NHS Blood and Transplant

NHSBT Board

Clinical Governance Report

January 2020

1. Status – Official

2. Executive Summary

One new Serious Incident (SI) has been reported within this period but was discussed at the last meeting. Incidents are updated as below

- **New SI ODT INC4397 –** A live kidney matching run was made with the incorrect suspension of a recipient. This run resulted in the disadvantage of five patients, 3 of the patients were prioritised on the kidney transplant waiting list. These three patients have been transplanted
- **SI ODT INC 4278** – Previously reported to the Board, this incident relates to the New Kidney and Pancreas Allocation Scheme where a piece of code in development for a future liver release was released into the live environment inadvertently, without testing (as it was not planned for release). This resulted in three patients not receiving the offer of a liver transplant, one of them has subsequently been transplanted. New processes for IT releases across the organisation are now in place. The incident has also been logged with the ICO under the categorisation of a data availability breach.
- **SI Filton Eye Bank QI15283**, this incident where a corneal cutting machine was cutting thicker than it should have resulted in eight cases of primary graft failure. This incident is due to be closed imminently. All clinicians treating the patients have been contacted, discussions are ongoing.
- **Major QI 6007** – previously communicated to Board, a confirmed Hepatitis E transmission resulted in the death of an immunosuppressed patient with pre-existing liver disease. An apheresis platelet donation tested positive on pooled NAT for HEV RNA. A lookback investigation was initiated, the archive sample retrieved, and the previous donation was positive by singleton NAT for HEV RNA. Previous archive samples were negative. Two patients received the positive donations; the recipient who died was found to be HEV positive, but the other recipient has so far tested negative and will continue to be followed up.

Following recent reports of a novel coronavirus infection in China, JPAC have assessed the risks to the blood supply chain. Donors are already deferred from China for 28 days because of tropical infection risk, however we considered that additional measures need to be put in place to ensure contacts are also deferred. The Change Notifications have been approved urgently by UKBS Medical Directors and will be implemented urgently. Work is ongoing on assessing the risk to the Tissues and Cell Guidelines.

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 Serious Incident (SI) has been reported within this period, in Organ Donation and Transplant (ODT) **(Serious Incident ODT INC4397)**. This was communicated to the Board in late November and discussed at the last Board meeting. A recipient was incorrectly suspended on the Living Kidney Sharing Scheme (LKSS) matching run. This caused an incorrect matching run. Discussion took place at the Kidney Advisory Group in relation to actions to be taken. Patient prioritisation was agreed with the patients affected and the clinical leads of the centres involved. The three patients prioritised have since been transplanted. A closure report has been submitted.

SI ODT INC 4278 (Previously reported): On the 11th September 2019 the new planned Kidney and Pancreas (KP) offering scheme went live. On 18th September 2019 a liver transplant centre made enquiries in relation to whether a patient had appeared on a matching run and why they had received an offer for a patient who had died in February 2019. Preliminary examination of the matching algorithm identified unexplained recipient exclusions from the Liver Matching Run (LMR). Patients who should have been present on the LMR were omitted. An immediate investigation took place. It was identified that there was a piece of code in development for a future liver release and that this was released into the liver matching run in the live environment inadvertently, without any testing (as it was not planned for release). After a detailed simulation of the matching runs it was identified that three patients were affected by this incident. Two of the patients were removed from the liver transplant waiting list. The third patient has been successfully transplanted. We continue to liaise with the clinical teams.

A significant piece of work in IT is underway to prevent recurrence, this involves improvements to the control checks in the initial work, the testing regimens and adding a series of additional reviews and checkpoints with the development team to add an additional mitigation prior to release. All IT releases have been halted whilst we have put this additional piece of work in place. Our proposed interim process involves a series of review workshops, one per scheduled change - each workshop will look at a range of criteria:

- Whether key stages have been executed – system test, regression test, user acceptance etc
- Whether they are properly documented – e.g. a documented test strategy in place
- Whether key exit criteria for each stage have been fulfilled

Alongside this 'process' focus, we are reviewing more subjective questions:

- Coverage and completeness of the testing
- Complexity of the release
- Potential risks to patient safety

We plan to test this strategy and implement for an interim period of time whilst we review this area more fully.

We have also logged this incident with the ICO under the categorisation of a data availability breach, which is defined as 'if critical medical data about patients are unavailable, even temporarily, this could present a risk to individuals' rights and freedoms; for example, operations may be cancelled.' The ICO have responded with a number of detailed questions about the incident and were provided a response on 21st January 2020 along with and a full copy of the RCA and action plan. This has now been sent to the ICO

SI QI5283 – Pre-cut Corneal Tissue (Previously reported); This incident where a corneal cutting machine was cutting thicker than it should have resulted in eight cases of primary graft failure. This incident is due to be closed imminently. All clinicians treating the patients have been contacted, discussions are ongoing.

