

The Minutes of the Ninety-Fourth Public Board Meeting of NHS Blood and Transplant held at 9.30 am on Thursday 28th November 2019 at the Courtyard by Marriott Edinburgh West, 2 Research Ave S, Edinburgh EH14 4BA

Present: Ms M Banerje	ee Mr J Monroe
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Ms B Bassis Lord J Oates
Mr R Bradburn Mr K Rigg
Mr A Clarkson Mr C St John
Mr G Methven Prof P Vyas
Dr G Miflin Mr P White

In Mr I Bateman Ms S Baker

Attendance: Mr B Henry Prof J Forsythe (Observer)

Ms K Robinson Dr S Thomas (Observer)

Ms C Rose Ms M Pappa Mr M Stredder Ms A Rashid Ms P Vernon

Mrs K Zalewska

1 APOLOGIES AND ANNOUNCEMENTS

Ms Banerjee welcomed Dr Stephen Thomas and Prof John Forsythe, who were attending as Observers, to the meeting.

Also welcomed were Ms Sam Baker from the Scottish Government, Ms Marina Pappa from the Department of Health and Social Care, and Ms Patricia Vernon from the Welsh Government.

Apologies were received from Ms Helen Fridell, Dr Huw Williams and representatives from the Department of Health in Northern Ireland.

2 DECLARATION OF CONFLICT OF INTEREST

Lord Oates advised that he had been appointed as Chair of an advisory board for public relations company, Weber Shandwick.

Ms Banerjee reminded Board members that NHSBT was subject to purdah during the general election period and this should be taken into account during discussions.

3 (19/95) **BOARD 'WAYS OF WORKING'**

The 'Ways of Working' were noted.

4 (19/96) MINUTES OF THE LAST MEETING

The minutes of the September 2019 meeting were agreed as a correct record subject to an amendment to the post-meeting note at item 16.2 to read: Following the meeting, DHSC re-sent to NHSBT the text of the amended Directions that reflect the changes in EU law for NHSBT.



OFFICIAL 5 (19/97)

MATTERS ARISING

The Board noted progress on the matters arising. The action was closed.

6 (19/98) **PATIENT STORY**

Mr Clarkson talked through the story of an organ donor, whose family supported the patient's decision to donate, and the complexities of facilitating the organ donation process. The process involved complex logistics with multiple retrieval teams. The retrieval process was completed with heart, lungs, liver, kidneys and pancreas being accepted for transplantation with a plan to retrieve the corneas the following morning.

This donor saved the lives of patients across the UK with the organs being transported over 3,000 miles collectively to the transplant centres. This involved significant logistical planning across multiple teams and in conjunction with the donor's family. The Board acknowledged both the complex, multi-team planning involved and the commitment of the donor family to ensure that the potential for donation and for every organ to be transplanted was met.

Ms Banerjee questioned how well recognised the work of the multidisciplinary teams involved was outside of NHSBT and suggested consideration of some form of recognition using this patient story as the basis.

7 (19/99) CHIEF EXECUTIVE'S BOARD REPORT

Ms Bassis reported on the work carried out to date on the operating model review. The report documented the journey to date and the proposed next steps. It was noted that the Executive Team was in a period of transition with a number of changes which were announced in October. Discussions were taking place with DHSC on managing the risk of having to pause the recruitment of a Director of Donor Experience and a Director of Strategy and Transformation due to the restrictions of purdah.

Ms Bassis reminded members that the operating model review was not limited to organisational structures but was also focusing on technology, governance, risk management, leadership and culture. It was recognised that the organisation would have to continue performing whilst it went about transforming.

The report also contained updates on the following areas:

- Governance Review: Focus on the recruitment of a permanent Company Secretary and assessing the structure and terms of reference of the Board and management-level committees.
- Risk Management: Scope of the risk review, the proposed structure of the new risk register and a draft set of strategic risks.
- Quality & Compliance: Four external regulatory inspections (MHRA and HTA) were carried out during September and



October with only one major non-conformance raised relating to incident management and inspection. The Executive and the Quality Team were working to address overdue items within the quality management system more vigorously with the relevant teams.

