NHS Blood and Transplant

NHSBT Board
January 28 2016

Clinical Governance Report.

1. Status – Public

2. Executive Summary

This paper reports on the key clinical governance areas discussed at the January CARE and GAC, and provides an update on safety policy matters reviewed by TPSG and SaBTO.

3. Action Requested

The Board is asked to:

- Note the contents of the paper and raise any concerns for further work.

4. Open Serious Incidents Requiring Investigation (SIRI)

4.1 Since the last report there has been one new SIRI in Blood Supply (BS); incorrect product transfused to baby requiring exchange transfusion (INC64666). The SIRI has been classified as a Serious Untoward Incident (SUI) and has previously been reported to the Board. The baby has now been discharged from Hospital.

4.2 The incident is agreed to have arisen due to errors at both the Trust and Hospital Services. Immediate actions were taken to alert hospital service staff and hospitals to minimise the risk of recurrence. There are 3 longer term actions to further minimise the risks of errors within Hospital Services: aligning the menu choices with JPAC component names; review of whether the 'free text' facility in OBOS is still needed (hospitals are indicating that it is useful to them); and a quality audit of how often hospital services pick up and correct ordering errors made by hospitals.

4.3 A constructive joint meeting was held with the Trust, and a joint final report is nearing completion. To facilitate timely provision of this report to the family, GAC have agreed to sign off this report offline. CARE will monitor longer-term actions, and provide updates to GAC.

5. Donor adverse events/reactions

A total of four Serious Adverse Events of Donation (SAED) occurred since the last report; one male donor and the female donor were first time donors aged 25 and 17 respectively. Two SAEDs had a definite link to donation: one faint in a first time donor and a needle injury. The other two were due to cardiac disease.

6. Clinical Audit Programme

6.1 There were a total of five overdue clinical audit actions in November (all in BS) but none in any area by the end of December.

6.2 Five final reports were presented to CARE:

- BS: Confidentiality on session (AUD2599). Improvements could be made at some venues/sessions and this is being taken forward
- DTS: Medical Involvement in Quality Incidents (QIs) (AUD2855). The distribution of QI reviews is to be reconsidered to ensure a more balanced approach, Qpulse training, and timely closure of QIs
- DTS: Audit of Red Cell Immunohaematology (RCI) Sample Reception (AUD2612). The sample rejection rate of 2% is comparable, or slightly lower, than the national average for Transfusion Laboratories.
- DTS: Re-audit of British Bone Marrow Registry (BBMR) Donor Follow Up (AUD2854). Some areas could still be improved, including level of donor follow up at years one and three
- DTS: Audit of Virtual Crossmatching (VXM) in Birmingham (AUD2634). Actions have been agreed to work with Hospitals to educate them on the requirements of this process.

7. Clinical risks.

7.1 The number of risks on the corporate risk register, for which the dominant risk is clinical, is 45; an increase of one from the previous report. The new risk is 'unable to appoint to two Microbiology Services Medical Consultant posts following two retirements within the next five months' (CLIN-09). Actions are being taken to review requirements and recruitment.
7.2 A new risk will be added to the clinical risk register, which is the significant change in senior clinical leadership over the coming months due to retirements and maternity leave, to be mitigated by structured handover.

8. Alerts.

8.1 NICE has issued 33 documents since the last report. Three were deemed to be relevant and require further review: IPG534: Implantation of a corneal graft-keratoprosthesis for severe corneal capacity in wet blinking eyes; IPG535: Living-donor liver transplantation; and NG24: Blood Transfusion Guidance, chaired by Professor Mike Murphy, and aimed at hospital prescribers.

8.2. A total of seven alerts were issued via the Central Alerting System (CAS); none was relevant to NHSBT.

9. Complaints and commendations.

9.1 In BS none were received since the last report. In DTS the total number of monthly Hospital Complaints has fallen since a peak in July and remains stable, with major complaints rated stable and low with no worrying trends. In ODT the majority of complaints related to the

implementation of the Welsh legislation on deemed consent; the total number of complaints received last quarter is 80 (Q2 number = 106).

9.2 Since the last report compliments were received in DTS in customer service, H&I, RCI, RCI reagents, Therapeutic Apheresis Services and Tissue and Eye Services.

10. Blood supply.

10.1 Both faints and rebleeds continue below target.

10.2 There have been no confirmed bacterial transfusion transmitted infections reported during this period.

10.3 There were no new clinical risks added to the risk register in this reporting period. However, a risk was raised following the Pulse Change Board; that whilst the infrastructure hosting move was taking place, there would be a small risk that Pulse could potentially be lost for up to four days. This is being addressed operationally.

10.4 Three events were reportable to Serious Adverse Blood Reactions and Events (SABRE) since the last report; one of which is attributable to Blood Supply due to an error resulting in a missed discretionary test for malaria.

