OFFICIAL

The Minutes of the Ninety-First Public Board Meeting of NHS Blood and Transplant held at 10.15 am on Thursday 30th May 2019 at the Royal College of Anaesthetists, Churchill House, 35 Red Lion Square London

Present:	Ms M Banerjee	Mr J Monroe
	Ms B Bassis	Lord J Oates
	Mr R Bradburn	Mr K Rigg
	Mr A Clarkson	Mr C St John
	Ms H Fridell	Prof P Vyas
	Mr G Methven	Mr P White
	Dr G Miflin	Dr H Williams
In Attendance:	Mr I Bateman	Mr D Bowen (item 13)
	Mr B Henry	Ms L Hontoria del Hoyo (item 11)
	Ms K Robinson	Ms A Rashid
	Ms C Rose	Ms J Hardy
	Mr M Stredder	Mr J Mean
		Mrs K Zalewska

1 **APOLOGIES AND ANNOUNCEMENTS**

Ms Banerjee welcomed Ms Alia Rashid, who had been appointed as Chief of Staff from 1st July,2019. Also welcomed were Mr Jeremy Mean from the Department of Health and Social Care, and Ms Joan Hardy from the Department of Health in Northern Ireland. Apologies were received from both the Scottish Government and the Welsh Government.

2 **DECLARATION OF CONFLICT OF INTEREST**

There were no conflicts of interest.

3 (19/37) **BOARD 'WAYS OF WORKING'**

The 'Ways of Working' were noted.

4 (19/38) **MINUTES OF THE LAST MEETING**

The minutes of the March 2019 meeting were approved subject to the following correction:
Item 14 ODT Hub Programme – 2019/20 proposal: Amend Outcome to read '*The Board to have oversight and responsibility for tracking the spend and outcome for the programme*' rather than the Finance Committee.

5 (19/39) **MATTERS ARISING**

The Board noted progress on the Matters Arising:

1 – Clinical Governance Report – to report on any changes required to testing as a result of the HEV transmission, e.g. move to individual testing: Carried forward to the September Board meeting (Dr Miflin) **GMi**

2 – Discussions on the need for a standing committee on bone marrow transplantation were ongoing. A report on transplantation numbers was included on the agenda.

3 – Addressing demand for Ro Kell Negative: an updated presentation to be brought back to a future Board meeting or development day by Mr Stredder/Ms Rose. **CR/MS**

6 (19/40) **PATIENT STORY**

Dr Miflin presented the story of Caz Challis who was infected with the Hepatitis C virus from a blood transfusion in 1992. Ms Challis was a witness at the Infected Blood Inquiry hearings and her statement told of how she was infected whilst pregnant with her third child and being diagnosed and then treated for cancer. She told of her experience of receiving her diagnosis through the look-back process which was run by a predecessor organisation to NHSBT. Then, the side effects of treatment, the terrible effects on her life and family and the difficulties she experienced with the compensation scheme which would not accept her.

Members noted the difficulties experienced by Ms Challis in asking for confirmation of batch numbers of blood units, specifically being told she did not have the authority to request this information. Work was being undertaken to try to identify if this was said by a member of NHSBT staff but there was no record of this conversation on the NHSBT Clientele database. Dr Miflin advised that issues raised at each hearing were being logged and reviewed. Any ongoing issues with which NHSBT could help were being monitored and responded to. A Board Seminar on blood safety issues arising from the Inquiry would follow this meeting.

7 (19/41) **CHIEF EXECUTIVE'S BOARD REPORT**

Ms Bassis presented the Chief Executive's Report as detailed in paper 19/41. Highlights included:

- Early reflections
- Appointment of an FTSU Guardian
- Appointment of Chief of Staff
- Regulatory activity
- Blood stocks situation
- LRP
- Organ Donation & Transplantation performance

It was noted that a Board session on the development of an organisational strategy was scheduled for the afternoon of 24th July. Engagement was also planned with stakeholders within the wider NHS (DH, NHS England, NHS Improvement, NHSX and hospital trusts) and

the organisational strategy would be followed by a stakeholder relationship strategy.

