NHSBT Board
November 24 2016

Clinical Governance Report
01 August- 30 September 2016

1. Status – Public

2. Executive Summary

The following should be noted:

2.1 Two Serious Incidents were reported to the Clinical Audit Risk and Effectiveness (CARE) Committee:

- ODT Cytomegalovirus (CMV) incident (INC1840) where a recipient of a pancreas died from CMV disease following an incorrect CMV result
- Manufacturing & Logistics National Transfusion Microbiology Reference Laboratory (NTMRL) incident (INC 71660) where samples have been tested outside manufacturers 'instructions for use' with respect to timeframes. This has been categorised as a serious incident on reputational grounds. The clinical risk is very low.

2.2 The National Institute for Health and Care Excellence (NICE) guidance published on 9th November 2016 recommends that non-invasive fetal RHD typing is undertaken for all D negative pregnant women in England and Wales. This could generate a workload of approximately 100,000 samples per year. Full automation and result transfer will be required with the associated IT resource, which is in progress.

2.3 Organ Donation and Transplantation (ODT) have submitted new never event in response to the Department of Health (DH) Never Event consultation.

2.4 The nursing revalidation report was presented to CARE. A survey has indicated significant positive feedback from nurses that had used the portfolio of tools provided by NHSBT to support their revalidation. In the first six month period all 130 nurses, who were required to, successfully completed the revalidation process.

2.5 The Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) Hepatitis E Virus (HEV) working group presented their report on the 1st November, this further considered the recommendations for which patients should receive HEV negative blood components and testing for donors of stem cells, tissues and organs. NHSBT are awaiting communication from the DH regarding the recommendation.

3. Action Requested

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

4. Serious Incidents (SI)

Two Serious Incidents were reported to 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. A letter has been sent to transplant units reminding them to inform ODT of any discrepant results. A request has been made to two units to investigate the non reporting of discrepant results. A letter has been sent to all specialist nurses for organ donation reminding them to continue performing the best practice with regards to labelling specimens. This incident has been reported to the NHSLA and funding is in place with separate panel solicitors available to assist. The joint root cause analysis (RCA) has been completed between ODT and the Public Health England (PHE) Laboratory. Documents have been submitted as part of a pre inquest review and an inquest date of the 24th-26th May 2017 has been set.

4.2 Manufacturing & Logistics National Transfusion Microbiology Reference laboratory (NTMRL) incident (INC 71660). An incident has been identified where the testing of blood samples has occurred outside the manufacturers' recommended timeframes. This has been classified as an SI due to potential reputational issues. More than one assay is affected. The most restrictive timeframe being antibody tests which require the samples to be less than 6 days old, the most liberal molecular assay allows the testing of samples up to 14 days old. The oldest sample identified as having been tested historically was 22 days old. The validation of tests is being undertaken and will be completed by the end of December and will validate all tests up to 31 days. The risk to patients has been assessed as very low as historical publications support the accuracy of testing older samples. The main concern was that older samples may give weaker results and an infection may be missed. The Human Tissue Authority (HTA) is aware and updated and is satisfied with progress and actions.

4.3 A substantial rating has been given by Price Waterhouse Cooper (PwC) following the internal audit of Serious Incidents in NHSBT.

5. Donor adverse events/reactions

Three Serious Adverse Events of Donation (SAEDs) were recorded in August and three in September, 2016. There were two donors who suffered fractures, two donors with problems related to venepuncture, one donor admitted to hospital after a vasovagal event and one donor who had a minor road traffic collision after a vasovagal event.

6. Clinical risks

There are 49 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 DTS: This relates to the elevated risk of a transcription error in the laboratory undertaking increasing volumes of non-invasive fetal genotyping for *RHD* as a result of NICE guidance (see 9.2 below).

7. Complaints and Commendations

- ODT: Complimentary Tales has been developed which shares positive feedback and compliments received with staff within ODT.
- Diagnostic and Therapeutic Services (DTS): A number of compliments were received relating to care, compassion, and professionalism and being informative.

8. Blood supply

There have been two quality incidents in the reporting period where Blood Collection staff have failed to implement urgent change notifications regarding Zika risk. The causes of these were a failure to ensure that all staff have been trained or failure of staff to implement the changes despite having a signed training record. There has been a review of the process for notifying collection staff of urgent change notifications and ensuring that they have been received. A value stream analysis event is being planned within the next four weeks to identify corrective actions to improve the process of training staff. These errors were reported as quality incidents and appropriate corrective and preventive actions have been undertaken .There are no risks to the blood supply.