- Infected Blood Inquiry: The current phase of evidence from infected and affected witnesses had concluded and a week of expert evidence would commence in February, which NHSBT would attend.
- Blood Supplies: Red cell stocks were currently healthy with no issues anticipated over the Christmas and New Year period.
 O negative stocks had been consistent since September, the challenge being with O negative demand.
- Logistics Review Programme: Following discussion on counter-proposals from Staff side the implementation of on-call rotas for Blue Light and TAS deliveries had been postponed for 12 months to allow for further dialogue.
- **Session Solution**: This was continuing to track on time and to budget against plan.
- Plasma: Following the Ministerial decision that UK plasma could be used to treat patients born after 1995, NHSBT had initiated the transition to 100% UK sourced plasma. The contract with Macopharma would be terminated on 1st December 2019, with the last consignment of imported plasma expected in March 2020.
- Organ Donation & Transplantation: Numbers of proceeding donors had increased recently due to higher consent rates with donations up 3% on last year. The Opt-Out campaign was on track with public awareness across England now at 53% and BAME awareness at 35%, up from 27%. Lord Oates expressed concern on the spikes in op-outs from the BAME community due to 'fake news' on social media and asked how this was being addressed. Ms Rose stated that this was being closely monitored and NHSBT was engaging with the internal BAME network and external BAME communities to get the correct message out as it was extremely difficult to ascertain the origin of the misinformation. NHSBT would continue to engage with the wider communications network to get the message across.
- Diagnostic & Therapeutic Services: Financial performance in DTS was strong with income and I & E ahead of plan. The business case for the expanded Clinical Biotechnology Centre was approved by DHSC in November, following Board approval in September. The CQC had confirmed that Therapeutic Apheresis Services would be subject to inspections which would take place next year. A revised stem cell strategy would be shared with the Board in the new year.

8 (19/100) CLINICAL GOVERNANCE REPORT

Dr Miflin presented the Clinical Governance Report as detailed in paper 19/100. The report focused on the annual review of the joint NHSBT/Public Health England Epidemiology Unit and, in particular, the data



relating to blood donation. During 2018 20% of donors in England were new donors providing 11% of all donations. The majority of these new donors were women (65%) and just over half aged under 35.

The unit was established in 1995 with responsibility for the surveillance systems used to report infections in blood, tissue, cell and organ donors across the UK and infections transmitted by blood transfusion.

Other areas of work undertaken by the team included:

- Contributing to and writing the SHOT chapter on transfusion transmitted infections
- Contributing to policy work through JPAC and SaBTO
- Calculating estimated risks of an infectious donation entering the blood supply in the UK
- Working with PHE colleagues to monitor new and emerging infections which may impact on the blood supply
- Working with the Canadian Blood Service to establish evidence to support an individual risk assessment policy for blood donors in higher risk population groups.

Ms Rose confirmed that NHSBT was working with Freedom to Donate, Stonewall and other groups around communication on the rules for blood donation.

Dr Miflin outlined a new serious incident which had occurred when pre-cut corneal tissue supplied by the Filton Eye Bank was reported to be thicker than it should have been. On investigation it was observed that the post cut thickness was greater than expected with NHSBT's equipment. NHSBT had now been informed of a total of eight cases of primary graft failure, four patients with reduced visual acuity and seven patients who needed additional interventions to reattach the graft. The service was temporarily suspended whilst the machine was recalibrated for a second time. In addition, a new machine was put in place to give a further level of assurance. The incident was reported to the Human Tissue Authority and, once approved, the pre-cutting service would resume. Prof Vyas asked what assurances were in place to check when machines failed such as in this instance. It was stated that the machine had failed after it was moved, and the SOP would now stipulate that, following any movement of the machine, it should be recalibrated. The Board noted that this incident had also been raised at the Governance & Audit Committee (GAC) when it was questioned which other NHSBT products and services were such that they needed to be sized precisely and what levels of assurance were in place.

Prof Forsythe joined the meeting to outline an incident following the launch of the new Kidney and Pancreas (KP) allocation scheme when a liver transplant centre expressed concerns around the liver matching run. An investigation identified an error in the release procedure whereby a piece of code in development for a future liver release had



inadvertently been introduced into the live environment. This code had not been tested as it was not planned for release. The national liver allocation scheme was immediately suspended, and the offering process reverted to centre offering until the problem was rectified. It had been identified that a small number of patients had been significantly impacted by the error and NHSBT was working with the transplant centres which were liaising directly with the patients/families and an NHSBT representative would meet with them if requested to do so.

A route cause analysis (RCA) was completed which identified actions that needed to be urgently carried out and others that would take place following a full investigation. Computational testing and outcome testing in order to reinforce NHSBTs procedures was taking place currently. Progress on all actions would be reported to the Clinical, Audit, Risk & Effectiveness group (CARE) and GAC.

Board members asked what assurances were in place in terms of a formal process to double check changes to code or for adding new code. An action from the RCA was to introduce comparative testing across all organ allocation and matching schemes. Media handling of any assurances would also need to be considered and the Communications team would be working with ODT and ICT on the handling plan. Key to this plan was the outcome of the discussions taking place between NHSBT and the transplant centres. **ACTION:**Ms Bassis was asked to consider what needed to be done to ensure this type of incident did not re-occur, including during the time that investigations were taking place, and to provide reassurance to Board members prior to the next meeting in January.

