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## NHSBT Board

### **Clinical Governance Report 01 April 2017 – 31<sup>st</sup> May 2017**

#### **1. Status – Public**

#### **2. Executive Summary**

##### 2.1 Two previously reported Serious Incidents (SI) occurred during this reporting period

- QI266: DTS /ODT. Tissue was removed after withdrawal of consent. On the 12<sup>th</sup> April 2017, consent was obtained by the SNOD for both organs and tissues following a DCD process. Subsequently as the donor did not proceed to organ donation the consent for tissue donation was withdrawn. This was fully documented by the SNOD (including on Donor Path). The TES National Referral Centre (NRC) did not have a record of the SNOD informing them that consent had been withdrawn. The retrieval of heart valves proceeded. The family have been made aware of the retrieval and have not expressed concerns. Immediate corrective actions were put in place for TES and ODT to better align their processes. The RCA has been completed and actions have been agreed. Donor Path training for the National Referral Centre nurses has been completed. A Rapid Improvement Event (RIE) has been arranged for September. The final report is being written.
- QI2408: DTS. The death of a fetus of a mother who had red cell antibodies against the K antigen following a false negative non-invasive test in the International Blood Group Reference Laboratory (IBGRL). There has been no error on the part of NHSBT, the reason for designating this a Serious Incident was on the grounds of reputation and NHS system wide failures. The wording of reports produced by NHSBT has been strengthened, a communication has been sent to all users of the test, suggestions have been made for changes to national guidance and an audit of practice is being performed to further inform NHSBT and broader NHS practice. The draft final report will be shared with the Trust and NHSBT will review the Trust report before finalising the report and closing the incident.

2.2 Subsequent to this reporting period two clinical risks have been added to the risk register. One concerns the ability to be fully compliant with GDPR by May 2018, the other concerns the risk of donors becoming iron deficient as a result of blood donation as results become available from research studies in NHSBT. Mitigating processes for both are being agreed and will be implemented promptly.

2.3 There is a global shortage of Hepatitis B vaccines. NHSBT has been working with our provider OH Assist to understand how they plan to manage this shortage. OH Assist have provided several recommendations in line with those from Public Health England to prioritise vaccine usage to those at most risk. NHSBT agrees with these recommendations.

2.4 The Safety of Blood, Tissues and Organs Committee (SaBTO) Donor Selection Criteria report was agreed at June 2017 meeting and had been now passed to Ministers for consideration. The announcement is expected imminently with NHSBT working closely with DH on communications. Implementation is expected early 2018.

#### **3. Action Requested**

The Board is asked to note the contents of the paper.

#### 4. Serious Incidents (SI)

As documented in the last report there were two new SI this reporting period

- 4.1 QI266: DTS /ODT. Tissue was removed after withdrawal of consent. On the 12<sup>th</sup> April 2017, consent was obtained by the SNOD. Withdrawal of consent had been fully documented as per ODT agreed processes (including on Donor Path). The TES National Referral Centre (NRC) did not have a record of the SNOD informing them that consent had been withdrawn. The retrieval of heart valves proceeded. The family have been made aware of the retrieval and have not expressed concerns. Immediate corrective actions were put in place for TES and ODT to better align their processes. The RCA has been completed and actions have been agreed. Donor Path training for the National Referral Centre nurses has been completed. A Rapid Improvement Event (RIE) has been arranged for September. The final report is being written with closure expected this month.
- 4.2 QI2408: DTS. The death of a fetus of a mother who had red cell antibodies against the K antigen following a false negative non-invasive test in the International Blood Group Reference Laboratory (IBGRL). There has been no error on the part of NHSBT, the reason for designating this a Serious Incident was on the grounds of reputation and NHS system failures. The wording of reports produced by NHSBT has been strengthened, a communication has been sent to all users of the test, suggestions have been made for changes to national guidance and an audit of practice is being performed to further inform NHSBT and broader NHS practice. The draft final report will be shared with the Trust and NHSBT will review the Trust report before finalising the report and closing the incident.

