic hepatitis and also led to infection in their partner.

We identified three donor exposures and tested a subsequent sample from all three donors. One of them tested positive for anti-HB Core antibodies but negative for HBV DNA by individual NAT testing. As this donor originated from the region where genotype D2 HBV infection is prevalent, further sampling was considered to exclude occult HBV infection (i.e. infection with a very low viral load, which is often detected

after concentration of sample only, despite that potential for transmission). Eight sample tubes were received for testing, but HBV DNA was not detected in a concentrated sample. However, this does not exclude the possibility that there might have been low levels of HBV DNA present in the unit transfused to him.

Following our investigations, we conclude that it is probable that they acquired a hepatitis B infection via a blood transfusion. We have identified a donor with past HBV infection with a very low level of surface antibodies. Although we could not confirm the transmission by sequence comparison, circumstantial evidence of this donor originating from the region where this genotype is prevalent, further supports transmission.

4.3 ODT INC 4157. NHSBT were approached to lead a review to establish any identifiable causative factors into this case in which a donor died. An internal review took place immediately. The review panel identified no causal factors and concluded the programme to be well run with excellent policies and protocols in place for the whole donor pathway from assessment to follow-up; consistent with UK best practice guidelines, achieving excellent patient outcomes. A full report with recommendations is expected in due course.

4.4 GDPR; a proposal to ET to close the project end of September supported with the implementation of transition plan for activity into IG business as usual was agreed. The key next focus will be to embed the role of the information asset owner and continue to develop and improve on the register, incorporating risk assessment and annual returns to SIRO. It is likely to take 2-3 years for the organisation become mature in this regard. Activity will be monitored by Information Governance Committee reported to CARE. A further audit is planned this year.

4.5 The request to report to the GAC on the importance of the five themes of patient safety and how we discharge this within the organisation is ongoing and will be reported to the November GAC meeting.

4.6 Research, There is a recent call from The National Institute for Health Research (NIHR) for research in solid organ transplantation following some work done with them: The call is specifically 'NIHR is interested in receiving research proposals from the community that will overcome barriers and challenges to organ donation and transplantation, specifically solid organ donation and transplantation of those organs that are included on a donor card; heart, lungs, cornea, liver, pancreas, small bowel, tissue, kidneys, and bone'.

The current round of NIHR Blood and Transplant Unit funding runs until 30th September 2020. Following discussions with colleagues at the DHSC, an 18-month extension to funding has been agreed and the Unit Directors will be asked to submit proposals for work to be carried out during this 18-month extension. Final approval on proposals will be given by DHSC, with prior review by the R&D Committee in December.

5. Safety Policy Matters

Two papers have been submitted to SaBTO, one is a summary of OBI transmissions within UK Blood Services together with a review of the current knowledge as documented in the literature. We recommend that SaBTO consider this an emerging risk and consider if there need to be changes to policy in light of this. The second is

on the prevalence of HEV testing and near miss events following the implementation of UK wide HEV testing in 2016.

6. Report Focus-

6.1 Actions from last focus item SHOT

The 2018 Serious Hazards of Transfusion (SHOT) report was reported last meeting. It was noted that delays in the provision of blood were a common cause of avoidable deaths. The eight deaths due to delay described in the SHOT report were as a result of failure to recognise the severity of bleeding and urgency of transfusion within the hospital, none were related to delays in provision by a blood transfusion service such as NHSBT.

Within NHSBT complaints and incidents are reviewed in depth each month by SMTs. In the year September 2018 to August 2019. NHSBT issued 1.87m components, via 109,200 deliveries of blood and utilised couriers for a further 46,800 deliveries. During this time 76/901 hospital complaints related to delayed provision of blood and hence delayed transfusion. Four of these resulted in a cancellation / delay to planned surgery until appropriate blood was available as the surgery was not urgent enough to warrant proceeding with alternative contingency blood. There is no evidence that patients died or suffered morbidity related to the speed of provision of suitable blood by NHSBT during the last year. These are all also reviewed through CARE.