BB

Prof Forsythe also reported on an incident involving the UK Living Kidney Allocation Scheme in which a donor and recipient pair who were in the sharing scheme were suspended on the morning of the matching run due to accepting a deceased donor kidney offer. The correct donor and recipient were suspended from the register and therefore removed from the matching run but, in addition another recipient was incorrectly suspended and therefore also removed from the matching run. This resulted in the matching run being undertaken without the recipient who should have been included and, as a consequence, it was found on investigation, and through re-running the matching run with the recipient included, that four recipients who should have achieved a match in the matching run did not. However, four different patients were matched who would not have been in the original run. The case was discussed at the Kidney Advisory Group on 20th November where consideration was given to declaring the original matching run as invalid and using the re-run matching results. It was, however, agreed that the original matching run should proceed as planned, as declaring the run invalid after notifying those recipients meant that they would also miss out as a result of the decision on this run being overturned. The outcomes of the root cause analysis were awaited.



9 (19/101) **BOARD PERFORMANCE REPORT**

Mr Bradburn presented a summary of performance for October 2019 focusing on the following:

- Blood: Red cell demand forecast for 2019/20 was increased by 12.5k during the October demand review and hence the collection plan was increased by 6.3k (part year effect for the remainder of the year). Stock performance remained strong throughout the month and stock levels were predicted to remain strong, particularly O negative. The Ro Kell negative donor base continued to grow whilst the O negative donor base was running behind plan, although this was not impacting stock levels. Short term financial performance was better than plan although there would be a sustained upward pressure on blood prices over the next few years.
- <u>DTS</u>: H & I (Histocompatibility & Immunogenetics) hospital referrals
 for solid organ transplantation and stem cell investigations continued
 to decline and a reduction to income had been built into the latest
 forecast. There was an income & expenditure (I & E) surplus of
 £0.5m year to date in DTS with most business units reporting an I &
 E contribution at or better than plan. The exceptions were H & I and
 Tissue & Eye Services (TES).
- ODT: October was the 6th highest ever month on record for deceased organ donors, contributing to an improvement in the moving annual total of 1,624 donors. However, this was still 7% lower than the TOT2020 strategic target. Concerns over the decrease in the eligible donor pool had eased with just 13 fewer eligible donors in October than at the same time in 2018. The number of deceased donor transplants had improved although this remained lower than the TOT2020 target. October was the 2nd highest month ever for BAME patients receiving a transplant.
- <u>Corporate</u>: Sickness levels in Logistics remained high at 8.26%. This was being closely monitored by both Logistics management and People to ensure there was no potential operational impact. NHSBT was reporting a surplus of £8.9m YTD, £10.9m ahead of budget. At the end of Q2, a deficit of £3.0m was forecast for 2019/20 versus a planned deficit of £11.3m; this was largely driven by lower transformation spending plus favourable variances in M&L and ICT.

Lord Oates queried the reason for the significant variance across blood donation mobile teams. These figures did not relate to staff productivity but were affected by whether the sessions were six or nine bed sessions and the distance travelled from base to the mobile location. Some six bed sessions were previously removed as they were proving less productive but had since been reinstated in order to reconnect with O negative and Ro donors. Ms Banerjee commented on the upward trend in sickness in Blood. There were no major issues with long term absence and the increase was spread over a wide group of individuals, so this was likely to be a seasonal trend and expected to return to normal levels.

Mr Methven reported on a rise in in absenteeism within Logistics. There were 150 applications for redundancy and work was taking place



on managing expectations. ACTION: Following closure of the consultation an update would be circulated to Board members outside the meeting.

GMe

Mr Bradburn provided the Board with indicative budget and blood pricing projections highlighting the key forecasting challenges based on projecting current trends. These projections did not take into account any change to existing practice. Cost increases were projected in both supply chain and Group Services, ICT being the main contributor to Group Services increases. There were limited cost saving projects at present and some projects would increase baseline recurring costs. The emerging position/plans were being developed with a view that new savings of £3m pa in each of the next three years would be needed as a minimum. A detailed budget would be submitted to the Board in March with a view to possible cost savings which could be achieved. The capital position for 2019/20 had been resolved subject to the DHSC position in March. There was a potential issue in 2020/21 although the spend on data centre was uncertain at this time.

Ms Bassis reiterated the need for increased knowledge of developments in the clinical world likely to affect demand in order to frame the budget. The strategy for investment in blood was also key and Mr Methven was working with the senior leadership in blood supply on costs and productivity. ACTION: Ms Bassis agreed to ensure that this was reported to the next Board meeting in January for Board input.

BB

Mr St John asked that a review of capacity be undertaken now that the impact of HB deferrals was clear, rather than wait for the McKinsey and operating model work to be completed. **ACTION: Ms Bassis would review the priorities with a view to assessing the existing plans.**

BB

Mr Bradburn confirmed that it was normal practice to show separately those costs which were a result of decisions made outside of NHSBT and for which NHSBT was reimbursed, such as the pension cost increase. It was noted that DHSC had not yet confirmed that the pension cost increase would be applied next year.

