NHS Blood and Transplant (NHSBT) Board
24 May 2018

Clinical Governance Report
01 February – 31 March 2018

1. Status – Official

2. Executive Summary

- There were no new Serious Incidents (SIs) in this reporting period. All SIs are closed. There were six SIs in the 2017/18 period.
- In 2017/18 there was one new case of the recognised serious complication, Transfusion Related Acute Lung Injury (TRALI), and no confirmed bacterial transmissions in platelets.
- NHSBT's 2018 submission of the NHS Information Governance (IG) Toolkit was completed and submitted as required by the 31st March 2018. The overall rating was 'Satisfactory' (green) with a percentage score of 85%, a 3% increase on the 2016/17 submission. There were no incidents of severity score 2 or greater reported to the Information Commissioner's Office (ICO) in 2017/18
- The Clinical Audit, Risk, and Effectiveness Committee (CARE) recommends that NHSBT adopts the NHS Improvement Just Culture Guide. This will be considered at the ET meeting in June.

3. Action Requested

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

4. Serious Incidents (SI)

There were no new SIs within this reporting period. All previous SIs have been closed.

CARE approved the SI 2017/18 annual report. In 2017/18 there were six SIs in total, all followed correct process, however, none of the time to report closure met the standards of 60 days for internal SIs and 90 days where multiple organisations are involved. The Assistant Director, Governance and Clinical Effectiveness will work with the SI authors in the operational directorates to understand, and address, the issues involved.

5. Risk

There was no change in the numbers of risks with the impact area recorded as clinical. In this reporting period two risks belonging to Diagnostics and Therapeutic Services (DTS) have seen a reduction in their residual risk scores:

- DTS -01: There is a risk that a patient may be harmed by the transfusion or transplantation of the incorrect product resulting from a failure or error in testing. The residual risk has reduced to 8 (4x2) from 10 (5x2).
- DTS-02: There is a risk that a patient may be harmed by a delayed or failed product or service. The residual risk has reduced to 10 (5x2) from 12 (4x3).

6. Complaints, compliments, and commendations

In Organ Donation and Transplantation (ODT) a new complaints process is now active and incorporates guidance documents to support staff responding to complaints and focuses on sharing the learning. ODT continue to receive high satisfaction scores; of the feedback received at the end of 2017/18 the percentage of families scoring nine or ten for overall satisfaction was 93%. A total of 112 compliments were recorded during 2017/18. In this reporting period ODT received three complaints and 22 compliments.

Compliments were received across most services in DTS with a maintained increase in compliments in Therapeutic Apheresis Services (TAS). Complaints are monitored at DTS CARE, and there have been no upward trends reported in this period.

7. Blood Supply (BS)

Two Serious Adverse Events of Donation (SAED) were reported in February 2018 and two in March 2018. One donor experienced acute coronary syndrome within 24 hours of donation. One donor was admitted to Hospital within 24 hours of donation; the atrial fibrillation was confirmed not to be due to donation. Two donors experienced arm pain at donation one year previously, symptoms persisted and are consistent with a nerve injury.

There have been no confirmed cases of bacterial transmission to patients from platelets.

8. Diagnostic and Therapeutic Services (DTS)

There have been no new cases of the recognised serious complication TRALI in this reporting period, in 2017/18 there was one case in total.

A National Comparative Audit (NCA) report has been published since the last meeting. The 2017 audit of red cell & platelet transfusion in adult haematology patients. This is available at http://hospital.blood.co.uk/media/29633/report_26007737.pdf Clinical practice had improved in almost all parameters measured. A number of key recommendations have been made about local guidelines as 11% of hospitals audited did not have local guidelines.

9. Organ Donation and Transplantation (ODT)

In the previous report the first case of a donor positive for Hepatitis E Virus (HEV) transmitting through transplantation was reported. The recipients of the kidney and liver transplanted are reported to be doing well post-transplant, the latter having received Ribavirin treatment.

The National liver offering scheme went live on 19th March 2018 and is running smoothly currently. Members noted increased activity for the Hub Operations team.

10. Information Governance (IG)

A separate paper is submitted to the NHSBT May Board regarding GDPR compliance.

CARE approved the IG Annual Report: NHSBT's 2018 submission of the NHS IG Toolkit was completed and submitted as required by the 31st March 2018. The overall rating was 'Satisfactory' (green) with a percentage score of 85%, a 3% increase on 2016/17 submission. The IG Toolkit will be replaced with the Data Security and Protection Toolkit (DSPT) in April/May 2018. The new toolkit will focus on the National Data Guardian (Caldicott) recommendations, GDPR and cyber security standards. There were no incidents of severity score 2 reported to the ICO in 2017/18, and the ICO confirmed no regulatory action will be imposed on NHSBT from the two reported incidents in 2016/17.

11. Clinical Audit

One clinical audit report was approved in this reporting period (DTS AUD2378): Audit of Engraftment Data for Autologous Harvests. The Stem Cell Immunotherapies (SCI) laboratories process and cryopreserve autologous Haemopoietic Progenitor Cell (HPC) products. This audit aimed to establish how many autologous transplants using HPC products were processed and then issued from each NHSBT site had a quick/prompt, slow or delayed engraftment. The key findings were; that engraftment data was received from 94.6% of all autologous transplants. A total of 95.7% of patients had either quick or prompt neutrophil engraftment, and 66.6% of patients had either quick or prompt platelet engraftment.

12. Research update

There were no research governance issues reported.

13. Just Culture Guide

Following the case of Dr Bawa-Garba, who was struck off the medical register after the death of a child, there has been unease in the medical profession nationally regarding the outcomes for the individual doctor given the system failures also apparent in the case. Part of the response of this case has been the publication of A Just Culture Guide by NHS Improvement to guide how individuals may be treated when things go wrong. CARE has reviewed the guide and recommends that NHSBT adopt its use, this will be considered at the June Executive Team meeting.

14. Safety Policy Matters

HEV antibody rich plasma for a patient with HEV infection not responding to ribavirin treatment has been collected and transfused. In anticipation of more requests for immune plasma for non-responding patients a standardised operational process is being developed.

The recommendation by SaBTO on imported plasma is expected in September 2018.

Authors
Louise Cheung, Assistant Director,
Governance and Clinical Effectiveness

Gary Mallinson, Safety Coordinator

Responsible Director
Dr Gail Miflin
Medical and Research Director