NHS
Blood and Transplant

NHSBT Board Meeting

Clinical Governance Report

27th September 2022

Status: Official

1. Summary and Purpose of Paper

This paper summarises the clinical governance meeting discussed at NHSBT CARE held on 1st September 2022:

1.1 All previously reported serious incidents have been closed following the meeting.

1.2 A new serious incident has occurred outside this reporting framework and subsequent to the CARE meeting. This event has been reported to the Board and will be discussed in the Board meeting through the CEO report.

1.3 NHS England and NHS Improvement have recently published a new Patient Safety Incident Response Framework (PSIRF), which will replace the current Serious Incident Framework (SIF). The introduction of this framework represents a significant shift in the way the NHS responds to patient safety incidents, increasing focus on understanding how incidents happen and on effective learning and improvement to prevent harm.

1.4 A near-miss bacterial screening incident occurred. A donor donated two units of platelets by apheresis. One unit was issued and transfused and the second was issued but then returned by the hospital due to clumps being observed in the unit. Samples from the pack were tested positive for S. aureus. The patient had no signs or symptoms of a bacterial transfusion transmitted infection (TTI). A subsequent sample from the donor was also positive for S. aureus, and hence the donor will be permanently withdrawn from donation.

1.5 Risks related to workforce challenges continue across directorates including staff shortage, turnover, skill mix gap, maternity leave and recruitment issues. Although there has been some progress with recruitment, it will take time to train new employees. Directorates are continuing to review and manage risks and related challenges.

1.6 A deep dive into the strategic risk 'Donor and Patient Safety (BAF-01)' was conducted and reviewed at CARE. The key themes identified are failure to follow processes / guidelines and/or human error; adverse events following blood products or stem cells donations; manual processes / lack or inadequate technology; and delay or failure to provide products or services. Key gaps in the management of this risk include a) differences in articulating and managing risks between directorates and within functions; b) Plasma for Medicine (PFM) risks are not all yet recorded in Pentana; and c) not all risks outside the Tolerance Zone have been reviewed and updated since the introduction of the new Board Assurance Framework (BAF). Actions to address these are underway.

1.7 Regulation 15 of the Health and Social Care Act 2008 requires that a Cleanliness Charter to be displayed at the entrances of NHSBT premises. This Charter has been finalised and now ready for the approvals and signatures of NHSBT CEO and Chairperson.

2. Action Requested

This paper is for information.

3. Serious Incidents (SIs)

3.1 Open SIs

No new SIs were recorded within NHSBT during this reporting period.

3.2 Closed SIs and shared learning

One previously reported OTDT SI (INC6230), has been closed. This is related to an incorrect ABO blood group that was entered onto DonorPath electronic system leading to the incorrect offer of organs (liver and kidneys) for transplantation. Shared learning from this SI was discussed during the CARE meeting, which are currently being addressed include:

- Ensure that any test results that are required to be manually entered are done with rigour with multiple safeguards in place.
- Ensure that checks are made when using hard copy results with 3 points of ID and checked against what has been entered onto an electronic system.
- Avoid any manual entries - assess feasibility of digitalisation of the results transfer.
- Staff health and well-being are paramount - awareness that during times of increased absences staff must not feel guilty and remain at work if unwell.
- Share and celebrate good practice of individuals and teams.
- Root Cause Analysis (RCA) methodology is not as useful as conducting a process mapping in ODT, and with the imminent arrival of PSIRF, shall no longer be used as a main tool for investigation.

Key shared learning from a previously closed OTDT SI (QI28175), in relation to cornea issued for training purposes without appropriate family consent, was also discussed. The key learning is to ensure that there is a system and checks in place to confirm appropriate consent is given before using/issuing samples/tissues for non-clinical use e.g., education, research, commercial use. Coincide with this, a group has already been set up which is currently reviewing the consent process across BS and CS directorate (see section 6.3)

4. Risk Management

4.1 A deep dive into the strategic risk 'Donor and Patient Safety (BAF-01)' has been conducted and reviewed at CARE. This was the first deep dive since the introduction of the new Board Assurance Framework (BAF).

4.2 The key risk themes identified are failure to follow processes / guidelines and/or human error; adverse events following blood products or stem cells donations; manual processes / lack or inadequate technology; delay or failure to provide products or services.

4.3 Key gaps have been identified include a) differences in articulating and managing risks between directorates and within functions, hence a systematic and central approach to risk management is required; b) Plasma for Medicine (PFM) risks are not yet recorded in Pentana; and c) not all risks outside the Tolerance Zone have been reviewed and updated since the introduction of the new BAF.

4.4 To address the gaps, a Risk Lead for the Clinical Services Directorate has now been appointed to the vacant post and three further risk managers are being recruited to support the central risk management team.

5. Clinical Audit

5.1 Six out of the planned 14 clinical audits for 2022/23 have now been completed. The other eight are currently on track to be completed as planned.

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

I. Infectious Disease Markers (IDM) Reporting (AUD4332) - This audit aimed to ascertain if procedures are being followed within NHSBT to ensure timely communication of abnormal IDM results of stem cell samples, thereby reducing the risk of transmission of disease via stem cell transplant. The audit indicated moderate assurance as the findings showed that current guidance for communicating screen reactive and confirmatory results is confusing and sparse. Additionally, due to lack of documentation template, audit trail is difficult to follow and unreliable. Actions for improvement include a review of the guidance provided to staff, and the introduction of a tracking document to follow samples and provide an audit trail.