8 (19/42) **CLINICAL GOVERNANCE REPORT**

Dr Miflin presented the Clinical Governance Report as detailed in paper 19/42. The key points discussed were:

- A new Serious Incident in Diagnostic and Therapeutic Services in early April when blood samples were switched during processing in NHSBT's International Blood Group Reference Laboratory. This affected four women who were receiving antenatal care in the Republic of Ireland. Two of these were carrying D positive foetuses and did not receive a routine dose of anti-D at 28 weeks due to the error. There was a very small increase in risk of harm to future babies of these two women. The incident was reported to the Medicines and Healthcare products Regulatory Agency (MHRA) and temporary fixes had been put in place whilst long term plans to fully automate the process were being explored.
- NHSBT's first submission of the new Data Security Protection Toolkit (DSPT) was completed and submitted as required by the 31 March 2019. All mandatory standards were met.
- Eight annual reports were signed off with all committees complying with their Terms of Reference.
- Further virology tests had been requested as part of a newly implemented scheme to enable organs from infected or potentially infected donors identified as being at risk of Hepatitis C Virus infection to be considered for transplantation into HCV negative recipients. The scheme was ready to go ahead in Wales and Scotland but due to the lack of a funding agreement the scheme would not go live in England yet.

9 (19/43) **ANNUAL MANAGEMENT QUALITY REVIEW**

Mr Bateman presented a paper on the quality management review process summarising the key points:

- A total of 19 external regulatory and accreditation inspections took place during the year with no critical non-compliances received in any of the inspections. Two major non-compliances were raised, both by the Medicines and Healthcare products Regulatory Agency (MHRA) in one inspection against NHSBT's Investigative Medicinal Products (IMP)/Specials Manufacturing licences. It was noted that there had been a significant improvement on 2017/18 when 12 majors were raised during external inspections.
- Overdue quality management system event levels across all directorates were now at record low levels.
- There had been a significant decrease in the number of Serious Adverse Blood Reactions and Events (SABRE) reports to MHRA this year. Serious Adverse Events and Adverse Reactions (SAEARs) reported to the Human Tissue Authority (HTA)

remained at similar levels when reporting changes were taken into account.
- A significant number of regulatory licence changes were submitted and processed this year.
- NHSBT successfully achieved immune effector cell (IEC) accreditation for four sites during 2018/2019.

Two further occurrences since publication of the paper were also highlighted:

- A breach of the Human Tissue Authority (HTA) licence in Colindale for collection of cord tissue; the licence included collection of cord tissue for research purposes, but not as a raw material for an Advanced Therapy Medicinal Product. The breach was discovered by NHSBT ahead of a recent HTA inspection. The HTA was advised and the necessary change to the licence was immediately requested and approved. The HTA was considering what regulatory action may need to be taken, any sanction would be reported to the Board immediately. The incident had been raised as a major quality incident but Mr Bateman was reviewing to assess whether this should be reported as a Serious Incident (SI).
- A limited assurance report from Price Waterhouse Coopers on how NHSBT handled and reported on internal and external inspection findings would be discussed at the Governance & Audit Committee as there was concern around the conclusions drawn from the evidence given.

10 (19/44) **BOARD PERFORMANCE REPORT**

Mr Bradburn gave a summary of performance for period 1 (April 2019):

<u>Blood</u>
Stock levels at/above target – outlook through to July was positive
Adverse and noisy trend in O neg red cell demand (as a % of total) which was a risk *
New 5-year demand plans produced - high level of uncertainty

* The increased demand for O negative blood was thought to be the result of transfusion de-skilling in hospitals leading to a more risk averse approach involving the use of O negative blood. Work was taking place liaising with those outlying hospitals using large amounts of O negative blood. NCG had also considered a national standard or guidance limiting its use. This risk should be part of the GAC remit.

<u>ODT</u>
Activity in April and early May was low
Highly adverse trend in both deceased donation and transplantation
Risk to performance in 2019/20

DTS
Ongoing growth in activity and income – but growth was slowing
Cord blood issues were picking up / UK stem cell forum to meet in July re strategy
Concern re ACT performance (being offset in CMT by CBC)

Members also noted the growing gap in A negative platelet issues although this was being managed currently. As a universal platelet this was a similar situation to the demand for O negative blood, albeit in this case issues were higher than demand, possibly in order to avoid expiry.

