NHS
Blood and Transplant

NHSBT Board Meeting

Clinical Governance Report

25th January 2022

Status: Official

1. Summary and Purpose of Paper

This paper summarises the clinical governance issues discussed at the January NHSBT CARE meeting.

1.1. There are two new open SIs, one recorded within NHSBT during this reporting period and one outside the reporting period, reported in December 2021. One SI related to a death of a patient with a diagnosis of sickle cell disease and COVID 19 following a Red Cell Exchange and the second one related to a cornea that was issued for training purposes without family consent. Two previously reported SIs have been closed.

1.2. Preparatory work is ongoing for the planning and implementation of the new Patient Safety Incident Response Framework (PSIRF) in NHSBT, which will replace the current Serious Incident Framework. Meanwhile, the PSIRF working group has also updated the current Serious Incident Management policy (MPD772) to improve and streamline the investigation process until it is replaced by the PSIRF Plan.

1.3. An independent audit to meet the annual requirements for an independent assessment of NHSBT Data Security and Protection Toolkit (DSPT) submission performed during this reporting period found an assurance rating of "Substantial" across the ten National Data Guardian's (NDG) Standard areas reviewed. This represents NHSBT's highest level of assurance (both self-assessed and / or audited).

2. Action Requested

The Board is requested to note the contents of the report and seek assurance where required.

3. Serious Incidents (SIs)

3.1. There are two new open SIs recorded in NHSBT; one recorded within this reporting period (INC83041) and one outside reporting period (reported to the board in December 2021 - QI28175):

3.1.1. **Blood Supply: INC83041 - Supply of incompatible blood**
A patient with sickle cell disease sadly died following a Red Cell Exchange. The patient was admitted to an NHS hospital with COVID-19 and Pulmonary Embolism. TAS involvement was investigated (incident reference: QI27566) during an earlier SI call.

It was agreed that this was not an SI from TAS side as no errors or omissions have been identified.

However, this incident was classified as a 'near miss' event by BS as incompatible red blood cell units were issued although not transfused. This did not in itself cause harm as the cause of death was related to COVID-19, but two previous incidents had occurred through the same process, where incompatible units were also issued. Due to the recurrent nature and potential for harm, it was decided that the incident would be investigated as a serious incident.
Immediate mitigating actions have been put in place, including communication with Hospital Services, to prevent this happening again whilst the investigation is ongoing.

3.1.2. **OTDT: QI 28175 – Cornea issued for training purposes without appropriate family consent**
Consent for corneal donation for clinical use was undertaken by the National Referral Centre (NRC), and taken from the Next-of-Kin (NOK). The NOK did not consent for Research and Development and other Non-Clinical Scheduled purposes. The left cornea was unsuitable for clinical use due to low cell count. The right cornea was successfully transplanted.

The left cornea was incorrectly issued for Training and Development (T&D) and sent to the Royal College of Ophthalmologists without consent from the NOK. The NOK has been contacted and an apology that this happened was given. The family do not wish to receive a formal letter of apology and were grateful that we were open and informed them of the situation. A full Root Cause Analysis (RCA) was completed and currently is being written and will be shared with the team.

At the time the incident was highlighted, all tissue stored for research or training across the Eye Banks and Research Tissue Bank was checked to confirm appropriate consent was in place. Retrospective confirmation for all other tissue issued in the cohort with the impacted tissue sent to the Royal College was checked and confirmed appropriate consent was in place. Also, all tissue moved from the Eye Bank to the Research Tissue Bank with the impacted tissue was checked and confirmed appropriate consent was in place.

3.2. Two previously reported SIs have been closed (BS: INC82403 - cytomegalovirus (CMV) positive granulocytes and OTDT: QI25942 - Pre-cut cornea was not acceptable for transplant). Shared learning from these incidents will be reviewed now in the other directorates.

3.3. Shared learning reports from previously closed OTDT SIs (QI24336 & INC5466) were reviewed by CS and BS CARE groups in December 2021. No actions were identified within CS directorate. In BS directorate, several actions for improvement were identified and are being implemented such as alignment of Pulse with the Donation Safety Check, standardising the process for managing Rh variants, reviewing processes where there is duplicated documentation, calling the donor to confirm

information received by other route about them, and disseminating feedback to other regional groups for actions related to their functions.

4. Risk Management

4.1 The strategic level (parent) risk: NHSBT-01, Safety and Quality of Clinical Care, currently has 55 recorded functional (child) level risks (compared to 53 in the previous report), with no high scoring, priority 1 risks (risks with a residual score =/>15). The current 'worst child' score is moderate, with a score of 12.

4.2 The parent risk has been reviewed as part of the Board Strategic risks, it has a current score of 8 and relates to potential donor/patient harm caused by either: failure of NHSBT processes to mitigate a known risk (a serious incident); failure to scan for emerging infections; a known complication of transfusion or transplantation that we cannot currently mitigate and /or complications occurring in the wider health system where NHSBT is responsible for advice and education resulting in a loss of confidence and goodwill from our organisational stakeholders and the wider public. Mitigations in place are regularly reviewed within the target timescales to ensure that they remain relevant and effective, and gaps addressed as appropriate.

