NHSBT Board
July 28 2016

Clinical Governance Report
April-May 2016

1. Status – Public

2. Executive Summary

The following should be noted:

- The final report for the Serious Incident Requiring Investigation (SIRI) INC67000, Human Leukocyte Antigen (HLA) transcription error has been approved and closed by the Governance and Audit Committee (GAC) at the 14 June 2016 meeting.
- The serious incident management process and terminology is being updated in line with NHS England and has been agreed by Executive Team (ET) and GAC.
- The annual report of all SIRIs closed during 2015/16 was received at the Clinical Audit, Risk and Effectiveness Committee (CARE); there were five SIRIs in total, one in Blood Donation, one in Manufacturing and Logistics (M&L) and three in Diagnostic and Therapeutic Services (DTS). There were no never events or recognised serious complication incidents.
- A probable transfusion transmitted Hepatitis E virus (HEV) infection (INC67926) has been reported to SHOT. A patient receiving two weekly red cell transfusions for aplastic anaemia became anti-HEV IgM and IgG positive. The component transfused on 09 October 2015 was HEV positive.
- A bacterial screening miss for an apheresis platelet pack was detected in Plymouth before the unit left NHSBT. The other associated pack was recalled. The investigation is ongoing to try to identify the source of infection. No process errors occurred
- Pregnancy testing in organ donors: The Intensive Care Society and the Faculty of Intensive Care Medicine (FICM) Joint Standards Committee have recently agreed that pregnancy testing for women of child bearing age admitted to critical care should be a standard of care. NHSBT will seek clarity from the DH regarding the retrieval of organs from a patient who is known to be pregnant in order to determine the appropriate course of action in relation to organ retrieval.
- Commendation – Organ Donation and Transplantation (ODT): During 2015/16 the service evaluation for donating families was adapted and changed to encourage receipt of more meaningful feedback. At the same time service evaluation was introduced for non-donating families. There have been a number of positive and complimentary comments made by families and a ‘complimentary tales’ is being considered to highlight positive feedback from service users.

3. Action Requested

The Board is asked to:

- Note the contents of the paper and agree any further actions if required.

4. Serious Incidents Requiring Investigation (SIRI)

4.1 The final report for SIRI INC 67000, HLA transcription error, has been approved and closed by the GAC in June 2016. An undisturbed environment for tasks requiring concentration has been identified in the affected laboratory. The manually generated cumulative reports have been discontinued and where required these will be generated from the Hematos system from November 2016.

4.2 The serious incident management process and terminology is being updated in line with NHS England and has been agreed by ET and GAC.
The predominant amendments contained within the revised documentation are:

- Change the term Serious Incident Requiring Investigation (SIRI) to Serious Incident (SI). A serious incident will be investigated initially and then it will either be downgraded to a major Quality Incident, remain an SI or upgraded to a DH Never Event. The Board will be notified of incidents in the latter two categories.
- The agreement of the classification of an incident as an SI will be made by a group of the responsible operational Director, the Medical and Research Director and the Director of Quality. This group will also sign off the final report rather than the GAC, who it will notify that this has been done.

4.3 A paper was presented to CARE with an annual report of all SIRI closed during 2015/16; there were five SIRIs in total, no never events and no recognised serious complications.

5. Donor adverse events/reactions

A total of eleven Serious Adverse Events of Donation (SAED) occurred. Eight had a definite link to donation; six were related to needle insertion, one hospital admission post fainting, and one donor with fractures; the remaining three SAEDs had a possible link to donation. All donors have been withdrawn from donation.

6. Clinical risks

There are 50 risks on the corporate risk register, for which the dominant risk is clinical. There are a number of amendments included within the May 2016 register. Eight new risks have been added, five risks removed and two risks with a change of residual score.

7. Complaints and Commendations

Commendation - ODT: During 2015/16 the service evaluation for donating families was adapted and changed to encourage receipt of more meaningful feedback. At the same time service evaluation was introduced for non-donating families. There have been a number of positive and complimentary comments made by families and a ‘complimentary tales’ is being considered to highlight positive feedback from service users.

8. Blood supply (BS)

8.1 A change in arm dressings has been approved. Both products meet the same specification and are of similar quality, this will generate cost savings.

8.2 One event was reported to SABRE (INC67847) A hospital was not contacted at the time that a bacterial monitoring (BacT) recall was initiated. The unit was transfused with no adverse patient impact reported.

8.3 A probable transfusion transmitted Hepatitis E virus (HEV) infection (INC67926) has been reported to SHOT. A patient receiving two weekly red cell transfusions for aplastic anaemia became anti-HEV IgM and IgG positive. The component transfused on 09 October 2015 was HEV positive.

