

**NHSBT Board Meeting
Chief Executive's Report**

29 March 2022

Status: Official

1. Strategy and Transformation

We are looking forward to launching our new vision and strategy to external stakeholders at a virtual event on 28 March. We see this as the start of a longer term engagement plan over the coming years as we look to deepen our relationships with colleagues across the system and collaborate on areas of mutual interest and patient need. We have already held a series of internal launch events to discuss our future direction and plans directly with staff.

The strategy has served to provide focus and structure to our business plan and transformation portfolio, as well as an updated Board Performance Report that we will be introducing from next month. It also unlocked our ability to develop a new Board Assurance Framework, which we shared with the Board in January.

2. Health and Safety

Our operations remain resilient despite the continued challenges of managing through the pandemic and the recent rise in COVID related infection levels across the country. Whilst sickness absence has reduced since the turn of the year, it remains above target (and this time last year) at 5.86%. The health and safety team are working with individual directorates to undertake audits and deep dives to identify what additional measures can be put in place.

We have reviewed and relaxed our Infection Prevention and Control measures (e.g. social distancing, temperature scanning and touch point cleaning) in line with the recent shift in COVID guidance. We have introduced CO2 levels to ensure our ventilation is adequate and will continue to keep our measures under review as the health and safety of our donors and staff remains paramount.

3. Quality and Regulation

We are entering a busy period of on-site inspections from both the MHRA and HTA. At the beginning of March, the MHRA spent 4 days in Liverpool inspecting our Blood Establishment licence. The Inspector was accompanied by a trainee (for Blood Establishments) who is an experienced pharmaceutical GMP inspector. This put our systems under increased scrutiny. The outcome of the audit was extremely positive with 3 “other” findings. These are relatively straightforward to correct and will give good opportunities for improvement. The MHRA will inspect our Plymouth site and associated donation sites from 30th March to 1st April.

The HTA inspected Colindale between the 16th and 18th of March. This was a blended inspection combining virtual with an on-site visit. They only identified 4 minor shortfalls which was another excellent outcome.

Our Quality Management System (QMS) champions initiative is bedding in well, with a new dashboard supporting the partnership between our QA and operational teams. Together, they have achieved a significant reduction in the number of overdue events, as well as increased awareness about the volume of events owned by each directorate.

Work continues to prepare for a future CQC Well Led inspection. The Key Line of Enquiry (KLOE) review is complete. Case studies have been written to showcase best practice whilst, in parallel, we work to address possible areas of concern. These will be covered in briefing documents for the Board and senior leadership team ahead of any inspection. Additional work is ongoing to ensure our regulated activities (Therapeutic Apheresis Services, Blood and Plasma Donation) are also inspection ready. This activity is being led by our Chief Nurses.

4. Donor Marketing and Engagement

As blood stocks have returned to green, our marketing activity has shifted to increasing the health of our donor base. We have increased the number of new (as opposed to returning) donor appointment slots and synchronised this with inflight marketing activity. In parallel to our ongoing Sky and BT Sports partnerships, we have launched two new blood campaigns:

- Many on the Board will have seen the BBC1 documentary “We are England” (<https://www.bbc.co.uk/programmes/m00143kj>). The individual stories of donor carer Sasha Cooke’s journey to donate her kidney, and Abdul Samad Abdullah’s experience as a sickle cell patient made for compelling viewing and excellent awareness.
- The Daily Mirror has also launched a campaign in partnership to ‘give a pint, save a life’ and has incorporated elements from our other campaigns such as a further interview with Emile Heskey on the need for more donors of Black heritage.

We have also worked with the Terrence Higgins Trust on a more focused campaign to recruit donors of Black heritage, highlighting recent changes to blood donation rules (<https://www.tht.org.uk/news/call-people-black-african-communities-give-blood-after-landmark-change-donation-rules>). We are supporting this campaign with dedicated calls to Black heritage donors to support and fill available appointments.

On the Board agenda is a fuller update on the health of our transfusion (e.g. blood, platelet and plasma) donor bases, highlighting the areas of particular focus for the coming year. We will be bringing a similar update on the health of our organ and stem cell registries later in the year.

