NHS
Blood and Transplant

NHSBT Board Meeting

22nd July 2021

Status: Official

Summary and Purpose of Paper

This paper summarises the clinical governance issues discussed at NHSBT CARE meeting held 24th June 2021.

- There are two open SIs in OTDT, both of which are linked to retrieval, these have previously been reported to the Board and remain under investigation. Root Cause Analysis (RCA) meetings have been held and the teams are now working on a corrective plan of action.

- A potential safety concern has been raised anonymously to the Care Quality Commission (CQC) regarding the use of machines collecting plasma. The concern related to the ability for air to collect in the 'lines' between the donor and the machine and how these were managed. A detailed response outlining the actions taken to manage these events has been sent to the CQC and we continue to be in correspondence with them over this matter. The machines are not being used currently. Both the manufacturer and NHSBT reported these incidents to the Healthcare products Regulatory Agency (MHRA).

- It was highlighted that NHSBT has not been compliant with Prevent training since its inception under section 26 of the Counter-Terrorism and Security Act 2015. This training aims to ensure the safeguarding of children, adults and communities from any threat of terrorism. This issue was raised at Executive Team (ET). We will be introducing this to our mandatory training portfolio in the near future.

- In relation to the Infected Blood Inquiry (IBI), an NHSBT executive level steering group has started meeting to oversee our preparation and interaction with this important inquiry as we move towards the next round of witness hearings. This group agreed a change in the governance route and will itself report to ET, approving and escalating events to the ARGC and the Board as appropriate. The IBI will therefore not be reported through CARE in the future.

- As governmental restrictions change, the social distancing measures are being reviewed in Blood Donation sessions, as we ensure we are in a position to collect blood. We will be reducing social distance to 1^{+} metre but remaining within guidance with our additional mitigations. Further conversations at ET have considered the wider government changes announced this month.

Action Requested

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

1. Serious Incidents (SI)

1.1 During April and May 2021, two new Serious Incidents (SIs) were reported. These two SIs have been reported to the Board in the previous report and are under investigation:

- ***OTDT: INC5466*** *– A heart was retrieved without the donor family's agreement*

Multi-organ donor was facilitated in April. There was a contraindication for heart donation due to a previous heart valve replacement and the family did not consent to heart donation. However, the heart was retrieved and went to a heart valve bank. The specialist nurse organ donation (SNOD) who had accepted consent for other organs later noted the error and the heart was returned to the donor's body.

The Root Cause Analysis (RCA) indicated that there were multiple factors that led to the heart being retrieved without consent in place. The unusual situation, testing requirements, and logistics appear to have contributed to a lack of adequate handover taking place. These may also have provided distraction and the consent form was not appropriately reviewed and fully comprehended by the SNODs involved and the Retrieval team.

- ***OTDT: INC5477*** *– Eye tissue was retrieved despite Coroner's restriction to the retrieval of corneas*

Consent for solid organ and tissue donation was given by the family and corneal donation was also agreed. However, despite an objection from the coroner to corneal donation, a referral was made to the National Referral Centre (NRC) for cornea and tissue donation and the corneas were removed. The family and the coroner have been sent letters of apology.

The RCA indicated that there were multiple factors that led to the corneas being retrieved despite Coroner's restriction. The main factor is that the SNOD and NRC processes were not aligned leading to the information regarding Coroner restrictions not being identified prior to retrieval. The team are currently working on corrective actions and improving documentation processes.

2. Care Quality Commission (CQC) update

2.1 A potential safety concern has been raised anonymously to the CQC regarding the air-in-line incidents during donation of plasma using machines within Convalescent Plasma (CVP)/ Plasma for Medicine (PFM). The concerns surrounded the malfunctioning of the machines but also concerns about the management of the incidents. A detailed response outlining the action taken to manage these events has been sent to the CQC and we are awaiting their response.

2.2 We are in discussion with our DHSC Sponsor team over regulation regarding organ allocation algorithms in the CQC framework. Discussions are ongoing on this in terms of who would be best to regulate this activity.

3. Risk Management

3.1 It was highlighted that NHSBT has not been compliant with Prevent training. Since 1st July 2015, all specified authorities have a responsibility to ensure that they demonstrate compliance to Prevent duty, as outlined under section 26 of the Counter-Terrorism and Security Act 2015. This training aims to ensure the safeguarding of children, adults and communities from any threat of terrorism. Work is currently underway to address this gap in training in NHSBT. This issue was raised at ET. We will add this to risk register whilst we put this training in place.

3.2 The strategic level (parent) risk: NHSBT-01, Safety and Quality of Clinical Care, was reviewed and has 50 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. Since the previous risk report, the three directorates have reviewed and updated their risks in the risk register, Pentana. There are no new risks added with a high score.

4. Infected Blood Inquiry (IBI) Update

4.1 The NHSBT Executive level steering group has started meeting. This group agreed a change in the governance route and will itself report to ET and approve reports to the ARGC and the Board as appropriate. The IBI will therefore not be reported through CARE in the future.

4.2 NHSBT continues to draft responses to Rule 9 Requests received from the IBI. Papers will be brought to the ET in the coming months on matters where we feel the Inquiry may wish to concentrate questioning of our witnesses

5. Clinical Governance

5.1 The 'For the Assessment of Individualised Risk' (FAIR) group changes have been successfully implemented on 14th June. This event received a lot of media attention.

5.2 Social distancing measures are being reviewed in Blood Donation sessions, the Infection, Prevention and Control (IPC) Committee and BOLT recommended reducing social distance to 1^{+} metre, including considering additional mitigations. Further conversations at ET have considered the wider government changes announced this month.

5.3 An incident in OTDT(ODT INC 1184) has been reviewed by internal and external stakeholders. All actions and recommendations discussed with the Executive team. Agreement and consensus that all the required actions have been completed and the incident can now be closed.

5.4 As a result of RCA for previous near misses and SIs, work is being completed within OTDT to look at the number of manual workarounds in the OTDT Hub and Information Services before any offers go to transplant centers, and the impact of these. Having a number of work arounds provides a significant risk and impacts on both patients and teams. Preliminary work has been completed. The provisional findings have been escalated to the OTDT Medical Director and the Chief Digital and Information Officer. The next step is to consider how to prioritise the IT solutions required for manual workarounds.

6. Clinical Audit

6.1 A total of twelve audits due for completion within 2020/21 and these are on track to be completed as planned.

7. Information Governance (IG)

7.1 The Data Security and Protection Toolkit (DSPT) is measured across ten Data Standards and NHSBT's 2021 submission demonstrates improvement in maturity and capability over 9 Standards.

7.2 IG maturity is high, with Cyber maturity growing (due to the Cyber measures being relatively new in comparison with the IG measures).

7.3 Data Protection Training compliance is 99.8% as of 31 March 2021.

8. Safety Policy

8.1 NHSBT is working with the Joint United Kingdom Blood Transfusion Services Professional Advisory Committee (JPAC) and Medicines and Healthcare products Regulatory Agency (MHRA) to put in place a UK wide position statement in order to help answer requests from members of the public who wish to have the option to receive blood from non-vaccinated donors should the need arise.