As mitigation to this risk

- Hospitals hold stocks of blood components sufficient to provide contingency for most emergencies. The urgent delivery of blood by NHSBT is required typically in relation to the following scenarios:
  - In the event of a major incident with multiple casualties when large volumes of standard and “universal” blood components are needed.
  - When higher levels of compatibility testing or specification are required (e.g. blood for neonatal exchange transfusion, provision of extended typed blood for a specific patient and/or reference laboratory matching of blood).

- NHSBT’s procedures have built into them requirements to contact NHSBT medical staff, nurses or clinical scientists who are available 24/7. There are also guidelines on the provision of blood rapidly when the ideal component is not available. The availability of staff working to these procedures minimises the risk that delays will result in harm.

In preceding years there has been 1-2 events per year when reference laboratories have been asked to provide compatible blood and we have been made aware that the patient has died prior to, during or following transfusion. The last three have related to patients with sickle cell disease. The provision of compatible blood was by necessity slow and consistent with international practice when suitable donations are scarce. All have been reported through CARE and one used as an example case for the Board. Two had coroner’s inquests where NHSBT was represented. The coroner was satisfied with the support provided by NHSBT and commented positively on the quality of evidence provided in person by a Therapeutic Apheresis nurse. The family of one of the deceased provided news articles highlighting the need for more donors of African ancestry

6.2 Shared Learning in ODT Focus

Cautionary Tales
in Organ Donation and Transplantation

NHS Blood and Transplant

Issue 23, July 2019

Hepatitis C transmission

Organ transplantation is associated with risk and the risk of adverse outcomes must be balanced against the anticipated benefit for the intended recipient. Clinicians have to make the difficult decision whether to accept or decline an offered organ, with the risk that the potential recipient may become too sick or die before another, potentially more suitable organ is available.

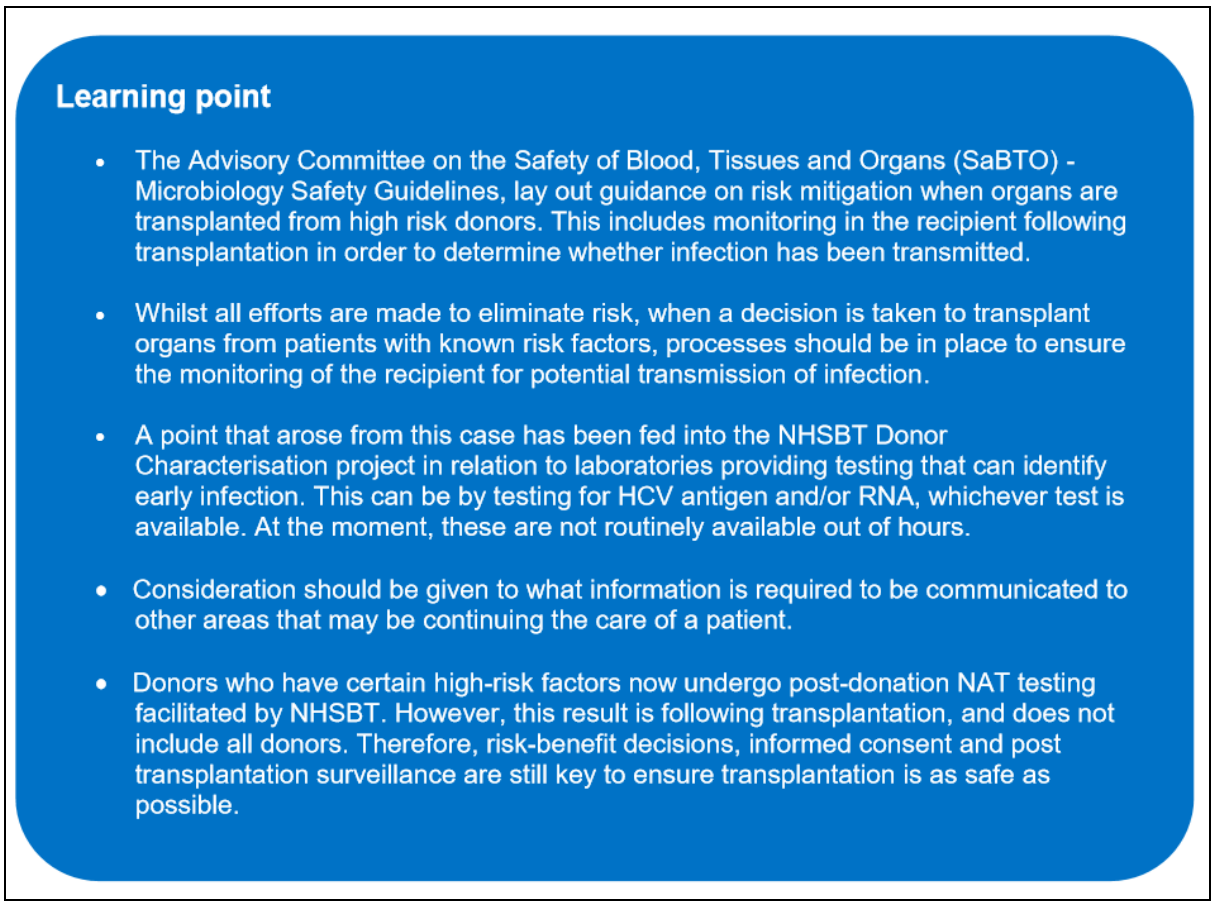
In a recent case, organs were offered from a potential donor with known behavioural risk factors. A full microbiology screen was completed and a negative Hepatitis C (HCV) antibody result was provided. The Consultant transplant surgeon accepted the liver for a recipient, taking into account the risk benefit as the patient was in urgent need for a transplant. As the virology results were negative, standard consent was obtained from the recipient at the time of transplantation.

