

NHSBT Board Meeting**Clinical Governance Report**

19th July 2022

Status: Official

1. Summary and Purpose of Paper

This paper summarises the clinical governance meeting discussed at NHSBT CARE held on 27th June 2022:

- 1.1 One new Serious Incident (SI) was recorded during this reporting period in relation to ABO blood group that was incorrectly entered into DonorPath. One previously reported 'near miss' SI' (INC83041 - Supply of incompatible blood) has been closed.
- 1.2 Risks related to workforce challenges remain across the Clinical Services and Blood Supply directorates attributed to vacancies, recruitment challenges, maternity leaves, and sickness absences. The risk continues to be proactively managed and monitored.
- 1.3 A clinical Audit which reviewed Tissue Donor Referrals process provided limited assurance. Only 2.1% of referrals forms sent from referring hospitals had all relevant fields completed resulting in NHSBT staff having to revert to the hospital for the missing information. This was attributed to the amount / type of information required on the form and the complexity in the process. It was highlighted that multiple different forms are in use increasing complexity and risk for the NHSBT Staff. An action plan has been put in place to address this issue.
- 1.4 Anti-HBc screening of blood donors has been successfully implemented. The team will continue to monitor the blood type of the donors being withdrawn to identify any rare blood groups, and clinical teams, together with operational colleagues, are drawing up a list of recommended priorities for implementation based on clinical risk.
- 1.5 NHSBT has submitted recommendations and information to the IBI Chair on areas that may be reviewed and considered prior to the completion of the inquiry's final report. The main opportunity to submit potential recommendations is in October 2022.
- 1.6 The Safeguarding Annual Report highlighted areas of need in education and process improvement. NHSBT has put in place strategies to learn from the issues and challenges which our colleagues face and, importantly, share this learning. This is being enabled through the NHSBT Safeguarding forum.

2. Action Requested

This paper is for information. It has been discussed at ARGC

3. Serious Incidents (SIs)**3.1 Open SIs**

One new SI was recorded within NHSBT during this reporting period (SI INC6230), which was reported previously and still under investigation. This related to OTDT where incorrect ABO blood group was entered onto DonorPath leading to the incorrect offer of organs (liver and kidneys) for transplantation. Work on changes to processes required to mitigate this risk is ongoing.

3.2 Closed SIs and shared learning

One previously reported Blood Supply SI has been closed: (INC83041 - Supply of incompatible blood). Shared learning from this SI was discussed during the CARE meeting on 27th June 2022. Key Points for Shared Learning, which are being addressed include:

- The need for clear processes for any staff groups that are not clinically registered/ qualified to ensure their processes and steps for support and escalation are clear and robust.
- The need for clear agreements/contracts in place clarifying the accountability of decision making where decisions are made with third parties.
- The need for a clear process flow and IT systems that support and complements the process flow, ideally one that enforces its adherence.

4. Risk Management

4.1 As a result of the implementation of the new Board Assurance Framework, the strategic risk 'NHSBT-01 Safety and Quality of Clinical Care' has been changed to 'BAF-01 Donor and Patient Safety'. Although the risk scoring has remained the same, the description has been broadened to correctly reflect the scale of the actual clinical risks.

4.2 Following the update, 45 functional level (child) risks have been assigned to the principal risk, BAF-01 Donor and Patient Safety. Ten of these risks are scored between 9 – 12, which is under the Judgment Zone in terms of risk appetite. Given the recent implementation, CARE instructed teams to review these risks to confirm scoring and actions before further scrutiny during the next meeting.

5. Clinical Audit

5.1 The Clinical Audit programme for 2022/23 currently consists of fourteen clinical audits. Of these, four audits have now been completed. The other ten are currently on track to be completed as planned.

