NHS Blood and Transplant

NHSBT Board

Clinical Governance Report
01 October - 30 November 2016

1. Status – Public

2. Executive Summary

The following should be noted:

- Two Serious Incidents were updated to the Clinical Audit Risk and Effectiveness (CARE) Committee:
  - Organ Donation and Transplantation (ODT) Cytomegalovirus (CMV) incident (INC1840) where a recipient of a pancreas died from CMV disease following an incorrect CMV result. The Root Cause Analysis (RCA) documents from both NHBST and Public Health England (PHE) have been submitted to the pre inquest review. A meeting is being arranged with PHE to look at joint learning from the incident. The inquest date is May 2017.
  - Manufacturing & Logistics National Transfusion Microbiology Reference Laboratory (NTMRL) incident (INC 71660) where samples have been tested outside of the manufacturers 'instructions for use' with respect to timeframes. The validation work continues and the majority are now completed. The results have validated the longer time frames.

- The Human Tissue Authority (HTA) has challenged the issue of blood samples taken pre mortem from patients for the Quality in Organ donation (QUOD) research bio-bank. The taking of pre mortem samples has full ethical approval from the appropriate research ethics committee. This relates to consent being deemed under the provision of the mental capacity act. NHSBT is seeking legal advice to understand this further and find solutions. Discussions are ongoing with the HTA

- Following DH advice organ retrieval has stopped on any donor known to be pregnant. Transplant Centres are being sent letters advising them of this decision pending QC advice on this matter.

- An information incident involving the incorrect transfer of 137 blood donor records to the Welsh Blood Service was identified. This has been notified to NHS Digital, the Department of Health and the Information Commissioner's Office. All donors have been sent a letter of apology explaining the error with no responses received to date.

- NHSBT has not yet been inspected under the CQC's new comprehensive inspection regime. There has been a discussion with the CQC regarding future inspections and the planned DH consultation, NHSBT has requested that Blood Donation sessions are not included within the scope of CQC inspections.

- The January SaBTO meeting agreed that the results of the Appendix III trial do not justify amending any of the current vCJD risk reduction measures for blood, tissues, organs and cells. Furthermore, that Club 96 is not a valid source of 'safe' donations in light of this study. More work will be required to understand whether the cohort of recipients born after 1/1/96 receiving non-UK plasma could be amended in view of these results.

- SaBTO also noted the recent legal ruling by Justice Hickinbottom in the case of Wilkes v DuPuy International Ltd on product liability may have implications for blood and organs. Further legal advice has been requested and consideration of the impact of the ruling will be considered.

3. Action Requested

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

4. Serious Incidents (SI)

Two ongoing serious Incidents were discussed and updated at CARE:

4.1 ODT Cytomegalovirus (CMV) incident (INC1840). A patient received an organ where the CMV status was reported incorrectly for that donor and the impact was that the recipient died from CMV disease. Root cause analysis from both NHSBT and PHE have been submitted as part of a pre inquest review and an inquest is scheduled for May 2017. The next step is a joint meeting with PHE to look at joint learning from the incident. A joint closure report will be issued following the meeting with PHE.

4.2 Manufacturing & Logistics National Transfusion Microbiology Reference laboratory (NTMRL) incident (INC 71660). The testing of blood samples has occurred outside the manufacturers' recommended timeframes and storage conditions. The validation and testing of samples is in the main complete with all the work completed on the core screening assays, some further work is required on less frequently used assays and on some assays in the Manchester Testing Laboratory. This will conclude in March 2017. Completed results for all of the core serological screening (up to 30 days) have been examined and none of the data generated indicate that there is a problem with target stability at the storage temperatures and times used for the study. The data demonstrate that any screening results generated by NHSBT laboratories on samples that were outside of the sample storage conditions outlined in the assay instructions for use are reliable and correct. The Human Tissue Authority (HTA) is aware and updated and is satisfied with progress and actions. A working group has been established to understand if there are any areas in NHBST where there may be issues around compliance testing with manufacturer's recommendations.

