NHS Blood and Transplant

NHSBT Board
Sept 29 2016

Clinical Governance Report
June- July 2016

1. Status – Public

2. Executive Summary

The following should be noted:

2.1 There have been no new serious incidents requiring investigation (SIRI) during this time period. Subsequently an incident INC1840 has been reported to the Board where a recipient of an organ transplantation died from CMV disease following transplantation of an, incorrectly reported, CMV negative organ

2.2 A number of operational proposals have been approved for blood donation including the management of transgender donors including the activation of 'Mx' title in Pulse and a proposal to remove lidocaine from use in Blood Donation.

2.3 The SaBTO HEV working party, chaired by Prof. Richard Tedder, has been looking into the current provision of HEV negative blood components and developing advice for clinicians managing patients awaiting transplant and other vulnerable groups. Recommendations will be presented to the SaBTO meeting on the 1st November.

3. Action Requested

The Board is asked to note the contents of the paper

4. Serious Incidents Requiring Investigation (SIRI)

There were no confirmed SIRIs during the reporting period. An incident (INC1840) has occurred subsequently in which a patient received an organ with an incorrect CMV status and subsequently died from CMV disease. This has been called a Serious Untoward Incident and reported to the Board.

5. Donor adverse events/reactions

Two Serious Adverse Events of Donation (SAED) were raised in June 2016 and four in July 2016. Four had a definite link to donation; all related to fractures within 24 hours of donation.

6. Clinical risks

There are 53 risks on the corporate risk register for which the dominant risk is clinical. There have been five amendments or recategorisation to these risks. There have been no new clinical risks added to the risk register

7. Complaints and Commendations

7.1 Blood supply: A commendation to the Manchester Clinical Support Team and Donor Records Department who identified and checked 805 Donor health Check forms (DHCs) from seven sessions where a new process was not implemented at the correct time. Their teamwork and collaboration resulted in a quick resolution of the initial problem.

7.2 Organ Donation and Transplantation (ODT): There were three complaints related to donor family concerns noted in June and July. The majority of the complaints received were due to ODR registrations issues.

7.3 Diagnostic and Therapeutic Services (DTS): The Voice of the Customer survey reported that 75% of hospital transfusion laboratory managers rated overall service from NHSBT as 9/10 or 10/10. A number of compliments were also received by the diagnostic services and TAS.

8. Blood supply (BS)

8.1 A number of operational proposals have been approved for blood donation:

- The management of transgender donors including the activation of 'Mx' title in Pulse was agreed, donations will be treated the same way as donations from women to reduce the risk of TRALI.
- A proposal to remove Lidocaine from use in Blood Donation collection environment was agreed.

8.2 An assessment of the effectiveness of training relating to rapid implementation of donor selection guidelines will be completed.

9. Diagnostic and Therapeutic Services (DTS)

9.1 INC68445 NHSBT has been 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 was investigating this as a serious incident. The investigation has not shown any failure by NHSBT or the Trust. The date of the coroner's inquest is awaited.

9.2 NHSBT started providing Therapeutic Apheresis Services in Birmingham based at City Hospital on the 1st August. Patients who previously travelled to London are now able to receive red cell exchange transfusions locally. Therapeutic Apheresis Services in London have also extended to the Harley Street Clinic since the last CARE.

10. Organ Donation and Transplantation (ODT)

10.1 Following a recent incident reported related to a QUOD biopsy, QUOD will now be included on the regular ODT CARE agenda for oversight.

10.2 Due to previous delays in HTA closure of SAEARs, the processes has been reviewed and streamlined and this will speed up the close out process with the aim to reduce overdue incidents.

10.3 An outline paper regarding the considerations for Solid Organ Transplantation if a potential organ donor has been exposed to Zika virus is under production. A horizon scanning algorithm for infectious threats has been developed and will be adapted for use.

10.4 Across the pathway a number of incidents have been reported related to delays in organ offering. As well as reviewing individual incidents, these will be incorporated into the wider review of the donation process taking place. A review of the organ donation offering process will be completed.

11. Clinical Audit

Three Clinical audit papers were presented to CARE following directorate CARE approval. All were accepted and agreed.

- RCI Sample Acceptance / Rejection Audit (AUD2613)
- Applied Muscle Tension in Blood Donors (AUD2842)
- Audit of Fetal Genotyping for Kell in IBGRL

Planned changes to the reporting of clinical audit performance were agreed by CARE.

12.0 Information Governance (IG)

12.1 NHSBT's response to the consultation over Caldicott 3 is complete and has been submitted to the DH on schedule.

12.2 A pilot of new support from Facilities staff for the administration of NHS Smartcard accounts is in progress.

12.3 Work will be prioritised to identify the Information asset owners within NHSBT and to ensure this is fed into the master data management work as part of core systems modernisation. Update training will be provided to information asset owners when the register is complete.

13. Risk Management

13.1 The approved implementation programme for changes to the risk management continues on track including the approved new risk register, staff training and communications. This has been cascaded to the clinical directorates via directorate CARE meetings.

14. Care Quality Commission (CQC)

14.1 NHSBT has not yet been inspected under the CQC's new comprehensive inspection. Communication is ongoing with the CQC and it is expected that direction around the future scope of inspection and planned scheduled dates for Inspection will be clarified following a meeting in September 2016.

15. Nursing Leadership Team report

£127k funding has been secured from Heath Education England to support Nursing across all Directorates in NHSBT. The NLT has arranged a series of meetings to consider potential initiatives and allocate funding.

16. Director of Infection Prevention and Control (DIPC)

16.1 The annual DIPC report was presented to CARE. Major achievements in 2015-16 were

- the discontinuation of Bacterial Arm Monitoring (BAM) post arm cleansing of donor arms in Blood Donation.
- the Level 2, Annual Refresher IPC training for donor and patient facing staff was written and is now available as mandatory training.

17 Safety policy matters.

17.1 The SaBTO HEV working party, chaired by Prof. Richard Tedder, has been looking into the current provision of HEV negative blood components and developing advice for clinicians managing patients awaiting transplant and other vulnerable groups. Recommendations will be presented to the SaBTO meeting on the 1st November. The morning session will be open to all stakeholders.

17.2 The SaBTO donor selection working group will meet on 11th November. Current work streams include comparisons with other blood services, donor motivation & compliance and individual risk assessments.

Authors
Ella Poppitt
AD Governance and Clinical Effectiveness
Gary Mallinson, Lead Scientist, Safety Policy.

Responsible Director
Gail Miflin
Medical and Research Director.