5.2 Three completed audits have been submitted and approved during this CARE meeting:

- i. An audit of fetal RhD screening in IBGRL (AUD4087) showed a good report on the accuracy of results and the risk impact assessment was graded as moderate (Residual score 8) due to the high manual error rate throughout laboratory processes due to lack of automated technology.
- ii. An audit on Review of Quality Incidents (QIs) and Input Needed from the Patient Blood Management Team (AUD4514) was a repeat audit and followed new processes being implemented last year. The audit showed good compliance with process (100%) however there were many events (94%) where doctors felt that value was not added as part of the process. The next step will be discussions with QA colleagues to understand how this process could be made more efficient.
- iii. Audit of Missing Information in Tissue Donor Referrals (AUD4624): This audit aimed at assessing the quality of referrals of deceased donors from all hospital referral routes, along with the impact on the ability of the Specialist Nurses (SN) to progress to the family contact. Tissue and Eye Services (TES) stock levels are currently operating at around 50% of target stock for ocular tissue, which has instigated an internal 'special measures' plan. Depending on the importance of the information in the referral, poor quality or incompleteness can lead to an inability for SNs within the National Referral Centre (NRC) to clinically assess potential donors and progress to approaching the donor family to discuss possible options, leading to a loss of tissue and lower stock levels.

The audit showed that only 2.1% of referrals for potential ocular tissue donation from hospitals have all relevant fields on the appropriate referral documentation complete. Therefore, currently there is a limited assurance, and the risk score is 12 for *'TES may be unable to provide products and services due to inadequate donation activity'*.

This was due to the amount and type of information required on the form and undue complexity in the process. It was highlighted that there are multiple different referral forms in use. The results of this audit highlight the need for a review of the whole referral process, rather than continue with numerous small-scale changes. The action plan includes coordinating a wide-scale review and simplification of the referral process for tissue donation; undertaking an additional clinical audit to evaluating the timing of referrals and include a re-audit as part of the 2023/24 NHSBT clinical audit programme.

6. Directorate CARE updates

6.1 Workforce challenges

As reported previously, risks related to workforce challenges remain across the service functions, these are attributed to vacancies, recruitment challenges, maternity leaves, and sickness absences. The most affected functions are TAS, CMT, PBM team and IBGRL in Clinical Services. The risk continues to be proactively managed and monitored. Additionally, there are unprecedented challenges in recruiting Nurses to Blood Donation in specific parts of the country and urgent action is needed to prevent the loss of collection due to the lack of registered staff. Clarity is being sought on whether the parameters of "Healthcare Professional" can be expanded to cover Paediatric Nurses as well as Midwives, as the revalidation requirements need to be met for their professional registration.

6.2 Supply Chain issues

Two supply chain risks were discussed, firstly a shortage of supply of Terumo Optia bone marrow processing kits, this is currently being appropriately managed. Active engagement with Procurement team and TAS shows an improving picture with anticipation of resolution from late summer. Additionally, there is a global Bone Marrow Harvest filter kit shortage which is impacting our ability to book in Bone Marrow Harvests. Notification has been sent out to transplant centres to ensure that they are aware of the issue and to promote sharing of kits within the NHS where possible. The MHRA has been approached to allow us to use non-CE marked kits from the US, which are FDA approved.

6.3 Complaints and compliments

OTDT Governance team continue to monitor, respond to, and share learning from complaints and compliments. Key themes from the Complaints and Compliments over the last year (April 2021 to March 2022) were identified and included issues associated with communication and approaches made to families in respect to organ donation.

The Blood Supply complaints and compliments subgroup has completed a deep dive into clinical complaints related to the Donation Safety Check (DSC). A total of 32 complaints were related to the DSC during the period of June 2021 to March 2022. Of these, 17 complaints related to donors attending the session, but then being informed during the screening process that they were not eligible to donate. BS CARE has approved recommendations to review all donor resources (website, app, letter that accompanies the DSC) to ensure clarity and consistency. An action plan is being developed and the results are being fed into the current DSC review.

