Blood and Transplant

NHSBT Board

Clinical Governance Report
May 2020

1. Status – Official

2. Executive Summary

There are no new serious incidents (SI) within this reporting period of February and March 2020. All SIs have been closed.

3 additional incidents were escalated to directors as requiring formal assessment calls during April and May, outside the reporting period. They continue to be investigated as major incidents. Of particular note

- INC 79914 in Blood Supply – A hospital transfusion laboratory requested 8 red cell units with several specific characteristics including D negativity. Three D+ve and five D-ve units were issued and were subsequently transfused. The hospital involved has raised this as a serious incident.
- QI 80019: Near miss event. A visually abnormal platelet was found to contain Staphylococcus aureus: this investigation relates to one pack of an apheresis platelet donation. The issuing hospital noted that the unit looked abnormal and returned the unit. This visual abnormality was identified on day 6. The associated pack 1 was recalled but no visual abnormalities were observed. Associated plasma has been discarded and was in our storage. We have confirmed the donor was a carrier of the same strain and they have been withdrawn from donation. The common reason for this occurring is due to biofilm generation and protection of infective focus. The Microbiology team are considering how we could focus some work on understanding this more fully. Prior to this event the last near miss *Staphylococcus aureus* event was in 2015.

There is no focus item in this report due to the COVID-19 pandemic.

3. Action Requested

The Board is requested to note the contents of the paper and discuss where relevant.

4. Overview of events in this reporting period

Previously reported events:

- SI DTS INC 15283 (Corneal cutting incident) has been closed. Amended procedures including an additional procedural step and the addition of a thickness measurement post-cutting have been successfully validated. The learning has been shared throughout the NHSBT operational areas, and also with the Human Tissue Authority (HTA), and external tissue bank, and with the surgeons utilising our grafts. The final actions will be completed once the service resumes as COVID-19 has led to only urgent corneal surgery being undertaken.

- OTDT INC 4576 (UK Living Kidney Sharing Scheme Matching Run (MR) issues) has recently been closed. This scheme is highly complex and is predominantly paper based and is reliant on manual checks. To improve safety, the process needs to be automated, but it is acknowledged this will take significant time and resource. A detailed action plan is being implemented and actions are being monitored through OTDT CARE. Since this SI, the last and next scheduled MR have been paused due to COVID-19. It is expected that all planned actions and checks will be fully implemented prior to the next run in October 2020. These checks and balances will remain until we have an automated solution for the scheme.

New events of note:

- INC 79914 Blood Supply (BS): A request for 8 units of red cells was received by Hospital Services in Colindale for transfusion on 6th January 2020 for an 18-year-old female patient with sickle cell disease (SCD). Five units which matched the original request were identified. The other three units were supplied as substitutions. These units were D+ve (the female patient is D-ve, and so an inappropriate substitution). All other specifications requested were met. The technical member of NHSBT staff involved discussed the substitution and it was accepted by the Trust Biomedical Scientist. All 8 units were transfused to the patient on 6th and 7th January. This event happened on a Sunday afternoon. The event was not realised until the next sample taken from the patient for a follow up transfusion on 21st February identified a mixture of D+ and D- cells in her blood and hence the transfusion error. This incident has been reported to the Medicines and Healthcare products Regulatory Agency (MHRA). Although all NHSBT processes were correctly followed we are reassessing how we ensure our communications with hospitals are clear and how we can avoid these decisions being made out of hours wherever possible. NHSBT continues to investigate this as a major quality incident working closely with the Trust team who are performing their own investigation.
- QI 80019: Near miss event. A visually abnormal platelet was found to contain Staphylococcus aureus: this investigation relates to one pack of an apheresis platelet donation. The issuing hospital noted that the unit looked abnormal and returned the unit. This visual abnormality was identified on day 6. The associated pack 1 was recalled but no visual abnormalities were observed. Associated plasma has been discarded and was in our storage. We have confirmed the donor was a carrier of the same strain and they have been withdrawn from donation. The common reason for this occurring is due to biofilm generation and protection of infective focus. The Microbiology team are considering how we could focus some work on understanding this more fully. Prior to this event the last near miss Staphylococcus aureus event was in 2015.
- QI 18462 Diagnostic and Therapeutic Services: Levels of anti-D detected in a sample from a pregnant woman had risen markedly from an already dangerous level of 16.9IU/mL in March to 144IU/mL in a sample taken on 7th April 2020 and tested on 10th April (bank holiday Good Friday). The result was communicated to a biomedical scientist from the referring hospital laboratory the same day (10th April) with advice to inform the consultant obstetrician responsible for the affected mother and baby. It was confirmed that this result had been communicated to the midwifery team and that the duty obstetrician at the referring Trust was made aware of this on Easter Sunday 12th April. Follow up calls were made by NHSBT staff on 14th, 16th, 17th and 20th April. On 20th April NHSBT was informed that the scan had been performed but the baby had died. No errors on the part of NHSBT have been identified. The Trust involved will report this to Care Quality Commission (CQC) and to the Serious Hazards of Transfusion (SHOT) haemovigilance scheme.

