NHS Blood and Transplant

NHSBT Board Meeting

Clinical Governance Report

2nd December 2021

Status: Official

1. Summary and Purpose of Paper

This paper summarises the clinical governance issues discussed at NHSBT CARE meeting held 1st November 2021.

- There are no new open SIs recorded within NHSBT during this reporting period. One SI occurred outside of this reporting period. Two previously reported SIs are continued to be under investigation and hence are still open. A new SI has been reported to the Board in November 2021.
- Following the publication of the Cumberlege 'First Do No Harm' (2020) and Paterson Inquiry (2020) reports, which outlined recommendations to improve patient safety across the NHS, an established Stakeholder Working Group has performed a Gap Analysis and reviewed NHSBT practices and processes. As a result, several actions related to these reports have been identified and will be presented to the Executive team for consideration.
- A new Patient Safety Incident Response Framework (PSIRF) is currently being piloted by NHS England/Improvement, which will replace the Serious Incident Framework (SIF) in England. The Framework is expected to be finalised and published in April 2022; NHS Healthcare providers are encouraged to start implementation thereafter. An informal working group has been established and has started preparing for the implementation of PSIRF in NHSBT.
- NHSBT has considered options to implement additional testing against occult Hepatitis B should we be instructed to implement this following work done by SaBTO. Implementation would start within six months of instruction to allow for the changes to processes and IT systems.

2. Action Requested

The Board is requested to note the contents of the paper and discuss where relevant.

3. Serious Incidents (SIs)

3.1 There were no new open SIs recorded within NHSBT during this reporting period. Outside of the reporting period, one SI has been reported:

Blood Supply - INC83041: Supply of incompatible blood

The Board has been notified of a new serious incident related to a patient's death within 24 hours of receiving a Red Cell Exchange. The patient with a diagnosis of sickle cell disease was admitted to an NHS hospital with COVID-19 and Pulmonary Embolism (PE) in November 2021.This incident was classified as a 'near miss' event as incompatible red blood cell units were issued in a complex case involving a patient with antibodies, after discussion between

NHSBT and the hospital involved. This did not in itself cause harm, but we became aware of two events in the past where, through the same process, incompatible units were also issued, in one event a potential serious incident call occurred. Due to the recurrent nature and potential for harm it was therefore decided we will investigate this as a serious incident. Mitigating actions and communications with Hospital Services departments have been put in place to prevent this happening again whilst the investigation takes place.

3.2 Two previously reported SIs continue to be under investigation. Although the timelines for the closure reports of both SIs have passed, CARE agreed that neither will be closed until the agreed actions had been completed as discussed below:

OTDT: QI25942 - Pre-cut cornea was not acceptable for transplant

The Optical Coherence Tomography (OCT) machine which will measure corneal graft thickness has now arrived. the HTA is being engaged to ensure the necessary approvals are in place prior to its use for clinical purposes. The cutting service remains paused, but it is expected to resume in January 2022. The incident team agreed to complete the closure report after the HTA approvals and paperwork are in place. Therefore, the closure report will be delayed beyond the 90 working day timeline as defined by the current SI Management policy (MPD772).

BS: INC82403- cytomegalovirus (CMV) positive granulocytes

A customer ordered some granulocytes and missed the requirements on the Online Blood Ordering System (OBOS) for CMV negative granulocytes. The Consultant Approval form included the CMV negative requirement, and this was not checked against the OBOS order when it should have been. This resulted in the CMV negative requirement being missed and not supplied. After the transfusion, but unrelated to this error, unfortunately the patient sadly died from complications of the bone marrow transplant.

Subsequently, another similar incident (INC82778) occurred in October associated with the same process, albeit not resulting in harm. We decided to investigate both together and the outcomes and shared learning will be outlined within the same SI closure report. In addition, a continuous improvement event has been held to inform the action plan. Therefore, the closure report will also be delayed beyond the 90 working days.