8.4 A bacterial screening miss for an apheresis platelet pack was detected in Plymouth before the unit left NHSBT. The other associated pack was recalled. The investigation is ongoing to try to identify the source of infection. No process errors occurred

9. Diagnostic and Therapeutic Services (DTS)

9.1 A national survey of Patient Blood Management (PBM) has been reported to the National Blood Transfusion Committee. The main areas for improvement were identified as: management of anaemia, single unit transfusion policies, better information to support clinicians, introduction of electronic systems and patient involvement. A proportion of Trusts (31%) had recently submitted business cases to support PBM, the majority of these were in the very high user group. Provision of education and resources and support for GP involvement around anaemia identification scored highly as ways that NHSBT could support PBM.

9.2 INC68445. NHSBT is supporting the Central Manchester Foundation Trust in the investigation of the death of a patient with sickle cell disease following the birth of her baby. The trust are investigating this as a serious incident. The investigation has not shown any failure by NHSBT or the Trust.

9.3 INC69391. A patient had their operation cancelled when it was discovered in the operating theatre that a package supplied by Tissue and Eye Services (TES) did not contain the intended amniotic membrane. The patient did not suffer any harm and subsequently did not require the operation.

9.4 Identification of organisational/transferable learning: work to identify all areas of transcription in DTS and Blood Supply has been undertaken. Plans for mitigation have been put in place where possible and residual risk recorded in the risk register.

10. Organ Donation and Transplantation (ODT)

10.1 Pregnancy testing in organ donors: The Intensive Care Society and the Faculty of Intensive Care Medicine (FICM) Joint Standards Committee have recently agreed that routine pregnancy testing for women of child bearing age admitted to critical care should become a standard of care. NHSBT are to seek clarity from the DH regarding the retrieval of organs from a patient who is known to be pregnant in order to determine the appropriate course of action in relation to organ retrieval.

10.2 INC 1400 (Candida transmission): Following a recent incident where there had been a breach of the gut during retrieval and Candida was subsequently isolated within the recipients it was advised that in circumstances where any gut breach

occurs, recipient centres should be informed. Discussions ongoing with Advisory Group chairs relating to the routine testing of transport perfusion fluid from abdominal organs. It is likely that the routine testing of fluid will be recommended.

10.3 INC 1749 (blood group transcription error): This incident related to a donor blood group discrepancy. The donor was registered by the Specialist Nurse Organ Donation (SNOD) as blood group A however the HLA report correctly detailed the blood group to be O. SNODs will be reminded of the importance of ensuring the correct process for blood group checking is followed prior to entering onto the Electronic Offering System (EOS) and IT safeguards are being examined to prevent this from occurring in the future. A letter has been sent to the Duty Office staff member thanking them for their diligence in identifying and acting quickly and reporting the error via the governance channels.

11. Information Governance (IG)

11.1 Formal confirmation of NHSBT's 'Satisfactory' attainment in its 2015-16 NHS IG Toolkit submission has been received. PricewaterhouseCoopers (PwC) will audit the submission as part of the internal audit annual plan for 2016/17.

11.2 The National Data Guardian and Care Quality Commission Reports have been released this month and a gap analysis undertaken. This is the subject of a separate Board paper to this meeting.

12. Montgomery ruling on Consent

A paper was submitted to the June ET and then GAC detailing conformance with the ruling. Some patient leaflets and consent sheets require updating and this is due to be completed late summer. An action has also been completed to cascade guidance to all nurses in NHSBT.

13. Risk Management

ET has approved proposals to improve risk management across NHSBT, including a new risk register, staff training and communications. This has been endorsed by the GAC and cascaded to the clinical directorates via the July CARE meeting.

14. Care Quality Commission (CQC) Report

14.1 A paper was provided to the CARE Committee to provide information outlining the CQC approach to monitoring and inspecting registered organisations, as described within the recently published CQC strategy document 'Shaping the Future' 2016 to 2021.

14.2 The CQC last undertook an inspection within NHSBT in 2014. This inspection was conducted under the previous CQC inspection regime and NHSBT is yet to have been inspected under the CQC's new comprehensive inspection approach. Ongoing communication with the CQC has been maintained and it is expected that direction around the future scope of inspection and planned scheduled dates for inspection will be clarified in the near future.

15. Safety policy matters.

There are two key SaBTO workgroups ongoing

- The HEV working group, chaired by Richard Tedder will review the current provision of HEV screened products to patients. The group will re-review the epidemiology of HEV and the clinical impact of HEV infection on patients at risk of persistent infection, the cost effectiveness of the current strategy to reduce the risk of acquiring HEV from blood components, evidence of HEV transmission from transplanted organs and the management of HEV in immunosuppressed patients. Feedback from hospitals is being sought on these issues. The working group is expected to provide a report with recommendations by Dec 2016 and complete the work plan by April 2017
- The Donor Selection working group, this held its second meeting on the 18th July to review epidemiological evidence.

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