Updates on previously reported SIs

- 4.3 ODT INC2293: Information communicated to the transplant team resulting in halted liver transplant surgery. Actions from the RCA include the review of a histopathology process, clarification of communication of intra operative findings by the retrieval team to the transplant center and appropriate documentation of findings/communications. These are all now completed and the final report is expected to be closed by the end of this month.
- 4.4 ODT INC 2306: ODT Removal of two kidney grafts following histology results in donor indicating lymphoma. The RCA found that all processes were followed and all relevant information was communicated during the donor and organ characterisation process by the SNODs. The high temperature of the donor and high white blood cell count may have been a coincidental finding and may not have been indicative of the lymphoma. It is possible that the underlying lymphoma may not have been symptomatic, and all findings attributable to sepsis and the SNODs involved communicated all information. This incident did not occur due to an error of NHSBT, however it has highlighted learning required to improve the process.
- 4.5 ODT INC 2495: Organ donation in Wales with subsequent known registered ODR opt out. The ODR was checked by the SNOD using the patient's NHS number only and no record was found. The SNOD also checked the ODR using 5 points of patient identification (ID) and no record was found. Consent was obtained and organs retrieved. It was found that one digit of the DOB was entered incorrectly which led to no record being found. The SNOD checked the ODR 3 days later and an opt-out record was found. Following investigation, it was found that shortly after the new ODR was released the NHS number tracing service was found not to work. This has led to a significant number of registrants without an NHS number, dating back to June 2015. Immediate corrective actions have been identified including the introduction of a new process for checking the ODR. The family have been told of the error in a face-to-face meeting and this has been followed up by letter. A letter has also been sent to the SNOD to thank her for her diligence in reporting the incident.

## **5. Risk**

The risk registers have been transferred into the Covalent risk management system. From the end of July 2017. A view only portal has been created for Senior Management Team members (SMT) which will be used to support risk discussions during SMT and CARE Group meetings. Further work to merge the current business partner and functional unit risks into the appropriate Business Units will be completed by November 2017.

Subsequent to the reporting period two clinical risks have been added to the risk register. One concerns the ability to be fully compliant with GDPR by May 2018 and is documented in 10.1 below. The other concerns the risk of donors becoming iron deficient as a result of blood donation as results become available from research studies in NHSBT. Mitigating processes are being agreed and will be implemented promptly.

## **6. Complaints and Commendations**

- 6.1 The Voice of the Customer survey in Patient Blood Management (PBM) demonstrated that average scores remain strong across all aspects of the business with hospital transfusion laboratories. Overall satisfaction continues with a long term upward trend in hospitals scoring 9 or 10/10.
- 6.2 The dedication and expertise of the Blood Donation staff and Clinical Support Teams in their response to the recent events in Manchester were noted and appreciated.

## **7. Blood Supply (BS)**

- 7.1 A total of nine Serious Adverse Events of Donation (SAEDs) were recorded in April and May 2017. Three donors suffered a fracture, four were admitted to hospital within 24 hours, one suffered an acute coronary syndrome and one suffered a road traffic collision. The review of numbers of SAEDs shows no single cause for this increase.
- 7.2 Blood Donation will revert to Cosmopore dressings following an increase in reported allergic reactions to recently introduced Healthcare 360 plasters.

## **8. Diagnostic and Therapeutic Services (DTS)**

- 8.1 Two incidents in DTS are being managed as SIs (as detailed in section 4).
- 8.2 Tissue and Eye Services (TES): NHS England has issued a communication advising that serum eyedrops are funded within existing tariffs and recommended that tertiary ophthalmic referral centres should consider serum eyedrops for patients meeting clinical criteria set out in that document. There has been an increase in the number of referrals and currently there is a waiting list for new non-urgent allogeneic serum eyedrops patients of up to two months. A communication has been issued to ophthalmologists who have recently referred patients. TES is implementing an action plan to clear the backlog and is considering the evidence to support moving towards universal provision of allogeneic serum eyedrops.
- 8.3 A working group has been established to consider the impact of the revised HTA Codes of Practice in relation of use and consent for blood, tissues and organs for research and within Non-Clinical Issues (NCIs) to ensure appropriate governance arrangements are in place.

## **9.0 Organ Donation and Transplantation (ODT)**

- 9.1 Three incidents in ODT are being managed as SIs (as detailed in section 4).