The retrieval and subsequent transplant were uneventful, and the liver recipient recovered well. They had required ongoing renal dialysis support pre-transplantation, and this requirement remained post-transplant and was managed by the renal dialysis unit. Again with no concerns.

During routine virology screening on the renal dialysis unit, approximately four weeks post transplantation, the liver transplant patient was reported to be HCV positive with a high viral load (they had been HCV negative pre-transplantation). On further testing of the donor sample, the organ donor was identified as being HCV RNA positive. It is important to note that it was confirmed that the organ donors HCV antibody negative result prior to organ donation was a correct result at the time, and there was no error during the testing process or any transcription error. The donor sample has undergone retrospective testing and there is evidence they were in the 'window period' (the time between potential exposure and the point when a test will give an accurate result) at the time of donation. The recipient was treated with a directly acting antiviral and has tested HCV RNA negative subsequently. All patients in the haemodialysis unit that could be followed up were confirmed as HCV RNA negative at the end of the screening period.

Potential transmission is a known risk when transplanting organs from high risk donors, however after reviewing this case, there are a number of learning points highlighted and actions taken. The transplant centre has identified and actioned the below:

- There was no standardised consent policy for patients receiving organs from high risk donors. Therefore, this has been developed to ensure that the risks and benefits are clearly communicated.
- All liver transplant patients were treated as high risk on the liver transplant unit. Therefore, no information was conveyed with regards to this to the treating Haemodialysis Team who were already dialysing the patient pre-transplant in an open bay. A clear communication pathway is now in place.
- A guide has been developed to standardise follow up of patients that have received high risk organs with guidance on serological surveillance.



A key element of good governance is to ensure that lessons are learnt, learning is shared, and practice is changed. A variety of methods are in place to share learning with all stakeholders in ODT, both internal and external**.** One of these is learning from clinical governance incidents where a quarterly bulletin 'Cautionary Tales 'is prepared to ensure key events are communicated as widely as possible to the Organ Donation and Transplant community. The bulletin is well received and serves as a useful forum to share learning widely. An excerpt from the July edition is above. In addition, there is also a quarterly 'Learning from Complaints' bulletin that is shared internally which was featured in the January 19 Clinical Governance report.

ODT have also introduced 'Learning form excellence'. Safety in healthcare has traditionally focused on avoiding harm by learning from errors, but this can miss opportunities to learn from excellent practice. Excellence in Organ Donation and Transplantation is highly prevalent, but there is no formal system to capture it. To redress the balance, we are now beginning to review examples of great practice and share widely. The CG team believe this will create new opportunities for learning and improving resilience and staff morale.

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