NHSBT Board Meeting
30 May 2019

Clinical Governance Report
01 February – 31 March 2019

1. Status – Official

2. Executive Summary

- There was one new Serious Incident (SI) in Diagnostic and Therapeutic Services (DTS) outside the current reporting period (INC77867). In early April we became aware blood samples were switched during processing in NHSBT's International Blood Group Reference Laboratory (IBGRL). This has affected four women who were receiving antenatal care in the Republic of Ireland (RoI). Of the samples from the four women, two were predicted to be carrying a D negative baby and two were predicted to be carrying a D positive baby. These all proved to be incorrect. There is a very small increase in risk of harm to future babies of the two women carrying D positive fetuses who, due to the error, did not receive a routine dose of anti-D at 28 weeks.
- NHSBT's first submission of the new Data Security Protection Toolkit (DSPT) was completed and submitted as required by the 31 March 2019. All mandatory standards were met.
- Eight annual reports were signed off with all committees complying with their Terms of Reference. In 18/19
    - Three incidents were classified as an SI. One remains open, the other two were closed within required time frames.
    - There were three incidents reported to the Information Commissioner's Office (ICO). All have been fully investigated by both NHSBT and the ICO, no action has been imposed on NHSBT.
    - Of the 15 clinical audits scheduled for this year, 11 have reported and three others are due to report in this quarter. One audit was removed from the programme due to a lack of cases to audit.
    - A total of eight incidents were classified as safeguarding incidents, none were escalated to external agencies for investigation and all were managed appropriately.
    - The costs of our clinical claims in 18/19 were £90k paid by NHSR and £23.5k paid by NHSBT. There have been two new claims of HCV transmission this year which may be related to the IBI, both of which have been referred to NHS Resolution. There remains one active longstanding claim from 2010 concerning a baby born with severe anaemia due to Haemolytic Disease of the New-born (HDN). This is currently reserved at nearly £13M by NHS Resolution and is expected to settle this year.
    - CARE and its subgroup TPSG (Therapeutic Products Safety Group), met their Terms of Reference. The Director of Infection Prevention and Control report was also accepted.

3. Action Requested

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

4. Serious Incidents (SI)

4.1 There was one new SI in DTS (INC77867) subsequent to this formal reporting period. In early April we became aware that blood samples were switched during processing in NHSBT's IBGRL. This has affected four women who were receiving antenatal care in the Republic of Ireland. Four samples were taken on the same day in September 2018 and sent from the treating Hospital. The samples were received, processed and tested by IBGRL. From retrospective testing it has been identified that a sample switch occurred when the samples were transferred into secondary tubes. The sample transfer is manual, and the checks performed are manual. Of the samples from the four women, two were predicted to be carrying a D negative baby and two were predicted to be carrying a D positive baby. These all proved to be incorrect. All babies and women are unaffected currently. The increase in risk of harm would be to any future D positive babies of the two D negative women who were carrying D positive fetuses and who, due to the error, did not receive a routine dose of anti-D at 28 weeks (RAADP). They did both receive anti-D after delivery. The risk of developing an antibody in this scenario rises from 0.3% to 1%. Both women had previous pregnancies before 28-week RAADP was introduced in the RoI last year. The women have both accepted testing at 6 months to see if they have developed an antibody.

We have apologised to staff members in the department of obstetrics and haematology both verbally and in writing. The obstetric lead at the hospital has met the affected women and offered each of them the personal apology letters we have sent the affected women.

The incident has been reported to the Medicines and Healthcare products Regulatory Agency (MHRA).

4.2 ODT-INC-3840 – Extended Cold Ischaemic Time (CIT) for heart donation – this incident remains open and is currently within the reporting timescales.

4.3 The SI annual report was approved by CARE. No never events occurred in 2018/19. In 2018/19 three incidents were categorised as SIs compared to six in 2017/18 and five in each of the two previous years. Two SIs were closed within the required SI standard timescales, compared to none being closed within the SI standard timescales the previous year. The events were

- INC 76020 Delayed Delivery of Cardiac Tissue (DTS) - closed
- QI 10809 Discrepancies in Blood Donors on BBMR – closed
- ODT-INC-3840 Extended Cold Ischaemic Time for heart donation - open

5. Risk

There are currently fourteen risks with the primary risk impact area recorded as clinical, this is a reduction of one from the previous reporting period. There remains one P1 risk - ODT-003 - Affecting organ donation and transplantation facilitation – which has a residual risk score 15.

6. Complaints, and compliments

Within ODT a total of 20 compliments and nine complaints were received in this reporting period, four of which were clinical and five non-clinical.