3.3 Two additional initial SI calls were held during this reporting period, but these were downgraded and managed as Major or Other Quality incidents:

CSO: QI26272 - A patient sadly died from an arterial stroke following a transfusion of washed red blood cells. The patient had a rare antibody which the red cells were not matched for resulting in a transfusion reaction. The Root Cause Analysis indicated that there was no error or omission on the part of NHSBT that contributed to the patient's unfortunate death.

OTDT: QI26051 - A patient was diagnosed with an eye infection following receiving Allogeneic Serum Eye Drops (AlloSED) provided through NHSBT. After the investigation and AlloSED batch testing, it was confirmed by a Microbiologist that the AlloSED batch was not contaminated. Therefore, it was clear that the infection was not caused by the AlloSED dispatched by NHSBT. We have sent a letter to the patient's mother to inform her of the investigation outcomes.

4. Risk Management

The strategic level (parent) risk: NHSBT-01, Safety and Quality of Clinical Care, remains moderate and the 'worst child' score continues to be 12. Currently it has 53 recorded functional (child) level risks (compared to 49 in the previous report), with no high scoring, priority 1 risks (risks with a residual score =/>15).

5. Clinical Governance

5.1 **Patient safety-** The Paterson Inquiry report was published in February 2020 and aimed to address public concerns raised in part by the case of Ian Paterson, a breast surgeon who, in April 2017, was convicted of wounding with intent / unlawful wounding and was subsequently jailed for 20 years. In December 2017 the Government commissioned an independent inquiry to investigate Paterson's malpractice and to make recommendations to improve patient safety. 211 patients, or their families, gave evidence. In summary, the inquiry report is primarily about poor behaviour and a culture of avoidance and denial whereby a surgeon performed unnecessary procedures despite complaints about his practice.

The Cumberlege 'First Do No Harm' report was published in July 2020. The Independent Medicines and Medical Devices Safety (IMMDS) review team, led by Baroness Cumberlege, met more than 700 women and families in its two-year review of evidence and personal testimony. The report published by the review team examines how the healthcare system in England responds to reports about the harmful side effects from medicines and medical devices. The focus of the review was harm caused by pelvic mesh implants and two drugs prescribed in pregnancy, which caused avoidable harm to thousands of people.

The medical and surgical interventions covered by these reports are not ones that sit directly within the remit or function of NHSBT. Nonetheless, there are important points within the reports that should resonate within all organisations involved with the delivery of healthcare.

During June-September 2021 a NHSBT Cumberlege and Paterson Gap Analysis Stakeholder Working Group reviewed NHSBT practices and processes and identified several actions related to the reports' recommendations in areas such as patient information, complaint management, HR processes and disciplinary procedures, duty of candour, informed consent, clinical audit, and records management.

This Stakeholder Working Group also considered this an opportunity to further scrutinise NHSBT current processes and procedures and explore other opportunities to strengthen and improve, and additional actions were also therefore identified in areas including patient [and donor] safety management, the NHS Learn From Patient Safety Events (LFPSE) system, managing serious incidents and freedom to speak up.

The next step is to review the context and proposed actions at the Executive team.

5.2 **Incidents Management Framework**- A new NHS England/Improvement (NHSE/I) Patient Safety Incident Response Framework (PSIRF), which is replacing the historical Serious Incidents Framework (SIF), has been developed and is currently being piloted with a small number of early adopters using an introductory version of the framework. The PSIRF guides the NHS on how to develop the cultures, systems, and behaviours necessary to respond to patient safety incidents in a way that supports and ensures learning and improvement. The PSIRF is expected to be finalised and published in April 2022; NHS healthcare providers Trusts are encouraged to start implementation thereafter.

The PSIRF is much broader in scope compared to the SIF; instead of focussing on a small proportion of incidents deemed 'serious', PSIRF aims to support the development of systems and processes for incident response more broadly. A culture shift is key in the successful implementation of this framework.

An informal working group led by Betty Njuguna (Chief Nurse for Clinical Services and Lead for Corporate Clinical Governance) has started preparing for the implementation of the PSIRF in NHSBT and liaising with NHS England and NHS Improvement. This will be discussed by the Executive Team in January to agree how this might be best implemented in NHSBT.