We held the first of our regular quarterly stakeholder meetings for 2022 with a range of charitable partners. We shared our strategy and plans for the coming year; heard updates from four of our partners (Societi, ACLT, Donate4Dáithí and Orgamites); and presented a summary of our 2021 activity (attached).

The Board will remember that we didn’t get DHSC and Cabinet Office approval for our paid marketing activity until part way through this past year. I’m pleased to report that we have already received approval for this coming year’s blood marketing, which will ensure

continuity of activity into April. Approval for paid plasma and organ donation marketing is still outstanding.

5. Blood Supply

I reported in my last CEO update that the impact of the Omicron COVID-19 variant had led to lower donor attendance and higher workforce absence, resulting in the decline of overall red cell stocks to c5 days in early-January. O neg and B neg stocks had fallen further, to below 3 days. Despite this, we maintained continuity of supply to hospitals and quickly recovered during January as our interventions and the decline of COVID cases resulted in increased collection levels. Since recovering and stabilising stocks, we have completed a Lessons Learned report (including actions to mitigate the risk of similar challenges in the future) and strengthened our resilience plans. A copy of this report is included in this month's Board papers for information.

The introduction of social distancing in our blood donation environments at the outset of the pandemic resulted in a reduction of c3,000 donation appointments per week and contributed to a loss of almost one third of our community venues. We managed these challenges by increasing our presence in other areas but, thanks to our CO2 monitoring, I am pleased that we are now in a position to start restoring capacity and lost venues whilst keeping these sites COVID-secure. Changes will begin to take effect from 1 April; we have worked with managers and Trade Union representatives to ensure front-line colleagues are informed of the rationale and evidence-base for these changes.

Storm Eunice affected our Blood Supply operations on 18 February, with red weather alerts declared by the Met Office for severe winds in parts of the South West and South East. We stood up two local emergency teams to manage the impact of the winds, with oversight provided by the national on call manager. Blood collection was approximately 50% less than expected on the day, as many blood sessions were cancelled to keep donors and colleagues safe. All non-essential business travel was restricted and we worked with colleagues in manufacturing to make adjustments to shift patterns to ensure no one was travelling to/from work during the storm. While we had no incidents of injury to our colleagues or donors, two near misses were reported involving falling trees.

The World Health Organisation (WHO) has been working through the European Blood Alliance (EBA) to explore the capability of blood operators to provide humanitarian support in Ukraine. While these conversations are only exploratory at this stage, WHO have specified that blood components and some consumables (e.g. blood bags) are likely to be required. We informed DHSC that we stand ready to support these and other requirements, subject to their approval.

6. Plasma

A small team, led by Gerry Gogarty, recently returned from an international plasma symposium organised by the International Plasma and Fractionation Association (IPFA) and European Blood Alliance (EBA). A key theme at the event was achieving 'Strategic Independence', with countries across Europe driving to increase domestic plasma collection in response to global immunoglobulin shortages, fragile supply chains and significant increases in forecast demand. There was significant interest in the UK's plans to re-enter this market.

As per our agreement with DHSC and NHS England, we have resized our source plasma operation to three collection sites. Recruitment to permanent posts is now underway and we are commencing a test and learn phase to develop an optimum operating model before scaling up collections. In parallel, we continue to collect recovered plasma and store stocks ahead of a fractionator being appointed by NHS England. We expect them to publish the contract notice in the coming weeks.

We continue to support a new arm of the REMAP-CAP trial exploring the benefit of convalescent plasma for immuno-compromised patients.

