NHS Blood and Transplant

NHSBT Board

Clinical Governance Report

March 2020

1. Status – Official

2. Executive Summary

There are two new incidents within this reporting period, one was classified as a serious incident and the other as a major quality incident.

• **New SI ODT INC 4576 –** One new Serious Incident (SI) has been reported during this period and an interim report was sent to the Board. This relates to the UK Living Kidney Sharing Scheme Matching Run (UKLSS MR), where a donor was incorrectly suspended, resulting in neither the donor nor the recipient appearing on the MR.

• **Major QI 38153 -** Probable blood component transmission of Hepatitis E virus (HEV) infection. A patient in their 20s with a severe form of bone marrow failure together with a separate genetic condition was diagnosed with acute HEV infection. They had received 24 donations as part of treatment. This has been reported to SHOT. The recipient remains well and has cleared their infection without a hepatitis but remains on treatment.

A significant clinical claim (£25M) has been settled by NHS Resolution that NHSBT was jointly liable for following the birth of a baby in 2010 with severe haemolytic disease of the new born.

NHSBT is working closely with Public Health England (PHE) and the Department of Health and Social Care (DHSC) to ensure the safety of donors, patients and staff in response to COVID-19, this is addressed in the CEO report to the Board.

3. Action Requested

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

4. Overview of events in this reporting period

One new SI **ODT INC 4576:** has been reported during this period and an interim report was sent to the Board. This relates to the UK Living Kidney Sharing Scheme Matching Run (UKLSS MR), where a donor was incorrectly suspended, resulting in neither the donor nor the recipient appearing on the MR.
In addition, when the MR was generated and sent to transplant centres, Information Services were contacted by a transplant centre to inform them that they had registered their patient with an incorrect human leucocyte antigen (HLA) type.
During our investigations into this incident, it was also noticed that a further recipient was incorrectly suspended from the UKLSS MR. There were therefore three errors in the MR. An immediate decision was made to declare the MR null and void, all transplant centres involved were informed. The current process was thoroughly reviewed and a number of specific extra checks were instituted and agreed prior to a re-run being completed. The MR was then sent to all transplant centres to be checked and agreed prior to it being implemented. After positive confirmation was received from all centres the MR was issued. A root cause analysis (RCA) looking at both recent matching run events has been completed and a rapid improvement event (RIE) event is underway.

Major QI 38153: Probable blood component transmission of Hepatitis E virus (HEV) infection. A patient in their 20s with a severe form of bone marrow failure together with a separate genetic condition was diagnosed with acute HEV infection. They had received 24 donations as part of treatment. The stored archive samples from all 24

donations she had received were tested individually. One of the red cell donations tested positive for small amount of HEV RNA (31 IU/ml). This was not picked up by the original screening test which was performed on a pool of 24, with a detection limit around 500 IU/ml, in accordance to NHBST procedures. A further sample from the donor confirmed their HEV infection. The low viral load prevented more definitive sequence comparison between the virus in the patient and that in the donor. This case has been reported to the Serious Hazards of Transfusion (SHOT) haemovigilence scheme as a probable transmission.

5. Infected Blood Inquiry Update

Please see CEO report for this update.

6. **Claims**

The High Court approved a settlement for over £25m on behalf NHSBT and a Trust, through NHS Resolution (NHSR). A baby was born in 2010 at the West Suffolk Hospital (WSH) with severe anaemia due to haemolytic disease of the fetus and new born. An important report from NHSBT had not been copied to an antenatal clinic as requested and action advised in NHSBT's report was not taken. The hospital also identified issues in its own care. NHSBT and the Trust accepted joint liability for deficiencies in the management of the child's mother's antenatal care. Unreserved apologies for the tragic incident have been offered to child and family. This incident highlights the importance of ensuring that information is available to those caring for a patient and the patient themselves. We improved our processes governing copies of paper reports at the time which reduces the likelihood of recurrence but being able to provide electronic reports direct into hospital laboratory systems would be a much more robust solution to ensure the mistake is not repeated.

7. **COVID -19 Update**

This is addressed in the CEO report to the Board

8. **Safety Policy Update**

8.1 Occult Hepatitis B

Work looking at the risk of OBI transmission through blood continues by SaBTO. The group intends to complete its work within one year and conduct a wider stakeholder consultation before recommendations are made.

8.2 Consent for Transfusion

SaBTO is reviewing its 2011 transfusion consent for transfusion guidance. A UK wide working group has been established to review any changes to the legal framework (e.g. Montgomery) and consider any new guidance produced since the 2011 recommendations. Revised recommendations are being developed and there will be legal review and wide stakeholder consultation before revised recommendations are published.