II. Donor Registry Searches audit (AUD4328) – This audit was prompted by an incident in which a patient's HLA type was manually entered incorrectly into the World Marrow Donor Association (WMDA) - database of donors used for preliminary checks. Following the incident, processes were agreed by the laboratories to check accuracy, thereby reducing the risk of this issue recurring. The audit provided substantial assurance that processes were adhered to.

6. Directorate CARE updates

6.1 Workforce challenges

Workforce challenges continue particularly in BS and CS directorates including staff shortage, turnover, skill mix gap, maternity leave and recruitment issues. Although there has been some progress with recruitment, it will take time to train new employees and reduce the workload of current staff. Each directorate will continue to review their workforce issues with HR partners more closely and report on progress and issues in the next meeting.

6.2 Patient Safety Incident Response Framework (PSIRF)

Following the piloting phase, NHS England and NHS Improvement have published PSIRF on 16th August 2022. The PSIRF will replace the current Serious Incident Framework (SIF) and makes no distinction between 'patient safety incidents' and 'Serious Incidents'. As such it removes the 'Serious Incidents' classification and the threshold for it. The introduction of this framework represents a significant shift in the way the NHS responds to patient safety incidents, increasing focus on understanding how incidents happen and on effective learning and improvement to prevent harm and improve safety.

The Board will be responsible and accountable for effective patient safety incident management.

The transition from the SIF to PSIRF will be a gradual process that is expected to be completed by Autumn 2023. A Task and Finish Group has started the preparatory work. There are also resources and training implications, which the group is currently reviewing.

6.3 Donor Consent issues

In light of two issues around blood donor consent, a Task and Finish group has been established to address these and agree the amendments required. The first issue is that donors need to be informed that NHSBT performs genotyping for red cell antigens, and the second is that although information is provided in the Consent Booklet, the current consent no longer covers the use of clinically suitable products for non-therapeutic use e.g., Non-Clinical Issues, research etc.

6.4 **A near-miss bacterial screening incident (QI31585)**

A donor donated two units of platelets by apheresis in June 2022. Bacterial screening was negative throughout. The first unit was issued and transfused. The second unit was issued but then returned by the hospital due to clumps being observed in the unit. The affected unit was returned to the Microbiology Services Laboratory. Samples from the pack were positive for S. aureus. These results were confirmed on a second sample from the pack and the hospital team was contacted. The patient had no signs or symptoms of a bacterial transfusion transmitted infection (TTI). A subsequent sample from the donor was positive for S. aureus. The donor will be permanently withdrawn from donation. This incident is being managed as a major and was reported to MHRA through SABRE (Serious Adverse Blood Reactions and Events) tool.

6.5 **HHV8 screening and testing of organ donors**

A group has been investigating the implementation of HHV8 screening and testing of organ donors since December 2021. SNODs (Specialist Nurses Organ Donation) are ready to go live with testing from 1 September, however this will require instruction from DHSC.

6.6 **Plasma for Medicine PfM update**

The CQC have advised that PfM does not fulfil the criteria for regulation and proposed to cease regulating PfM. Clarity is being sought to understand the impact this will have on the collection of Source PFM (sPFM) for the purpose of research (e.g., REMAP CAP trial) where it will be directly transfused to patients, and to repurpose sPFM into clinical FFP (Fresh Frozen Plasma) should stock levels dictate it.

6.7 **Review of critical manual processes and digital solutions**

All directorates have been reviewing their critical manual processes associated with potential risk of harm to patients/donors. The purpose of the review is to support identifying the scale of the risk and to inform the priorities in terms of urgency to address these by long term digital solutions. The need for the review was identified following shared learning from several SIs where one of the identified themes is the risk associated with manual transcriptions.

The lists of the manual processes have been discussed at each directorate CARE. There is more work required than anticipated to finalise the priority lists for CS and BS directorates. These will be discussed at each directorate SMT before discussing at NHSBT CARE.

7. Safety Policy Update

No new updates. There have been no Therapeutic Products Safety Group (TPSG) meetings since last report.

8. Information Governance (IG)

8.1 From the 1st of August 2022, all NHS organisations must have been compliant with the National Data Opt-Out, which allows a patient to choose if they do not want their Confidential Patient Information (CPI) to be used or disclosed for purposes beyond their individual care and treatment – i.e., for research and planning. A questionnaire has been sent out to staff to ensure baseline understanding and a mesh mailbox has been set up to enable encrypted transfer of research data to NHS Digital.

8.2 The Data Security Protection Toolkit (DSPT) was submitted on 30th June 2022 highlighting a number of significant improvement areas across both Data Security and Privacy. This included improvements in Supplier Risk Chain, continued uplift of Security and Privacy policies, as well as process improvements across Firewall management. Few gaps remain in standards and desired capabilities, with risks remaining for example in patching of legacy systems. Gaps have activities planned under differencing levels of maturity, and all are resource and priority dependant.

9. Standards for Healthcare Cleanliness

Regulation 15 of the Health and Social Care Act 2008 requires healthcare environments to be clean, secure and suitable for use. A Cleanliness Charter is required to be displayed at the entrances of NHSBT premises. This Charter has been finalised and will be sent to NHSBT CEO and Chairperson for approval and signatory.

Stakeholder engagement has been achieved across all functions and colleagues are already working on implementation.

Author

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