5. Donor adverse events/reactions

Six Serious Adverse Events of Donation (SAEDs) were recorded across October and November 2016. One donor suffered a fracture, two donors with problems related to the venepuncture lasting more than 12 months, two donors admitted to hospital after a vasovagal event and one donor who had a road traffic collision. There were two donors where the SAED related to needle insertion, one donor admitted to hospital after a faint and one donor who had a minor road traffic collision.

6. Clinical risks

There are 47 risks on the corporate risk register for which the dominant risk is clinical. There has been one new clinical risk added to the risk register in ODT. This relates to the risk of organs potentially being designated as products resulting in NHSBT liability for the quality of organs.

7. Complaints and Commendations

- Blood Supply: Two complaints have been investigated dealing with questions of management of personal data or DNA testing results.
- DTS: A customer survey conducted into the services provided by Cellular and Molecular Therapies (CMT) shows high levels of satisfaction for the service. 100% of the respondents are satisfied with the knowledge and expertise provided by the CMT staff and agree that their CMT department provides a high quality service. Actions are in progress to improve satisfaction. A report will be presented to Specialist Services Leadership Team in January 2017.
- ODT: Between April – November 2016, 64 complaints were received. This is an increase over the average received in a two month period for ODT. The length of the donation process was one of the foremost complaints. A review of the length of the donation process has commenced with a stakeholder event in January 2017.

8. Blood supply

8.1 Four events were reported to SABRE in total in October & November 2016.

- Two incidents related to BactAlert Failures (incident numbers 72251 & 71955). One was due to an oversight from a staff member who did not follow the relevant SOP, which has been addressed. The second occurred during a period of pulse downtime with no adverse patient outcome reported.

- Quality Incident (QI 15): A collection staff member was not trained to the appropriate policy until after the effective date. This meant an additional screening question was not asked to donors screened by the individual, regarding sexual contact with a partner with a confirmed Zika Virus infection. Staff member was trained to the policy as soon as the omission was discovered. The Customer Service Team contacted donors who had been screened by the staff member and holds placed on products as appropriate. Root Cause analysis identified multiple contributory factors. The process for updates has been reviewed.

- Quality Incident (QI 349): During a period of time when the Online Blood Ordering System (OBOS) was not working a hospital requested an irradiated unit (by fax). When the request was transferred to OBOS, the request for irradiation was not transferred and non-irradiated platelets were sent to the customer. The patient was not transfused but the required transfusion was delayed.

9. Diagnostic and Therapeutic Services (DTS)

9.1 Red Cell Immunology (RCI) laboratories have been accredited by the UK Accreditation Service against ISO15189.

9.2 The ‘Choosing Wisely UK’ campaign was launched on the 28th October by the Academy of Medical Royal Colleges. The campaign focuses on a list of 40 treatments that bring little or no benefit to patients and is aimed at improving conversations between patients and their doctors to make better decisions about care. The Patient & Blood Management (PBM) Consultants team worked with the Royal College of Pathologists to ensure. Three recommendations related to transfusion were included as part of the campaign.

9.3 A new paediatric red cell exchange service was introduced in October in Leeds providing

automated exchange transfusion following NICE guidance recommending apheresis red cell exchange procedures for sickle cell disease**.**

10.0 Organ Donation and Transplantation (ODT)

10.1 The Human Tissue Authority (HTA) has challenged the issue of blood samples taken pre mortem from patients for the Quality in Organ donation (QUOD) research bio bank. The taking of pre mortem samples has full ethical approval from the appropriate research ethics committee. The next of kin of the potential donors are unable to provide consent for research pre mortem unless in exceptional circumstances. In addition it is challenged that consent for this is unlikely to fall under the provision of the mental capacity act. NHSBT is seeking legal advice to understand this further and find solutions. Discussions are ongoing with the HTA.