8.3 Risk tolerability working group

The SaBTO risk tolerability subgroup held a meeting focussing on how cost thresholds for safety related decisions were assessed and applied in health care settings. The group had looked at the experience NICE had in creating and applying cost thresholds for QALYs (quality adjusted life years) to see if some elements could be applied to SaBTO work. A third meeting will explore how risk tolerability and cost effectiveness can be balanced in establishing and maintaining a robust and consistent safety framework.

8.4 HEV

SaBTO continue to review of the testing strategy for HEV at the next meeting in May.

8.5 FAIR group (For the Assessment of Individualised Risk)

FAIR is a UK forum funded collaboration between PHE and the University of Nottingham. The group are looking the application of individualised risk assessment for donors who are currently deferred for 3 months as they fall within a category of high-risk behaviour but as individuals are low risk and compliant with donor deferral criteria. The FAIR group recommendations will go to SaBTO for consideration before going to UK health ministers

9. Clinical Audit Programme Update

The clinical audit programme is based on priorities identified by the operational directorates. Proposals are submitted to the directorate Clinical Audit Risk and Effectiveness (CARE) committee. The reasons for undertaking audit include risk (clinical audit can be listed as a control method), to assess the impact of service or procedural changes, to re-audit and assess progress since previous audits or to support the investigation of serious incidents.

The Clinical Audit department commits to supporting the audits proposed by the directorates and CARE process but is flexible to changes in prioritisation. It is anticipated that ten of the seventeen clinical audits planned for completion in the financial year 2019-2020 will be completed. The outcomes will be reported in detail to GAC in May 2020 as planned and the GAC has reviewed the future clinical audit plan at the recent meeting.

Thirteen clinical audits are timetabled to complete during the financial year 2020-2021. Two within Blood Supply (BS), seven within Clinical Services (CS) and four within Organ and Tissue Donation and Transplantation (OTDT). Six have already commenced and seven new audits will commence and complete in 2020-21. Two rolling audits (in CS and OTDT) will also continue in 2020/21.

10. Report Focus: UK Kidney offering scheme changes and early outcomes.

Background

In the UK each year around 2500 kidneys from deceased donors are transplanted into recipients on the waiting list. There are around 5000 patients actively waiting for a kidney transplant, with another 2500 joining the waiting list each year. At NHSBT we try to be as fair as possible in offering kidneys to patients on the waiting list, recognising that some patients have different requirements to others. For example, some people are more difficult to find a suitably matched kidney for than others; some patients are more likely to reject a kidney than others; and younger patients need a kidney that will last them a long time, something that is not as important for an older recipient. We balance the needs of different groups of patients while trying to keep the length of the wait as short as possible for everyone.

What is the new offering scheme?

When a donor is registered with NHSBT details of the donor, such as age, sex, and tissue type, are entered onto the national computer. The computer then looks to see if the kidneys will be a match for any of the 300 or so most difficult patients to match on the waiting list, the ones likely to wait the longest for a transplant. If there are no difficult to match patients waiting, priority is then given to the few patients waiting for a liver, heart, lung or pancreas transplant on their separate waiting list. After that the computer

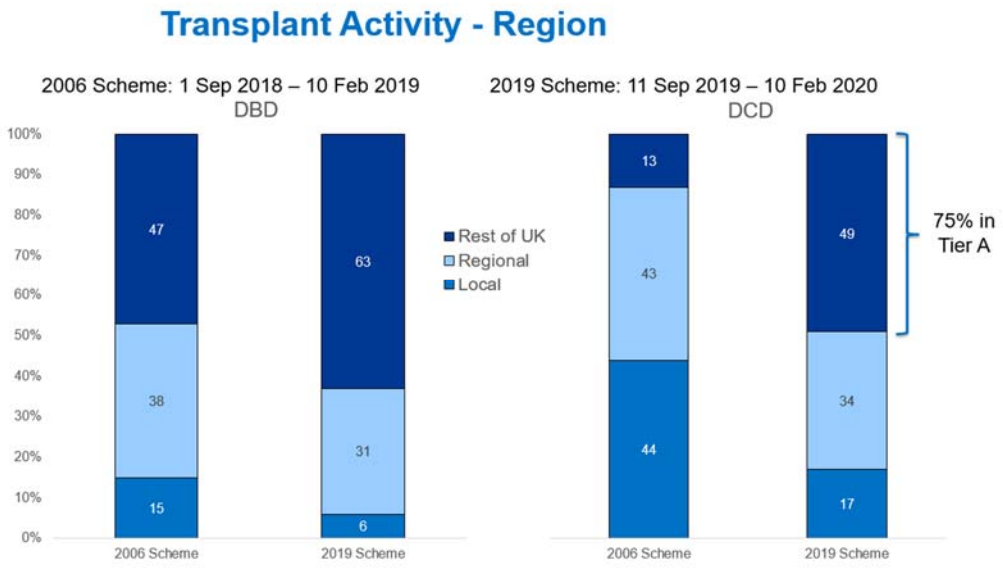
then looks at all the other 4700 patients on the kidney transplant waiting list. It gives points to each patient depending both on recipient factors (e.g. how long they have been waiting), and on how well the donor – patient pair meets all the objectives of the offering scheme, such as tissue matching, age matching and trying to give younger patients kidneys that are likely to last longest. The combination of donor and patient that score the highest will get the kidney offer. This offer is then phoned to the transplant centre where the transplant surgeon will consider whether this kidney is suitable for the patient for whom it has been offered. If it is the patient will then be called in to receive the transplant.