- 9.2 Two further ODT incidents were discussed at CARE:
- ODT INC 2573: There was an outage to the National Transplant database (NTxD) where a shutdown occurred but this is being investigated to understand if there were any delays or impacts in patient being listed for transplant or to the offering of organs for transplantation as the fall-back position of local offering was implemented for a short duration. The shutdown occurred due to overheating of the servers in the Stoke Gifford server room.
  - ODT INC 2391: It was reported that a change to the banner on the Organ Donor Register webpage was requested by the NHSBT digital team and subsequently delivered by NHSBT's third party provider. The ODR team were unaware of the change and therefore appropriate test scripts were not completed to confirm the safety of the change. The website amendment unintentionally created a fault with the address look-up application in the ODR Web forms. A fix has now been deployed. This was reported as an information governance incident to the Information Commissioner's Office (ICO) and a detailed reply submitted to further questions raised by the ICO. Subsequently a request for further information from the ICO was received, on the 13<sup>th</sup> July 2017, which we are responding to.
  - ODT INC (SI- closed) 1840 – This incident involved the swapping of a microbiology sample (involving a Public Health England laboratory (PHE)) that led, ultimately to the death of a patient. It was not identified where or how in the donation process the swapping of samples occurred. At the inquest, the coroner recorded a narrative verdict of human error and requested assurance that action has been taken to prevent this type of incident recurring, particularly in non-PHE labs. Correspondence has been sent to laboratories to remind them of the actions to be taken. The coroner also noted the level of detail and diligence of the NHBST investigation.
- 9.3 Clinical policy changes/ updates POL 228/6 Heart: Organ allocation and POL 230/6 Lung: Organ allocation have changed and were implemented on 17<sup>th</sup> May 2017. Following some clinical issues related to these changes a subsequent change has been agreed and implemented. A 'lessons learned' activity has been arranged.
- 9.4 ODT CARE considered a request for approval for the hosting of an audio-visual guide to brain-stem death testing that would include patient-identifiable features on the ODT website for all healthcare professionals to access. This guide would provide training for clinicians. Filming would take place after death has been declared and between the timing of consent and retrieval. ODT CARE was supportive of the proposal but noted full consent would be required.
- 9.5 Discussion regarding the implications of women who are of potential child bearing age who may become organ donors is ongoing with the CMO office.
- 9.6 ODT has been invited to become involved in the mandatory training of coroners and coroners' assistants. This is a very positive initiative and is already changing attitudes to organ donation amongst the coronial community around major trauma and terrorism.

## **10. Information Governance (IG)**

- 10.1 A GDPR gap analysis, identifying areas of risk and priority for action was planned to be completed by the end of August. However due to a sudden and unexpected loss of a member of the Information Governance team the risk of compliance with GDPR by May 2018 is being added to the risk register. Compliance with GDPR legislation is a requirement. A plan is in development to address the workload required by GDPR and will be taken forward as a cross directorate project led by the Clinical Directorate, with the AD Governance and Clinical Effectiveness as the Accountable Executive and Head of Information Security in support. Recruitment is underway for a replacement member of staff.

- 10.2 Due to a recent upheld complaint by a blood donor NHSBT has agreed to review all of its existing privacy notices. The blood.co.uk privacy notice has been revised in light of the complaint raised.
- 10.3 The big data project (P-16-015) relating Donor Behaviour has been approved by the Senior Information Risk Officer (SIRO), Caldicott Guardian and Information asset owner. Full IG Assessments have been completed and the data has been released to IBM.

## **11. Clinical Audit**

No clinical audit reports were approved in May 2017. There are 27 clinical audits in progress.

## **12. Clinical Claims/ legal issues**

The Consumer Protection Act (CPA) - The case of DePuy V Wilkes was highlighted to CARE to provide a legal opinion of the potential impact on blood, organs and tissues for NHSBT. The Chair of the SaBTO Committee has received a copy of the paper.

## **13. Nursing Leadership Team**

Catherine Howell will receive an OBE for services to Nursing and Rosie Godfrey, Senior Sister in Leeds Blood Donation has been awarded the Associate Royal Red Cross Medal for Military Nursing.

## **14. Hepatitis B Vaccine Shortage**

There is a global shortage of Hepatitis B vaccines. NHSBT has been working with our provider OH Assist to understand how they plan to manage this shortage. OH Assist have provided several recommendations in line with those from Public Health England to prioritise vaccine usage to those at most risk. NHSBT agrees with these recommendations. The implications are that some staff may need to travel further to be vaccinated. In addition, the shortage will impact on OH Assists' ability to reinstate missing Immunisation Records for our staff where a routine booster is required, the record interrogation can continue but there will be a holding list of those requiring boosters once stocks become available.

## **15. Safety policy matters**

- The Safety of Blood, Tissues and Organs Committee (SaBTO) Donor Selection Criteria report was agreed at June 2017 meeting and had been now passed to Ministers for consideration. The announcement is expected imminently with NHSBT working closely with DH on communications. Implementation is expected early 2018.
- SaBTO discussed the importation of plasma for individuals born post 1995 and agreed to review this in line with a revised blood risk assessment for vCJD at the next meeting.
- Non-blood HEV Testing – There are six streams within the project; organs; live tissues; deceased tissues; cord blood; stem cells and bone marrow. Planning is for implementation in September 2017.

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