6.4 Research and innovation

A research request was discussed from the London School of Hygiene and Tropical Medicine (LSHTM) asking NHSBT to collect contact details of non-consenting donor families for the purpose of inviting them to participate in a research study evaluating the impact of the Deemed Consent legislation introduced in England in May 2020. The proposal is that NHSBT acts as a conduit to obtain and retain non-consenting donor families' details without their explicit consent to invite them to participate in the research later. This approach has raised several concerns particularly related to information governance where details of donor families are kept and used without consent, and risk to NHSBT reputation as it may impact on NHSBT's relationships with both donor families and hospitals. OTDT CARE agreed that interviewing Specialist Nurses Organ Donation (SNOD) would be more beneficial than contacting non-consenting families. Therefore, consensus was reached not to take this approach to the research.

A pilot study has been completed at Bristol Donor Centre, where apheresis cones were collected with specific consent from blood donors for the material to be used in research involving animal models between January & April 2022. This pilot showed that specific consent can be obtained from donors using a very considered and personal approach. The pilot has achieved its objectives with no negative feedback. The next step is to develop a formal, documented process for obtaining donor consent for this very specific area of research – and to define the criteria under which it will be used.

7. Safety Policy Update

- 7.1 Anti-HBc screening of blood donors has been successfully implemented. The team will continue to monitor the blood type of the donors being withdrawn to identify any rare blood groups and clinical teams and operational colleagues are drawing up a list of recommended priorities for implementation based on clinical risk.
- 7.2 5.2 Following the recently reported cases of Monkeypox, a rapid assessment for solid organ transplantation has gone live, and details are on the ODT website. A JPAC risk assessment and position statement has also been agreed with relevant changes to donor eligibility put into force.
- 7.3 5.3 Infected Blood Inquiry – NHSBT has submitted recommendations and information to the IBI Chair on areas that may require more evidence to be considered prior to the completion of the inquiry's final report. These have been shared with the Board. The next, and larger, opportunity for core participants to comment on potential recommendations will require submission in October 2022.

8. Information Governance (IG)

- 8.1 The IG and Information Security Team will be merging from 4th July 2022. The team will be re-named 'Data Security, Privacy and Records Management' to ensure that NHSBT continues to be in line with industry best practice, Arm's Length Bodies (ALBs) and reflects the new functions broader remit of work.
- 8.2 An incident was raised to the ICO in May 2022 following incorrect information being shared as part of processing two Subject Access Requests. Immediate mitigations were made to manage this incident to ensure that the information sent in error had been deleted and the individual affected was formally written to. The ICO responded to this incident and confirmed no further action would be taken following the steps put in place to mitigate by NHSBT. The ICO provided a number of recommendations that we will be reviewing and

implementing as part of the Root Cause Analysis and onward management of Subject Access Requests (SARs).

9. Safeguarding Annual Report

- 9.1 The Safeguarding Annual Report was reviewed. Oversight for Safeguarding and Prevent is managed under the Safeguarding Oversight Group (SOG), which was formed in 2020 following endorsement at NHSBT CARE. The SOG has identified areas of need in education and process improvement. NHSBT has put in place strategies to learn from the issues and challenges which our colleagues face and, importantly, share this learning. This includes Safeguarding forum, promoted on the updated Safeguarding page on the NHSBT intranet.
- 9.2 A total of 30 Safeguarding incidents have been reported this year compared to 16 incidents in the previous year (2020/21). It is assumed the increase in reporting is due to raised awareness with the launch of the new MPD and policy, however we are aware anecdotally that there is still some underreporting through the internal process. Of the 30 incidents 14 related to NHSBT colleagues and the rest involved patients/ donors and members of the public. There were none related to children and/ or young people. Of the 30 documented cases, 5 were closed by the nurse involved, 12 after consultation with a senior nurse, 15 were referred to emergency services and 3 referred to local authority (social care). All followed process, and auditing has allowed the SOG to identify areas of need in education and process improvement.
- 9.3 It was noted that only 64% of relevant employees completed their level 3 online Safeguarding mandatory training. The committee asked that urgent actions are required to prompt relevant colleagues to complete the online training.

Authors: Samaher Sweity, Head of Clinical Governance, Clinical Services

Betty Njuguna, Chief Nurse Clinical Services / Corporate Clinical Governance Lead

Responsible Director: Gail Mifflin, Chief Medical Officer

Date: July 2022