Why the need for the change and what was the change

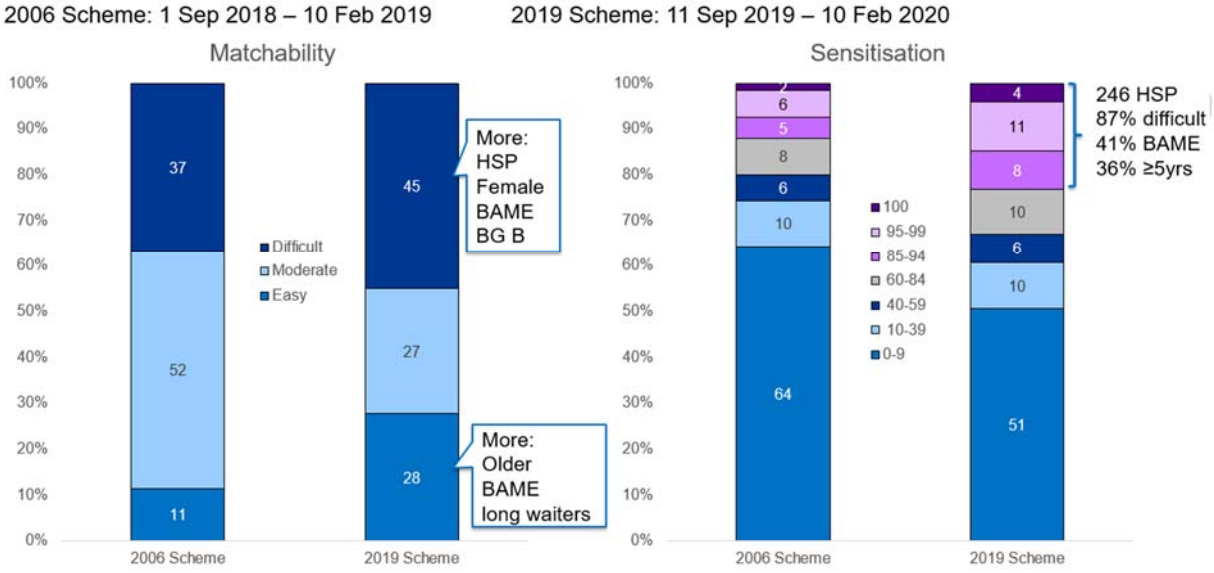
In 2006 the current scheme was drawn up which offered both kidneys from every donor after brain death (DBD) to anyone on the national waiting list. Priority was given to children, to patients who were difficult to find a match, and increasing priority was given for every day a patient was waiting. This scheme has been very successful, but inevitably some groups have been identified for whom the scheme is not fair enough. The new scheme which was introduced in September 2019 looks to fix those few problems that remain. It is an evolution of the 2006 scheme, without dramatic changes. It has been put together with the help of transplant experts from around the country, as well as patient representatives, ethicists, and transplant scientists (histocompatibility and immunogenetics experts). The old five tier system will be replaced with a new two tier system such that the patients who are the most difficult to find a transplant for, and who we think will have a long waiting time, will get most priority (they will be in Tier A) and all other patients will appear in Tier B.

Early impact and benefits (including BAME)

45% of all transplants performed in the first 3 months were in difficult to match patients compared with 35% in the year prior to the scheme release. 23% of patients were classed as highly sensitised compared with 10% in the year prior. 37% of transplants performed in the first 3 months were in BAME patients compared with 32% in the year prior. There were 35 patients who were 100% sensitised that received a transplant in the first 3 months of the scheme, of these 16 were BAME and 17 had waited >5 years.



Transplant Activity - Demographics



How will the scheme benefit patients long term?
In the long term the scheme has been designed to reduce waiting time to transplant for difficult to match patients to bring it in line with easy and moderate to match patients. As a consequence of this more BAME patients will receive a transplant as they tend to have rarer tissue types in the UK. Paediatric patients and young adults will benefit by having access to kidneys that will last longer hoping to reduce the number of transplants they need in their lifetime, whilst older patients will wait a shorter time to transplant than currently for an organ that will meet their requirements.

This data was shown at the recent BTS/NHSBT conference and was well received. Thanks to Rachel Johnson, Lisa Burnapp and their teams for this information.

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