In answer to a query on the cost effectiveness of the process to recruit O negative blood donors, it was noted that the success in growing the donor base had arisen from a combination of new, more sophisticated recruitment methods and concentrating on a specific cohort of lapsed donors.

Mr Bradburn stressed the need for awareness of the high capital demands at the moment due to the building of the new Barnsley centre, CBC and Data Centre set against the background of potentially lower capital funding.

11 (19/45) **ORGANISATIONAL STRATEGY**

Due to a number of recent issues there was a need to review the organisation's operating model and Members received a presentation giving an overview of the case for change within NHSBT and the proposed approach and sequencing of activities. Advances in medicine and technology and changes in demographics and consumer trends together with changes in the political and regulatory environment would all have implications for NHSBT for the future.

A five-part approach to reviewing the organisational strategy was proposed:

1. Limit the change portfolio to 'must do' projects whilst the operating model was under review
2. Review the lessons learnt and external trends to develop vision and design principles
3. Optimise the operating model (starting with Blood)
4. Explore the strategic choices in light of external trends & iterate the operating model accordingly
5. Develop leadership & cultural shift through programme design & targeted interventions

The sequence of activities and approach to resourcing was outlined and Board members were asked for their initial reactions to the approach to this piece of work.

Comments:

- Although the work would initially focus on Blood it would be useful to mention Organ Donation & Transplantation within the operating model.
- At the development day in July it would be useful to consider who NHSBT ultimately represented and served as this had a bearing on the model
- It would be useful to talk through how the team arrived at what should be focussed on. Also, there was a need to know the journey to set the operating model in place.
- Acknowledge that other areas, such as risk and governance, need urgent work whilst the review takes place.
- Consider the importance of the approach taken, looking at the service end points or where NHSBT touches its stakeholders to get a view of the front-line issues and the ability to transform.
- Seek a decision on NHSBT's relationship with change and how agile it is.
- Provide detail on the key external trends and the key questions arising from those trends
- Perform a scan of developing trends as well as the socio-regulatory aspects,
- Record observations on what is happening in the wider NHS.
- Consider stakeholder engagement on whether it was NHSBT's role to influence best practice
- Prior to the development day on 24th July it would be useful to have some pre-reading on how other countries organised themselves in the breadth and scope of their services together with horizon scanning information.

12 (19/46) **ICT STRATEGY UPDATE**

Mr Henry reported on paper 19/46 which provided an update on ICT showing:

- the position in January 2019, specifically NHSBT's key technology risks
- progress made, and actions taken since then
- a forward plan of the work required to mitigate these risks, and the 'anticipated' implementation timetable
- the delivery approach, including where support would be needed and how the risks would be managed.

NHSBT was currently sitting on several major technology risks, these being the loss of significant technology skills and capability; insufficient investment in critical infrastructure; an increasingly fragmented solutions architecture; and a confused operating model with significant overlaps and gaps, and increasing year on year ICT costs. Although good initial progress had been made, a major change programme was needed

within ICT over the next 18-24 months, requiring significant investment in:

- infrastructure;
- third-party support (Solution Strategy, Data Centre, Application Migration);
- re-structuring costs.

The following comments were received from Board members on the update:

- On the anticipated forward plan for Data Centre the length of time to reach delivery of the detailed business case (DBC) and contract awards was queried. It was noted that there was a 6-month process of tendering and specification involved, although it may be possible to compress this timescale and bring forward the DBC to March. Different ways of approaching that stage could also be considered.
- In response to a question on how long NHSBT was planning to continue with the existing operating system for whole blood (Pulse) Mr Henry advised that this would be supported for the next 3 – 5 years and would be included within the Data Centre.
- There was concern over the potential inability to recruit permanent skilled staff into ICT to gradually replace the augmentation resources. Getting a timeline of the ratio of augmented and permanent resource was key. As part of the revised operating model the priority would be to put the top team in place, then to begin work on the business case for recruitment.
- There would be an expectation from stakeholders that this would be a constant cycle of incremental change and improvement.