5. Care Quality Commission (CQC)

CQC inspections are currently on hold due to COVID-19. Contact is being maintained with CQC. As resource permits during this period, Therapeutic Apheresis Services are working to be inspection ready. For Blood Donation this will recommence in due course when past the COVID-19 additional peak of work.

6. Clinical Claims

The clinical claims annual report was presented and approved. This will be discussed by the Executive Team and reported next time.

7. Safeguarding

The safeguarding annual report indicated that during 2019/20 there were 20 reported safeguarding incidents. This is double the number for 2018/19. It is noted that this increase may reflect the influence of the senior nurses in NHSBT who advocate the reporting of all safeguarding incidents, even if these incidents were resolved relatively quickly. All incidents were managed appropriately, with two escalated to external agencies for further investigation. Five of the incidents were in relation to NHSBT colleagues, which were handled sensitively and professionally, and with appropriate support to line managers. Compliance with safeguarding training is 90% across NHSBT, but some areas have been highlighted to have lower compliance and this is being addressed.

8. Information Governance

The Information Governance annual report was discussed. One incident reached the threshold to be externally reported to the Information Commissioners Office (ICO). This is in relation to SI ODT INC 4278 (live kidney matching run with the incorrect suspension of a recipient). This has been fully investigated by NHSBT and we are waiting feedback from the ICO. During 19/20 there were 463 incidents reported to the IG team. A high level of these were categorised as ‘availability’ incidents which related to the handling of paper documents, particularly Donor Health Check (DHC) forms, nearly all of which have subsequently been recovered, with ongoing actions to identify any that are outstanding. Regular communications and training are being provided to these areas to support them with the handling of personal information.

Compliance with the EU General Data Protection Regulation (GDPR) continues to be delivered and a moderate internal Audit opinion provides assurance with improvements planned. This will be discussed at GAC. The deadline for submissions to the new Data Security and Protection Toolkit (DSPT) across the NHS has been extended to September 2020 due to COVID-19. NHSBT will meet this deadline.

9. Clinical Audits

Due to COVID-19 and its impact on NHSBT services and resources, the planned clinical audit programme for 2020/21 has been reviewed at the request of CARE. This will be discussed by the Executive Team in the next few weeks prior to coming to the GAC.

10. Safety Policy Update

An extraordinary SaBTO meeting was held in March to consider and approve two recommendations related to Convalescent Plasma for treatment of Severe acute respiratory syndrome – corona virus 2 (SARS-CoV-2) infection: to review whether pathogen reduction was required, and secondly whether those patients receiving CP could subsequently donate plasma for treatment. The decision was made that pathogen reduction is not required as these components are collected under the same guidelines as all other blood components which are not pathogen reduced. The latter decision is awaiting recommendation from the Minister.

11. CARE Annual Reports

Annual reports were approved from the following areas. There were no areas of concern

- NHSBT CARE
- Serious Incidents
- Infection Prevention and Control
- Nursing Leadership Team
- Non-Clinical Issue
- Therapeutic Products and Safety Group

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