11. Organ Donation and Transplantation

11.1 There has been a recent increase in microbiology transcription errors and errors in donor family letters. This reversed the previous trend of significant reduction in in microbiology transcription errors from 22 in an 11 month period to 3 in a 13 month period. These recent incidents have had no clinical impact but ODT continues to monitor closely.

11.2 Feedback is starting to be received from family surveys, including some families that declined donation.

11.3 It is still not possible to reliably upload attachments to Q Pulse and this is being investigated. The system is not only relied upon for incident management, it also holds information used for clinical inquests and therefore this issue is a potential clinical and reputational risk.

11.4 The urgent heart offering incident remains open due to a delay to implementing the change required to NTxD. The delay was a result of the availability of user acceptance testing resource, now resolved, and a technical issue with the deployment of an EOS / NTxD release preceding this. The urgent heart fix has been incorporated in to the ODT Scaled Agile programme with an aim to deliver in early February. However, this fix was approved in August 2015.

11.5. GAC discussed an unsatisfactory Internal Audit report of the use of Personal Identifiers in the Duty Office. There was very low compliance

during phone calls with the new policy (since September 2015) of requiring 3 points of identification of all donors and patients during verbal or written communication. Actions already taken include a personal letter to all staff from the Director of ODT, and posters within the Duty Office. It was agreed at GAC to investigate the use of a behavioural factors approach.

12. Diagnostic and Therapeutic Services.

12.1. There have been no new recognised serious complications during the reporting period, with still only one case of Transfusion Related Acute Lung Injury (TRALI) reported in the year to date.

12.2. A detailed clinical risk assessment has been written for the modernising manufacturing project. A similar clinical risk assessment has been requested for the Leeds/Sheffield project; drafting will commence once a shortlist of locations has been drawn up.

12.3. An incident occurred in Red Cell Immunohaematology (RCI) which led to a delay in treatment for a patient (INC64750). A sample referred at 0200 was triaged by NHSBT Duty Consultant as suitable for urgent analysis first thing in the morning and placed in the 'urgent' tray. However, it was missed and the error was discovered when the Hospital contacted RCI for the result. The patient's non-urgent surgery was rescheduled for the following day as a result. A new process for handing over outstanding on call work has been implemented replicating the process used during the day.

13. Information Governance (IG).

Final target scores for the March 2016 IG Toolkit Submission were approved by CARE.

14. Review of CARE and related groups.

Recommendations have been agreed by CARE and endorsed by GAC.
Updated proposals have been submitted to the GAC as a separate paper.

15. Safety policy matters

15.1 The HEV testing implementation project continues, with guidelines for appropriate use developed between members of SaBTO and the British Society of Blood and Marrow Transplantation and now endorsed by main SaBTO. This simplifies guidance for HEV-negative blood components to commencement at the point of listing for stem cell or organ transplantation. However, further work and consultation through BTS is needed regarding testing of organ and stem cell donors and patients.

15.2 The change in HTLV testing from universal to new donors only, plus non-leucodepleted components will follow HEV implementation. A manual process for their identification can be implemented in a matter of weeks,

subject to a risk assessment, with full PULSE control taking up to a year to develop and implement.

15.3 After discussiosns with the MHRA, we will continue WNV testing in pools of six samples as currently.

15.4 The Bacterial Risk Reduction project has concluded that we are not in a position to implement pathogen inactivation at this point, due to the heavy resource needed for manufacturing consolidation and core systems modernisation projects. Further operational validation work required for the implementation of pathogen inactivation will be undertaken over the next one to two years.

15.5 NHSBT imports Fresh Frozen Plasma for transfusion from Austria for patients born after 1 January 1996. The current supplier has indicated that they may not be able to meet the 100% requirement of male plasma. An initial inspection of a new supply centre was successful and a quality audit will be undertaken in late January. An overall review of FFP policies and products is planned for later in the year.

15.6 Currently, the effectiveness of donor arm cleansing is monitored using contact plates. The Therapeutic Product Safety Group (TPSG) has approved an alternative mechanism of assurance, namely continuous observational monitoring of donor carer technique, which simplifies processes at donor sessions and saves £18k/year.

15.7 Following an internal audit, a task and finish group has mapped and documented the process for horizon scanning and risk assessment of infectious threats to blood, tissues and organs. This has streamlined the process across the UK, with a key role for JPAC and its Standing Advisory Committee for Transfusion Transmitted Infections in monitoring and RAG rating new theats. This work has been endorsed by SaBTO.

15.8 SaBTO received a presentation of the UK Blood Service survey of donor compliance. Overall, compliance with deferral guidance regarding sexual and intravenous drug risk is high. Additional points will be considered to improve the quality of information to donors.

15.9 SaBTO agreed new guidance for selection of donors who have recovered from, or been in contact with, Ebola virus. Collection of convalescent plasma will be permitted under concession.

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