7. Organ and Tissue Donation and Transplantation

As at the time of writing this report, it looks like we will end the year with 20% fewer patients eligible for organ donation vs 2019/20. However, the teams have worked hard to maximise every opportunity and, hence, proceeding donors remain at 86% of pre-pandemic levels, which is strong compared to many other countries. There are several key reasons for this:

- Operational resilience: despite heightened sickness absence, we didn't lose any opportunities for donation and, in February, were able to support 107 deceased donations.
- Innovation: once again, donors after circulatory death in February (57) overtook those after brain-stem death (50). This development in UK practice is unusual by international standards and gives us increasing confidence in our ability to recover. In transplantation, February also saw the launch of our patient information website and risk information tools which provide patients with clear and accessible information on kidney, lung, liver, heart, and pancreas transplantation.
- Donor pathway: the referral of potential organ donors and the presence of a Specialist Nurse for family conversations have returned to pre-pandemic levels. Consent/authorisation rates have also recovered to c70%, including from donors after circulatory death who are often associated with lower rates.

Despite these successes, we cannot entirely mitigate NHS pressures at the most impactful points for donation and transplantation. We therefore end the year short of our targets for deceased donors and transplants, with a consequent increase in the transplant waiting list.

As we go into 22/23, there is a real opportunity to increase organ donation and tackle the transplant backlog by delivering transformational change in living donation and organ utilisation. The outcome of the Spending Review is now critical to whether we are able to implement these changes.

This period has continued to be challenging for our Tissue and Eye services, with areas of elective surgery such as sports injury not yet significantly restarting and resulting in sales income being below target in both January and February. Despite a focus on ocular donation across the Directorate, donation levels have also continued to decline due to a range of operational and clinical issues including changes in referral pathways, medical deferral and mortuary access. We have therefore mobilised a 7-step recovery plan including actions to:

- innovate based on research evidence;
- expedite new referrals; and
- increase the effectiveness in our key pathways, including organ donation.

We have seen continued growth of our Serum Eyedrop programme. This is one of the key drivers of our overall financial performance for Tissues & Eyes, which remains £0.7m higher than planned. We also expect hospitals to continue their elective recovery during 2022/23 and we have used market intelligence to refine our pricing structure and expected volumes of sales. As a result, we aim to increase our income again in 2022/23. On the Board agenda is a wider update on our strategy in this area.

The Organ and Tissue (Deemed Consent) Bill was unanimously passed through the Northern Ireland Assembly on 8th February and is expected to receive Royal Assent shortly. Accompanying the passage of the Bill, the business case has also been agreed with the Northern Ireland finance department. It is anticipated that Deemed Consent will 'go-live' in spring 2023. The Isle of Man are currently engaged in a programme of work to ensure a regulatory body and associated clinical guidance documents are in place ahead of the implementation of their organ donation law, which is anticipated for late 2023 / early 2024. Guernsey's progress to implement their law remains unchanged as other priorities on the island take precedence.

Finally, it was a real pleasure to attend the official launch of the Commonwealth Tribute to Life project

(<https://www.odt.nhs.uk/odt-structures-and-standards/clinical-leadership/commonwealth-tribute-to-life-project/>), which aims to increase ethical organ and tissues donation and transplantation across the Commonwealth by sharing knowledge and expertise. Colleagues from across the Commonwealth joined by video to share the challenges they face and the many opportunities this project will bring. We were honoured to have a range of dignitaries launch the project, including the Secretary of State for Health and Social Care, Sajid Javid MP.

8. Clinical Services

NHSBT continues to collaborate with the UK Health Security Agency (UKHSA) and the UK National Institute of Biological Standards and Controls (NIBSC) to support the production and characterisation of the serological reference standards for SARS-CoV-2. We are the sole supplier of large volumes of plasma needed for the production of these standards, which are then used to determine thresholds of protective antibody levels needed to prevent infection.

We have identified blood donors known to have been infected with the major pandemic SARS-CoV-2 variants, through matching data obtained from UKHSA variant surveillance with our blood donor database. Anonymised donations are provided to NIBSC for the production of the serological reference standards, which are then available for assay development and standardisation by the international community, including diagnostic laboratories, researchers and assay manufacturers.

The importance of this work is highlighted by the continued emergence of diverse SARS-CoV-2 variants, such as Omicron, that will continue to challenge assay development, their performance evaluation and global comparability of data generated.