10 **REPORTS FROM THE UK HEALTH DEPARTMENTS**

10.1 England

 Ms Pappa reported that as this was a pre-election period the normal business of government was on hold although exemptions had been agreed for the organ donation opt-out campaign and the blood donation campaign.

10.2 (19/102) Scotland

The report from the Scottish Government was noted. Ms Baker summarised the key points from the report:



- Post 2020 action plan for Scotland: It was planned to submit the first outline draft of the plan to the Scottish Donation & Transplantation Group on 18th December for consideration with a view to sign off in April 2020.
- Opt Out in Scotland was on track and NHSBT would lead a programme session in Edinburgh on 5th December.
- Public consultation on the Human Tissue (Authorisation) (Scotland)
 Act 2019 type A pre-death procedures: This consultation was taking
 place between 30th October and 11th December 2019 and was
 seeking view on the list of procedures to be specified in
 Regulations.

10.3 (19/103) Wales

The report from the Welsh Government was noted. Ms Vernon summarised the key points from the report:

- Consideration was being given to changing the Human Transplantation (Excluded Relevant Material) (Wales) Regulations 2015 to achieve parity across the system in light of the recent consultation on the equivalent regulations in England.
- A set of Directions to NHSBT on Group 1 and Group 2 patients had also been drawn up to achieve parity.

10.4 (19/104) Northern Ireland

The report from the Department of Health in Northern Ireland was noted.

11 (19/105) NATIONAL ADMINISTRATIONS COMMITTEE

Ms Banerjee presented a paper seeking approval for the dissolution of the National Administrations Committee and recommending the continued support of nominated Non–Executive Directors (NEDs) with special responsibility for each country. Representatives of each of the devolved administrations had been contacted on an informal basis regarding these proposals and agreed that there was significant crossover with other groups and the Committee should be dissolved.

Outcome: The Board approved the dissolution of the Committee with the continued support of nominated NEDs to each of the devolved administrations, together with more effective liaison with the devolved administrations' representatives attending the Board meetings.

12 MINUTES FROM BOARD SUB-COMMITTEES

12.1 Governance & Audit Committee (GAC)

Mr White gave a verbal report from the meeting held on 18th November 2019. Key points:

Strategic risk of blood supply and adequacy of meeting demand:
 There was much work to be done to mitigate the risk in supply and demand. In light of the copper sulphate issue, the Executive Team (ET) had been asked to consider those areas where there was a single supplier on whom NHSBT was dependent for the



- quality of a product and to ensure that the services supplied were fit for purpose.
- One or two strategic risks would be identified for review at each GAC meeting as nominated by ET.
- Serious incident review: GAC conducted a 'deep dive' into switching of samples and concluded there were more than adequate changes made to the control environment to move forward.
- Overdue reporting: IB had explained the difference between overdue events and overdue events of major importance (10%). At the next meeting the length of time that major overdue events were overdue would be considered together with the reasons why these had not been closed.
- Legal compliance: A report giving reassurance on mandatory training levels was received.
- A report on risk management was noted with the organisation now close to having a complete set of strategic risks for review. It was encouraging that training was taking place within the senior leadership on the management of strategic risk. It was suggested that the NEDs may also benefit from training on risk management. ACTION: Ms Bassis and Ms Rashid to look at incorporating this into a future Board development day.

BB/AR

- Internal Audits: GAC reiterated the need to keep up with the plan
 of internal audits in order to avoid a backlog at the end of the
 year. These were currently on track to deliver a compressed
 programme with no scope for slippage.
- GDPR follow up: One action was outstanding, and some dates had been extended. A further report, together with a report on information governance, would be considered at the next meeting.
- Progress on cyber security was good.
- External audits: The timetable for the year-end process was confirmed and Mazars had been reappointed as external auditor.

12.2 (19/106) Transplant Policy Review Committee

The minutes of the meeting held on 2nd October 2019 were noted.

Mr Monroe highlighted that the new draft Terms of Reference had been paused due to the governance review taking place.

13 ANY OTHER BUSINESS

Ms Banerjee thanked both Ms Rose and Mr Henry for their contribution to the meeting as this would be their last meeting of the Board.

14 FOR INFORMATION

14.1 (19/107) Health Safety & Wellbeing Senior Management Review Report 2018/19

The report was noted for information.

14.2 (19/108) **BOARD FORWARD PLAN**

The plan was noted for information.



15 DATE OF NEXT MEETING

The next meeting of the Board would be held on Thursday, 30th January 2020 at the Chartered Institute of Arbitrators, 12 Bloomsbury Square, London WC1A 2LP.

16 RESOLUTION ON CONFIDENTIAL BUSINESS

The resolution was noted.

Meeting Close