NHS
Blood and Transplant

NHSBT Board

Clinical Governance Report

28th January 2021

1. Status – Official

2. Executive Summary

This paper summarises the NHSBT CARE meeting held 5th January 2021.

- Within the reporting period of October and November 2020, one new SI was recorded, the investigation has now been completed.
- The FAIR recommendations have been accepted by Ministers with planning for implementation Summer 2021.

3. Action Requested

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

4. Overview of events in this reporting period

One new SI was recorded during the reporting period:

QI21561 - NHSBT undertakes human leucocyte antigen (HLA) typing, also known as tissue typing, on potential recipients of stem cell transplants in the UK. NHSBT also undertakes the same typing on potential donors in the UK including family members, British Bone Marrow Registry (BBMR) donors and NHS Cord Blood Bank (CBB) donations. BBMR and CBB tissue types and other relevant information are entered manually into international databases by NHSBT and a search for potentially matched donors is run.

In November 2020, the patient's folder and donor search results were reviewed in response to a request to explain the issues in finding suitable donors to NHSBT's Board. As a result of this review, an error made in 2019 was identified where a colleague made a single digit error when manually entering a patient's HLA type into the database. "A*68:01" was manually entered, not, as it should have been "A*68:02" and hence no suitable donors were identified. Had apparently matched donors been selected in error, this would have been identified at the confirmatory testing stage, if not before (when reconciling reports) so a never event (an unintentionally mismatched transplant) would not have occurred. There has however been a delay in correctly searching for suitably matched donors for this recipient. With the corrected tissue type entered a new run identified three potential donors, however none is suitable after further investigation, therefore the stem cell transplant has not been delayed. Letters of apologies have been sent to the clinicians and the patient.

The team undertake approximately 300 searches per annum and have been performing similar searches for decades, so the incidence of such errors is extremely low. We have performed a lookback of all recipients for whom a suitable donor was not found on searching internationally and no similar errors have been identified.

This incident has been reported to the World Marrow Donor Association (WMDA) and Human Tissue Authority (HTA).

Three additional incidents were escalated to directors as requiring formal SI assessment. These are now all being managed as Major Quality Incidents:

- **QI21129 – Possible bacterial contamination:** An initial potential SI meeting was held after we were notified that a patient had been receiving a red cell transfusion and approximately 25 minutes into the transfusion he was found collapsed. There were no signs of angioedema or anything to suggest anaphylactic type of reaction, all blood cultures have since been negative. There is nothing to indicate that this was due to the transfusion. This was investigated as a possible bacterial contamination with an SI call to ensure that there were no issues with other transfused units but subsequently managed as a major QI.
- **QI21186 – Inappropriate donation under the 12-week deferral period:** An initial potential SI meeting was held 10th November 2020. A National Health Service Professional was employed as an agency worker at West End Donor Centre as a Donor Carer. This individual was able to create three PULSE accounts with similar but not identical information in order to enable them to donate blood more frequently than it is safe or permitted to do so. There was no harm, and this was managed as a major QI
- **P01226626 – Solicitor request regarding delivery time of components:** An initial potential SI meeting was held following contact by solicitors acting for a patient raising questions about the delivery time of components on 12th August 2018. This was in relation to a claim being raised against the hospital. There was no evidence of error by NHSBT, we are responding to the solicitor's request.

5. Infected Blood Inquiry Update

NHSBT continues to provide boxes of documents to the IBI although at a much slower rate than previously due to ongoing COVID. The IBI are sending documents, from the earlier box deliveries, for review. The review includes consideration of relevance, Legal Professional Privilege and redaction.

NHSBT is continuing to prepare Rule 9 Responses to requests for information. These are very lengthy requests both from an organisational perspective and also individual request to clinicians.

The witness hearings recommenced on 22 September 2020 covering in the main haemophilia clinicians. The IBI medical ethics experts are due to give evidence in January 2021.

6. Care Quality Commission (CQC) - Convalescent Plasma Clinics

Convalescent Plasma collection sites are currently registered with the CQC as temporary sites. The CQC currently remain happy to continue with this approach. This will be reviewed once the implications of the outcomes of the trials are understood.

7. Clinical Audit

Previously it has been reported that the planned Clinical Audit programme for 2020/21 has been revised due to COVID. We are currently on track to complete eight of the

nine planned audits by the end of Q4. One audit has been delayed due to insufficient data as a result of the pandemic, and so likely to complete in early 2021/22.

8. Risk Management

The strategic level (parent) risk: NHSBT-01, Safety and Quality of Clinical Care, currently has 47 recorded functional (child) level risks, with no high scoring, priority 1 risks (risks with a residual score =/>15). The current 'worst child' score is moderate, with a score of 10.

9. Information Governance (IG)

The Data Security and Protection Toolkit (DSPT) was released on the 3rd December 2020. Submission is due by 30th June 2021.

The IG team have been dealing with one reportable incident. The Information Commissioner's Office (ICO) have made further enquires related to the incident and they are now reviewing our responses.

10. Research

There have been no clinical trials adverse events or incidents reported in the period from July 2020 to 17th December 2020.

11. Safety Policy Update

The FAIR recommendations have been accepted by Ministers with planning for implementation Summer 2021.

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