In this reporting period a total of 75 complaints were raised relating to DTS and 57 raised relating to Manufacturing and Logistics (M&L) which is consistent with previous levels. DTS CARE reviewed the complaints and there are no trends of

concern.Compliments continue to be received across DTS, with an increase in compliments in Therapeutic Apheresis Services (TAS) in March.

7. Blood Supply (BS)
Three Serious Adverse Events of Donation (SAEDs) were reported in February and four in March. Six SAEDs related to needle insertion after one year and one related to a fracture within 24 hours of donation; the donor has been withdrawn.

Four research requests were agreed in principle. None with significant operational impact. These were a proposal from PHE to use discarded microbiology samples to do a serological geographical survey of the incidence of Lyme disease. A study on restless legs syndrome (on-line questionnaire, an additional sample at donation and for some donors a wearable device to use when sleeping), a trial of a haemodynamic monitor to tract changes to predict syncope that will work alongside the STRIDES study and a study to understand whether blood donors are taking PrEP (Pre/post exposure prophylaxis to prevent HIV infection).

8. Diagnostic and Therapeutic Services (DTS)
Tissue and Eye Services (TES) are investigating an incident in which a paediatric heart valve was not used for an operation as it measured larger on receipt than recorded by TES at the time of issue. An alternative operation was performed. This is currently classified as a major Quality Incident (QI) and the corrective actions are currently being implemented.

Twenty-four events were reportable to the Human Tissue Authority (HTA) as Serious Adverse Events and Reactions (SAEARs), however there is no evidence of any errors by NHSBT resulting in harm to patients.

9. Organ Donation and Transplantation (ODT)
Since the end of March, Specialist Nurses-Organ Donation (SNODs) have requested further virology tests on a subgroup of potential donors identified as being at risk of Hepatitis C Virus (HCV) infection as part of a newly implemented scheme to enable organs from infected or potentially infected donors to be considered for transplantation into HCV negative recipients. Wales and Scotland are potentially ready to go ahead with the Scheme and the use of anti-HCV drugs, however, there is currently no funding agreement for use in English centres. The Scheme will therefore go live in the rest of the UK but not in England.

10. Information Governance (IG)
NHSBT's first submission of the new Data Security Protection Toolkit (DSPT) was completed and submitted as required by the 31 March 2019. All mandatory standards were met.

The IG annual report was approved by CARE. There were three incidents reported to the Information Commissioner's Office (ICO) in 2018/19. All have been fully investigated by both NHSBT and the ICO, no regulatory action has been imposed on NHSBT from the reported incidents.

11. Clinical Audit
The 2018/19 clinical audit annual programme included fifteen audits which were scheduled to be completed and report within 2018/19. Of those fifteen, eleven have now reported. All, except one will report in 2019/20; one was removed from the

programme due to a lack of suitable cases to audit and replaced by an alternative audit in the 2019/20 programme. All changes to the programme were approved by CARE throughout the year. Four clinical audits were completed in BD, one in M&L, and six in DTS. There we no major gaps in assurance found in any audit.

12. Research update; No research governance issues were raised.

13. Clinical Claims

The clinical claims annual report was approved by CARE. The value of individual claims continues to rise. This is in part due to the change in the personal injury discount rate in 2017, but also impacted by inflation. In total this year the costs of our claims were £90k paid by NHSR and £23.5k paid by NHSBT.

- There have been two new claims of HCV transmission this year which may be related to the IBI, both of which have been referred to NHS Resolution. One existing claim for the transmission of HIV has been discontinued without any payment being made.
- In DTS there remains one active longstanding claim regarding a 2010 case concerning a baby born with severe anaemia due to Haemolytic Disease of the New-born (HDN). This is currently reserved at nearly £13M by NHS Resolution. This is expected to settle this year or early in 20/21.
- In Blood Donation (BD) there were three cases settled, three discontinued and five new cases in 2018/19. Thus, at the end of the year there remained six active claims consistent with previous years.
- Within ODT there were no new claims in 2018/19.

14. Safeguarding

The Safeguarding Annual Report was approved by CARE. In 2018/19 a total of eight incidents were classified as safeguarding incidents, none were escalated to external agencies for investigation. Compliance with safeguarding training is currently 97%.

15. Care Quality Commission (CQC) Annual Reporting

NHSBT continues to be registered with the CQC for three activities. Dialogue is continuing regarding NHSBTs future regulated activity. During 2018/19 there were no inspections undertaken by the CQC at any of NHSBTs registered locations.

16. CARE

The CARE Annual Report was approved, and CARE met its Terms of Reference.

17. Safety Policy Matters

Within this reporting period there have been no meetings of the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) or the Joint Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee (JPAC).
The Therapeutic Products Safety Group (TPSG) and Director of Infection Prevention and Control (DIPC) Annual Reports were approved by CARE.

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