5.3 **Infection Prevention and Control (IP&C)**
The Lead Nurse for IP&C is working with operational teams to review the COVID secure measures that were put in place in the pandemic which will be reduced in accordance with UK Health Security Agency (UKHSA) (previously PHE) guidance.

The new NHS England National standards for Healthcare Cleanliness (2021) have been published and include guidance for implementation. All NHS providers are expected to meet with the mandatory requirements as they are aligned with Regulation 12 of the Health and Social Care Act. The standards seek to drive improvements whilst being flexible enough to suit the complexities of different healthcare organisations and their settings, and focus on a collaborative approach, different staff groups, clinical and non-clinical who need to work together to meet the cleanliness standards.

The standards introduce a 'Commitment to Cleanliness Charter' to promote the ethos of the 2021 standards, this publicises the organisations commitment to achieving a consistently safe and high standard of cleanliness. There will be a requirement for some functional areas or buildings to display a new 'star rating', to give donors/patients, staff and public an understanding of the standards of cleanliness being met.
A paper is being prepared for the Executive team to review these standards, our gap analysis against them, together with recommendations for action.

5.4 **Redress Scheme-** The Health and Social Care Quality and Engagement (Wales) Act received Royal Assent in June 2020 and is likely to come into effect in Spring 2023. The Redress scheme for complaints may become part of the act. The Redress scheme is when a health board or Trust in Wales receives a complaint that says a person has suffered harm because of care or treatment, for any potential claim would be worth

£25,000 or less, the Health Board/Trust must consider whether there was or might be a qualifying liability (i.e., they must consider whether there was negligence in the provision of the care or treatment). While the new legislation only covers Welsh patients, it may also cover Welsh patients who come to England for transplantation. Work is ongoing to ensure NHSBT is covered in the guidance and stakeholder meetings have started to discuss the potential implications of the Act, including whether NHSBT would be involved in the liability.

5.5 **Higher Level Responsible Officer (HLRO) visit**- All NHS organisations have a statutory requirement to have a Responsible Officer who is accountable for clinical governance in the organisation as well as having processes in place to appraise and revalidate doctors. NHSBT maps to NHS England for this and we recently had a HLRO visit and report. The NHS England London Revalidation team commended NHSBT on having comprehensive policy documentation in place and demonstrating a number of elements of good practice. We were given several helpful recommendations to further improve systems and processes. There were no comments of concern, and an action plan is being agreed.

6. Clinical Audit

One OTDT clinical audit report was approved in October 2021:

Tissue Donor Referrals Audit (AUD3872). A high proportion of referrals for deceased tissue donation were deferred for predominantly medical reasons, which caused significant work for National Referral Centre (NRC) staff. A training programme for SNOD (Specialist Nurse – Organ Donation) was initiated to address this issue.

This audit compared deferral rates before and after rollout of the training programme. After completing the training, 85% of SNODs felt their knowledge around consent for tissues had improved. The deferral rate reduced from 39.7% to 19.9%. Actions for further improvement include: improving documentation; reviewing the list of outcome codes and exploring further reasons for deferral, which will feed into future training development.

7. Information Governance

A new data sharing code of practice has been published which provides practical steps to ensure personal data is shared in a fair, safe and transparent way, but also protecting people's privacy and technological innovation. IG Team will use this updated guidance to continue to advise business areas across NHSBT to ensure we are complaint with Data Protection Act (DPA) 2018.

8. Safety Policy Update

In anticipation of new recommendations on testing for donors with Occult Hepatitis B infections, NHSBT has considered how they would implement these if instructed to. The Executive team considered recommendations following an options appraisal. NHSBT intends to start implementation of these recommendations within six months of instruction to allow changes to processes and IT to be introduced. Full implementation will require the new

microbiology serology contract to be in place, but we can implement in a 'fail safe' manner prior to this starting on our current testing machines. The implementation would start with 70% donors being tested and this would increase to 100% over the following months. The risks of a staggered implementation were assessed as being the lowest practicable and extremely low, these were accepted. With additional testing of 70% donors in place they will be significantly lower than the risks are today.

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