Hepatitis E Virus (HEV) transmission QI 6007 resulting in the death of patient was reported to the Board in early December. The patient was immunosuppressed and had pre-existing liver disease. This is the third confirmed case of HEV transmission since universal screening began. An apheresis platelet donation tested positive on pooled nucleic and technology (NAT) for HEV ribonucleic acid (RNA). A lookback investigation was initiated, a sample from the previous donation was positive by singleton NAT for HEV RNA. Previous samples were negative and thus this is a 'window period' transmission. Two patients received the window period donations; the other recipient is not

immunosuppressed, has so far tested negative and will continue to be followed up. This case has been communicated to the Infected Blood Inquiry (IBI) team and the Advisory Committee on the Safety of Blood Tissues and Organs (SaBTO) and reported to SHOT. A further paper has been submitted to the SaBTO meeting in January with more data on viral load and the potential to transmit at low levels. We are also considering if there are additional mitigations that could be employed.

5. CQC

Please see CEO report for this update

6. Risk

Please see Board paper on governance and risk

7. Information Governance Matters

As detailed above, one serious incident has been reported to the ICO. In addition, the ICO are also mediating a complaint from an individual regarding a request under the Freedom of Information Act. The request was for the first 20 pages of records contained in an archive storage box. As the documents related to a Queens Bench Division case which is not in the public domain disclosure was refused by NHSBT with legal advice. The ICO will make a ruling as to whether this was a correct application of the exemption, NHSBT has provided all necessary information to the ICO to support their ruling.

8. Clinical Audit Update

The 2019/20 Clinical Audit Programme contained 17 clinical audits due to be completed in 2019/20. Ten of the seventeen clinical audits planned to report in 2019/20 are currently on track to report during that period. Seven have been subject to short delays which will not impact significantly on organisational efficiency, patient or donor safety. Two are delayed until 2020/21 for operational resourcing reasons. The audit plan for 20/21 is being compiled based on incidents, risks and new guidelines, it will be reviewed at CARE and at the GAC together with a summary of the completed audits this year and an update on their actions.

9. Five themes of Clinical Governance

The GAC discussed an interim discussion document on the five themes of clinical governance which arose from a discussion at the Board. These themes as defined by the RCN are applicable to NHSBT and demonstration of assurance against these themes was discussed. The GAC were assured that clinical governance processes in NHSBT are good. However, a point was made questioning how we understand the outcomes of patients who receive our blood components and other products. This data is currently not routinely available to NHSBT without significant work to download it from Trust IT systems. Members of the GAC indicated that it would be desirable to understand this in more detail, particularly for transfusion recipients, but understand that this would be a significant amount of work and would need to be considered as part of the future blood strategy.

10. Safety Policy Update

- Following recent reports of a novel coronavirus infection in China, JPAC have assessed the risks to the blood, tissues and cells supply chains. For blood, donors are already deferred from China for 28 days because of tropical infection risk, however we considered that additional measures need to be put in place to ensure contacts are also deferred. The Change Notifications have been approved urgently by UKBS Medical Directors and will be implemented urgently. We have also had a call with international blood services to understand the approaches in different countries.

- Following two probable transmissions of hepatitis B virus (HBV), SaBTO has established a working group to investigate the risk of transmission of HBV from donors with occult HBV. The group will conduct risk assessments for transmission risk, cost effectiveness and operational requirements for these options. This is expected to be completed in 2020.
- A SaBTO working group has been reviewing the SaBTO patient consent guidelines. The recommendations of the group will go to SaBTO in January.
- The SaBTO risk tolerability working group will meet in January to look at UK blood services' current and historic cost benefit/thresholds for safety related decisions. The group has already considered risk tolerability thresholds and the final aim is to produce a robust contextual framework for future safety decisions.
- The SaBTO virology review group has looked at the risk to organ recipients from HHV-8 and seasonal influenza. For influenza, the recommendation to permit donation from bowel and pancreas was accepted. A report on the risk and possible testing for HHV-8 for organ donations will be made to SaBTO in May.