10.2 Incident (INC 2148): Clinical information was not communicated to recipient centres as an MRI report was not noted in the patient's electronic medical records at the time of donor characterisation. On this occasion the information did not have any patient impact but nonetheless the centres were informed of the new information. As a result of this investigation we have identified that there exists some confusion over which aspects of Donor Path can be visualised by Transplant Centres. Two sections of Donor Path cannot be viewed by the Transplant Centres. Key actions have been agreed related to this, including clear colour coding of these sections of Donor Path so it is clear for the Specialist Nurse Organ Donation (SNODs) to see what will be visible to Transplant Centres. In addition, communication has been sent to all SNODs reiterating what sections and attachments can be visualised by Transplant Centres. The Clinical Audit Team is to conduct an audit to provide assurances of information transmitted to centres in proceeding donors.

10.3 Following DH advice organ retrieval has stopped on any donor known to be pregnant. Transplant Centres are being sent letters advising them of this decision pending QC advice on this matter.

11. Information Governance (IG)

11.1 An information incident involving the incorrect transfer of 137 blood donor records to the Welsh Blood Service was identified. This has been notified to NHS Digital, the Department of Health and the Information Commissioner's Office. All 137 donors affected have been sent a letter explaining the error and apologising.

11.2 Owners for the requirements within the NHS IG Toolkit have been confirmed, and arrangements made for the submission of sample evidence for audit by PwC on January 17th &18th 2017. The new registers of Information Assets (IA) and their owners are also completed, and IA owners are in the process of completing the relevant training.

12. Clinical Audit

Three clinical audit protocols were approved. A further 24 clinical audits are in progress**.**

13. Risk Management

13.1 The approved implementation programme for changes to the risk management process continues on track. During October and November, Risk Leads from each service area undertook a review of their risk registers and transferred the validated

data across into the new risk register template. The majority of risk registers have been updated and transferred across to the new template.

13.2 A number of meetings have been held with Covalent, the suppliers of the web-based risk management system, identifying and agreeing an effective process for embedding this system within NHSBT. Once the risk registers have been uploaded into the risk management module, the required risk management process will be tested prior to the delivery of training to Risk Leads.

13.3 A draft risk management manual has been produced which pulls together a number of the current risk management documents. A staff training package has been developed. This will be ready to 'go live' with the release of the risk management manual. The intranet based risk reporting tool for staff will go live in January 2017.

14. Care Quality Commission (CQC)

NHSBT has not yet been inspected under the CQC's new comprehensive inspection regime. There has been a discussion with the CQC and NHSBT have been informed that the future scope of inspection for NHSBT by the CQC will be reviewed and will form part of a formal consultation by the DH. NHSBT has requested that Blood Donation sessions are not included within the scope of CQC inspections.

15. Nursing Leadership Team (NLT)

The NHSBT Nursing Conference will place on the15th March 2017 to launch the nursing strategy.

16. Safety policy matters

16.1 The November 2016 meeting of the Safety of Blood, Tissues and Organs (SaBTO) Committee considered recommendations from the SaBTO Hepatitis E Virus (HEV) Working Group to adopt universal testing for HEV. The recommendation of universal testing for HEV will be kept under regular review to ensure it remains cost effective.

16.2 The January SaBTO meeting considered the following

- It agreed that the results of the Appendix III trial do not justify amending any of the current vCJD risk reduction measures for blood, tissues, organs and cells. Furthermore, that Club 96 is not a valid source of 'safe' donations in light of this study. This will also be considered in the ACDP TSE (Advisory Committee on Dangerous Pathogens Transmissible Spongiform Encephalopathy) subgroup meeting in February. More work will be required to understand whether the cohort of recipients born after 1/1/96 receiving non-UK plasma could be amended in view of these results.
- It noted the recent legal ruling by Justice Hickinbottom in the case of Wilkes v DuPuy International Ltd on product liability may have implications for blood and organs. Further legal advice has been requested and consideration of the impact of the ruling will be considered.

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