13 (19/47) **SESSION SOLUTION**

Dr Miflin presented the project business case for Session Solution, an investment in technology for frontline Blood Donation teams to reduce their reliability on paper-based processes. The project would deliver new hardware to frontline teams and would improve connectivity to enable real time information to be used for donor decisions. The software application would give the ability to manage the donor journey more effectively.

The hand-held software and hardware had been tested on session and the web-based software was developed by NHSBT's Pulse database partner as part of the Core Systems Modernisation (CSM) programme. It was not envisaged that there would be a new system to replace Pulse within the lifetime of this contract and the app (with appropriate modifications) could be integrated with a different IT system in the future should this be required. Failing to invest now would still require a like for like replacement with no benefits and the risk of falling even further

behind the expectations of donors and donation teams. A contract for a three-year period, with the option to increase by a further year if required was felt to be the most pragmatic solution. The reasoning behind tying into a three-year contract was questioned, given the pace of technology and product evolution in addition to the question of how this tied in with the ICT strategy. B Henry confirmed the proposal was built on reasonable assumption around consistency with the service model and was linked to the ICT strategy and the lifespan of Pulse.

The high cost of ownership was also highlighted. This was mainly due to support costs which were predicated on a business decision that support was needed during sessions, particularly when setting up and closing down a session. It was suggested that a clear objective of the programme should be to reduce this cost over the life of the contract.

OUTCOME: The Board approved the proposed option C.

14 (19/52) **NHSBT BOARD RESPONSE TO DHSC SECONDARY LEGISLATION CONSULTATION**

The Department of Health and Social Care had launched consultation on the secondary legislation regarding novel and rare forms of organ donation for public consultation on the 29th April. Prior to releasing the consultation and draft regulations, the Opt-Out Implementation Team within NHSBT was asked to review the consultation and supported the DHSC proposals, recommending that the Board's response should note the potential impact should the regulations change significantly after the consultation closed.

OUTCOME: Members approved the recommended response to the DHSC consultation subject to the addition of future proofing the regulations in light of medical advances without the need for change to legislation.

15 **REPORTS FROM THE UK HEALTH DEPARTMENTS**

15.1 **England**

- Mr Mean reported that the consultation on the secondary legislation for opt-out was ongoing and that the HTA were preparing to consult on their code of practice as it related to opt-out.

15.2 **Northern Ireland**

- Work was ongoing to appoint a NI Co-ordinator to take forward the statutory duty to promote organ donation; however, it was unlikely the successful candidate would be in post before organ donation week in September.
- Work was progressing to establish a NI Organ Donation Steering Group to take forward the Organ Donation Policy Statement, which was launched in December 2018.

- Work had stepped down on BREXIT preparations, but could be escalated quickly if required.
- There had been considerable media coverage of the Infected Blood Inquiry.
- J Hardy had been liaising with colleagues in the Health and Social Care Board and Public Health Agency to discuss appropriate representation on the various NHSBT groups.

15.3 (19/48) **Scotland**

- Report noted

15.4 (19/49) **Wales**

- Report noted

16 **REPORTS FROM BOARD SUB-COMMITTEES**

16.1 (19/54) **Governance & Audit Committee**
The minutes of the March 2019 meeting were noted.

17 **ANY OTHER BUSINESS**
Following the meeting a 'Know Your Blood Type opportunity would be available for Board members.

18 **FOR INFORMATION**

18.1 (19/50) **Update on Lessons Learned from Blood Stocks**
Members received an updated paper for information.

18.2 (19/51) **ODT Hub Update**
The Board noted the additional details provided within the paper as requested following approval of the 2019/20 ODT Hub Programme at the March Board meeting. Mr Clarkson and Mr Henry agreed to work on the financial and milestone metrics for the project for inclusion in future updates. **AC/BH**

18.3 (19/53) **Board Forward Plan**
The Plan was noted.

19 (19/51) **DATE OF NEXT MEETING**
The next Board meeting was scheduled to take place on Wednesday/Thursday, 24th/25th July 2019 at the voco St David's Hotel, Cardiff.

22 **RESOLUTION ON CONFIDENTIAL BUSINESS**
The resolution was noted.

Meeting Close