11. Report Focus; Surveillance and reporting of transfusion transmitted infections within NHSBT

A routine surveillance system of suspected transfusion transmitted infections (TTIs) have been in place since 1995. This is managed by the joint NHSBT/PHE Epidemiology Unit and forms part of the Serious Hazards of Transfusion (SHOT) UK haemovigilance scheme. The system monitors the number and type of suspected and confirmed transfusion transmitted infections reported to NHSBT and the other UK blood services. Although TTIs are rare they do still occur both due to bacteria and viruses including those which are part of routine screening, and rarely, where there is no routine test in place. The last reported and confirmed hepatitis C transmission was identified in 1997 and the last HIV in 2002. The last two years have seen reports of both hepatitis E transmissions, the first since universal screening was introduced, and hepatitis B from donors with occult hepatitis B infection (OBI), a potential emerging risk. As the data for SHOT is collected in calendar years a summary of the NHSBT data for 2019 which has been submitted to the SHOT report is detailed below.

Definitions

TTIs are suspected if, following investigation there is evidence of infection post-transfusion, which was not evident prior to transfusion, and there is no evidence of an alternative source of infection and, either at least one component received by the infected recipient was donated by a donor who had evidence of the same transmissible infection, or, at least one component received by the infected recipient was shown to contain the agent of infection.

A TTI is defined as 'probable' if there is evidence of the infectious agent in both donor or donation and recipient, and as confirmed if molecular typing shows the infectious agent from both donor and recipient to be indistinguishable.

Number of suspected transmissions

Each year around 10 suspected viral transmissions, and 100 possible bacterial transmissions are reported to NHSBT for investigation. Suspected bacterial transmissions are usually reported at the time of the transfusion following a significant adverse reaction patient, the last confirmed bacterial transmission was reported in 2015.

Possible viral transmissions are identified in two ways:

- Post Transfusion Infection (PTI): Report from a hospital clinician, microbiologist or Public Health England following identification of a blood borne infection in a patient where transfusion has been identified as a likely source.
- Lookback Investigation: Initiation of investigation by the blood service following seroconversion in a regular donor- i.e. a new blood borne virus (BBV) in a regular donor.

Suspected viral TTIs are often reported months or years after the transfusion, hence year of report may not reflect year of transmission. The patient may be asymptomatic, but infection identified due to testing for some other reason, for example, prior to commencing immunosuppressive therapy. Viral transmissions occur when infections are not detected on screening either because there is no routine test or as in the cases reported here due to low levels of virus, below the level of detection of current tests. This may be because the virus has been recently acquired as a 'window period infection' or in the case of donor occult hepatitis B due to a long-standing chronic infection resulting in fluctuating levels of virus in the blood. Donation screening uses both serological and molecular tests, recent infections may only be detected on these molecular tests which detect actual virus, however, these tests are carried out in a pool of 24 samples which decreases sensitivity compared to individual testing.

Following emergence of hepatitis E and evidence of transmission risk and potential for chronic infection, SaBTO recommended selective screening (from March 2016) and universal screening (April 2017) using molecular tests (NAT) in pools of 24 to be cost effective. Hepatitis E screening has been highly effectiveness in removing positive donations from the blood supply, at a rate of more than 400 donations per year. The first transmission due to hepatitis E post introduction of screening was reported in late 2018, as part of a lookback investigation following routine screening. The donor had previously donated a month earlier and following the usual lookback process an archive sample from this previous donation was tested and found to be HEV RNA positive using individual NAT testing. Based on previous work this very low viral load was thought to be very unlikely to transmit but unfortunately one recipient, a haematology patient undergoing chemotherapy, developed hepatitis E infection. Samples from the donor and recipient were sequenced and the hepatitis E virus and found to be indistinguishable confirming transmission. The patient was treated and successfully cleared their infection.

In the same year a transmission of hepatitis B from a donor with occult hepatitis B was identified, the first hepatitis B transmission since 2012. The hepatitis B infection was not detected in pooled samples, further samples from the donor required concentration to detected presence of virus. Sadly, this patient had a number of underlying conditions and developed chronic infection and died.

2019 Cases

Three cases have been reported to SHOT in 2019. Two were HEV lookback investigations, identified due to frequent donors seroconverting for HEV. In one case two apheresis platelets were transfused, to date both recipients are well with no evidence of transmission, in the second incident apheresis platelets were transfused to two patients, one patient died soon after transfusion due to their underlying condition, sadly the second patient developed hepatitis E, was unable to clear their infection and died due to multi-organ failure. During 2019 a possible hepatitis B transmission associated with a red cell transfusion given in 2015 was investigated and found to be a probable transmission, again as in 2018 this was associated with an occult hepatitis infection in the donor.

During investigations no errors in testing were found, hence following assessment of current risks and possible mitigations it was decided to ask SaBTO to review whether current donation screening is appropriate and whether further risk reduction measure are required. SaBTO has asked a small working group to look at occult hepatitis B infection and report within 12 months. The hepatitis E transmissions will be discussed at the main SaBTO meeting in January 2020.

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