9. Diagnostic and Therapeutic Services (DTS)

9.1 INC 68445. NHSBT have shared draft reports with Central Manchester Foundation Trust relating to a level 3 (external) investigation of the death of a patient with sickle cell disease following the birth of her baby. The investigation has not shown any failure by NHSBT or the Trust. The date of the coroner's inquest is awaited.

9.2 NICE guidance recommends that non-invasive fetal RHD typing is undertaken for all D negative pregnant women in England and Wales. This will generate a workload of approximately 100,000 samples per year and full automation and result transfer will be required with the associated IT resource, which is in progress.

10. Organ Donation and Transplantation (ODT)

10.1 ODT have presented a suggested new Never Event as part of the DH Never Event consultation. The proposal is that the all patients on the Organ Donor Register (ODR) who are eligible to donate organs are referred to a SNOD. ODT will identify missed donors via the Potential Donor Audit (PDA) and report back to each Trust for discussion at their Organ Donation Committee.

10.2 A further CMV incident occurred in ODT. Following investigation it was not classified as an SI as the SNOD followed all appropriate procedures. The issue was identified as being mis-reported at the time of donation by the PHE/ Manchester Royal Infirmary laboratory. Working is ongoing in liaison with the laboratory. There has been no patient harm. The SNOD has been commended for their vigilance and expert practice.

11. Clinical Audit

Three Clinical audit papers were presented to CARE following directorate CARE approval. All were accepted and agreed. There were no significant comments or concerns noted at CARE.

- Therapeutic Apheresis Services – Medicines Management AUD3322
- Management of Problematic Venepuncture AUD2602
- Patient Group direction AUD284.

12. Information Governance (IG)

Work is ongoing in conjunction with IT to understand the process of how smartcards will be issued in the future. This should be completed in December 2016. Work is ongoing to review NHSBT's Information asset (IA) register.

13. Risk Management

The approved implementation programme for changes to the risk management continues on track including the approved new risk register, staff training and communications. Training to super users on the new Covalent online risk reporting system will be completed in November. A rollout plan is in development to outline the users, responsibilities and access to the Covalent risk management system. The plan will be completed in December 2016. The Executive Team half day on risk was conducted on the 12th October and the role of the risk lead is being developed.

14. Care Quality Commission (CQC)

NHSBT has not yet been inspected under the CQC's new comprehensive inspection regime. Communication is ongoing around the future scope of inspection for NHSBT with a meeting arranged with the CQC on the 19th January 2017. The CQC have completed a site inspection of the Horsham blood donor site which is now designated as a site for blood collection.

15. Nursing Leadership Team (NLT)

The nursing revalidation report was presented to CARE. A survey has indicated significant positive feedback from nurses that had used the additional NHSBT support at the time of revalidation. In the period April - end of September 2016 130 nurses

were required to revalidate, 130 successfully completed the process, with only one being asked to provide further information prior to registration being confirmed by NMC.

16. Clinical Claims

A Freedom of Information (FOI) request has been received from the BBC requesting details on the type of claims taken out against NHSBT from blood donors, the number raised and settled and the total paid out in the last three complete financial years. The request is being managed by the AD for Governance and Clinical Effectiveness in liaison with NHSBT Communications and Customer Services.

17. Occupational Health (OH) Contract

A report presented to CARE outlined the findings of a clinical risk assessment relating to the missing OH files and associated loss of hep B immunisation records at the point of records transfer from Capita to OH assist. This has been managed as a national quality incident and is on the HR risk register.

18. Joint PHE/ NHSBT epidemiology group presentation

Data was presented of infection rates for organs, tissues, living bone, cord and blood. The format of the report was revised this year with the data being presented as infographics. The information will be published on the 18th November with joint communications from PHE and NHSBT.

19. Safety policy matters

19.1 The SaBTO HEV working group presented their report to the SaBTO meeting on the 1st November. The working group considered the recommendations for which patients should receive HEV negative blood components and testing for stem cells, tissues and organ donors. NHSBT are awaiting communication regarding the recommendations. Discussions regarding operational impact are underway.

19.2 The report on the Appendix III study on the prevalence of abnormal prion protein in human appendix samples in the UK population has been published. The study data have not produced a clear answer to the question of whether the presence of abnormal prions is limited to those exposed to the bovine spongiform encephalopathy (BSE) outbreak. The Blood Safety Risk Assessment is expected to be reviewed in early 2017 by the Advisory Committee on Dangerous Pathogen TSE [vCJD] Subgroup.

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