4.3 Teams across all directorates continue to review and update risks and actions. Currently there are no risks or actions which are overdue for assessment and/ or review.

5. Clinical Governance

5.1 **Clinical Governance arrangements-** the new Chief Nurse and Lead for Corporate Clinical Governance is currently reviewing our Governance structure and systems to further strengthen the process. This will include a review of how the current groups/ forums are aligned to support comprehensive and proportionate governance oversight across NHSBT with the right escalation to ET, ARGC and the Board. The outcomes from the review will be reported in April 2022.

5.2 **Patient safety - Incidents Management Framework** - The NHSBT working group has continued the preparatory work for the implementation of the new Patient Safety Incident Response Framework (PSIRF) in NHSBT. The Group's activities include resources gap analysis and the appropriate governance structure required to support the implementation of the Framework. This will be discussed by the Executive Team in February to agree the best implementation approach in NHSBT.
Meanwhile, the group has updated the current Serious Incident Management policy (MPD772) to improve and streamline the investigation process, reflect the changes in NHSBT structure and provide clarity on the SI definition in alignment with the Serious Incident Framework (SIF). This policy, however, will be replaced by the upcoming PSIRF Plan once finalised and implemented in NHSBT.

6. Clinical Audit

6.1 The clinical audit team have reported significant workforce resource issues due to long-term sickness absences. These issues have resulted in delays in completing and starting some clinical audits across all directorates. The current focus is to complete the scheduled ongoing audits rather than starting new ones until the staffing gaps can be filled. Secondment opportunities are being considered to fill the gaps whilst long term solution is sought.

6.2 One OTDT clinical audit report was approved in December 2021:
Audit of Organ Decline After Arrival of a Deceased Donor Kidney at a Primary Receiving Hospital (AUD4230) was approved in December 2021. This audit reviewed the duration between the deceased donor kidney being delivered to a primary receiving centre to be inspected for suitability and the time of the decline call to NHSBT Hub Operations. Delays in this can lead to subsequent organ decline or discard. No guidance exists on an acceptable duration, but it was assumed that centres would be able to decide on organ usability for a patient within 6 hours of kidney arrival at their centre at least 90% of the time.

From the limited data available, only 3/17 (18%) of the centres were able to notify Hub Operations of a kidney-only organ decline decision within 6 hours of organ arrival at the centre on 90% of occasions or more. In contrast, for SPK (simultaneous pancreas-kidney) organs the figure is 5/6 (83%) centres. The results will be shared and discussed with the Kidney Advisory Group to consider the implications, a national benchmark and performance targets and/or recommend further analysis or re-audit. CARE members were assured that OTDT were taking appropriate action.

6.3 The National Comparative Audit (NCA) report for the Use of fresh frozen plasma (FFP) and Cryo (2018) has now been approved by the NCA. Although the report was published three years after the audit, it was agreed that it is still relevant. This audit reviewed the practice of the use of prophylactic FFP and cryoprecipitate in neonates and older children, and of transfusions to treat bleeding and trauma. The audit found that there is much excellent transfusion practice in this patient group.
However, it identified that there were many areas where practice may be improved in the NHS hospitals trusts. This includes organisational issues as well as transfusion care for individual infants and older children. A local action plan to address the main findings has been included within the report and will be shared with hospitals involved.

7. Information Governance

7.1 The IG Team won the 'Special Recognition for Supporting the Covid-19 Effort with Information Governance' award at the National Health and Social Care Strategic Information Governance Network Ceremony. The award was presented to the team for their proactive, forward-thinking, and supportive work undertaken during the pandemic to enable the organisation to deliver its commitments to the Department of Health and Social Care (DHSC).

7.2 **Data Security and Protection Toolkit (DSPT) Audit -** DSPT is a key mechanism in place to support Health and Social Care organisations manage and measure their data security and data protection risk against the National Data Guardian's (NDG) ten data security standards, as well as supporting compliance with legal and regulatory requirements.

The objective of the audit on NHSBT was to meet the annual requirements for an independent assessment of the DSPT submission. The audit focused on an evaluation of the veracity of NHSBT's self-assessed DSPT return and the Independent Assessor's degree of confidence that it aligns with their opinion on the level of risk exposure across NHSBT and the effectiveness of the associated control environment.

The overall finding was an assurance rating of "Substantial" across the 10 NDG Standard areas. This represents NHSBT's highest level of assurance – both self-assessed and / or audited. The independent assessor stated that they recognised that the governance for data protection is very strong within NHSBT with well-defined governance roles, responsibilities, and authorities in addition to relevant working groups. They also acknowledged the significant amount of work being undertaken to improve the technical and policy control environments as well as the initiatives being undertaken in the culture and awareness space.

8. Safety Policy Update

8.1 JPAC (Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee) change in the deferral for donors whose sexual partners have been sexually active in Sub-Saharan Africa has been implemented for all blood and component donors, this was a recommendation from FAIR-II. This is a significant step in improving the diversity of our donors by removing a barrier to those who have previously lived in, or are partners of, people from this area of the world.

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