There are a number of important milestones to note in NHSBT's research, including clinical trials and other studies being conducted to benefit NHSBT's donors and patients:

- The REMAP-CAP trial is restarting to see if convalescent plasma improves outcomes for patients with impaired immunity, who are at risk of severe and fatal COVID-19. The

NHSBT Clinical Trials Unit are working with clinical NHSBT colleagues to support the relaunch.

- The five new NIHR NHSBT Blood and Transplant Research Units (BTRUs) which will run from April 2022 for five years, have been launched at an event on 16 March. All BTRU plans were presented and there was an opportunity for the Executive Team and others to ask questions and seek clarification about the planned work programmes.
- The STRategies to Improve Donor ExperienceS (STRIDES) study is progressing very well and the STRIDES BioResource recruitment has managed to double the non-Caucasian participants in the study over the last few months. As of 1 February, there were over 1.2 million participants in the main STRIDES trial and almost 70k in the STRIDES BioResource. The STRIDES study will finish later this year.
- The Preventing maternal ANaemia to avoid preterm Delivery and other Adverse outcomes (PANDA) Programme has commenced with the opening of a pilot clinical trial to test the acceptability and feasibility of different doses of oral iron supplementation to prevent maternal anaemia. 240 non-anaemic pregnant women will be recruited, with results expected in 2023.
- The UK QUality in Organ Donation (QUOD) biobank has seen the rate of sample distribution to researchers doubling over the past year. At 1 Jan 2022, almost 6k donors have made about 110k donations to the Biobank including kidney, liver, heart and blood samples available to be distributed to researchers across the UK. The biobank was recently awarded 'The UK Biobank of the Year 2022', which shows an incredible recognition of a truly collaborative effort to enable research.
- CAGT is a co-founder and key investor in a new clinical trials vehicle, Accelerated Clinical Trials (ACT) Ltd. A commercial company co-developed with an associated not for profit foundation, ACT aims to build on the legacy of the IMPACT clinical trial network while moving to an agile commercial model where profits are reinvested in the clinical community. ACT Ltd provides critical UK infrastructure to support and deliver novel therapies and transformative benefits in stem cell transplant patients.

9. Digital, Data and Technology Services

The Blood Technology Modernisation programme successfully released the first modules of modernised code on our Blood Supply system to users working in live environments on the 20th of March. This is a critical milestone in this complex multi-year programme, proving our approach and providing a baseline for future years' delivery. The full business case for 2022/23 delivery lays out our ambition for the next phase of modernisation and will be presented at the private board for approval.

Geopolitical unrest from the Russian invasion of Ukraine has increased the risk of cyber-attack. We have responded by increasing security monitoring and heightening communications across the organisation to raise awareness of the potential risks. We are actively collaborating with NHS Digital's National Cyber Security Operations Centre to share data and intelligence throughout the health network. Additionally, we are utilising the National Cyber Security Centres' Active Defence Services and will continue to roll out any updates as a result of their cyber programme.

10. People and Culture

A key element of our people strategy is to adopt a resolution approach when matters go awry. To support this we have awarded a framework contract to TCM as an external partner who specialise in resolution work. They have commenced their "5D review" which consists

of meeting with various stakeholders across the organisation to review current systems and culture. TCM will complete this phase by the end of March and will produce a set of recommendations. These will help shape the design and delivery of a new resolution model.

We have started to receive emerging insights from the Our Voice engagement survey that we launched in January. These indicate that Goal Setting and Meaningful Work are our highest scoring drivers. Both received an average score of 8.5 out of 10, putting NHSBT in the top 25% of benchmarked government organisations.

Reward, Environment and Personal Growth are shown as our lower scoring drivers at 6.3, 6.4 and 6.5 respectively. Early analysis of the comments reflect the fatigue felt by staff and a desire to return to some level of 'normality' after two years of living and working in the pandemic. Engagement scores are highest where managers are deemed to be skilled in building relationships, have regular catch ups with their teams and provide consistent performance management.

We will share the final set of results, and start to develop action plans, following the third and final survey of this series which will close on 2nd April. As highlighted in our strategy, investing in people and culture is and will remain a top priority for us over the coming years as we look to recover from the pandemic and build a high performing and inclusive organisation.

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