NHS
Blood and Transplant

NHSBT Board

25 May 2022

Chief Executive's Report

Status: Official

This is our first Board since the start of the new financial year. It is also my first report since it was agreed to remove separate agenda items on Clinical Governance and Finance in favour of summarising here the reports that have been reviewed in depth by the ARGC and Finance and Performance committees, respectively. The wider Board is still invited to raise any questions or concerns from these reports, which will continue to be provided for information and assurance.

Also appended to this report is our new form Board Performance Report which has been restructured in line with our new strategic priorities. This will no doubt require continuous improvements but it has already started to flush out key risks and issues that were getting lost in our previous approach.

Clinical Governance

The Board will remember that we recently reported a Serious Incident in OTDT which involved the incorrect blood group being entered into Donor Path for a potential DCD donor. As a result, organs were incorrectly offered to three patients who were called into hospital and prepared for theatre before the error was discovered during the handover between two SNODs. The surgeries were cancelled, and the organs re-offered with the correct blood group. One kidney was accepted and successfully transplanted. The liver was not transplanted but, as DCD livers are not always accepted, it is impossible to know if this one would have been transplanted if it had been offered in a timely way. We have apologised to the patients who received offers in error, commenced a full investigation and – as an interim measure – briefed SNODs in order to reduce the risk of this type of error occurring again.

Another transmission of occult Hepatitis B infection has been reported to CARE. It is probable that the patient acquired HBV infection when they received Fresh Frozen Plasma (FFP) via plasma exchange from a first-time donor. No errors were made in the acceptance or testing of this donor. Confirmatory viral genotyping on samples from both donor and patient are being carried out by UK Health Security Agency (UKHSA), and a lookback on components from two donations is underway.

This transmission would have been mitigated by anti-hepatitis B core antibody testing, which we are in the process of rolling out following receipt of a letter on 7 April confirming that Ministers have accepted the recommendations from the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO). We will be testing c40% of blood donors from the end of May and up to 80% by the end of June, once additional equipment and resources are in place. We plan to fully implement this new test by the end of the financial year.

The Board will no doubt have read media reports about a recent increase in the number of acute hepatitis cases being seen in children. UKHSA has recently issued an urgent public

health alert and are investigating the potential cause. In addition to supporting them with this work, we have seen a consequent increase in the number of children being listed for liver transplantation – about double the number we would usually see.

The Infected Blood Inquiry (IBI) continues to hear evidence. As a Core Participant, we have been invited to submit suggestions on possible recommendations and submit any final submissions or closing statements. We understand that Sir Robert Francis QC – who recently completed a study for Ministers on the compensation framework – will be called to give evidence. In the meantime, NHSBT has been approached by solicitors on behalf of a small number of people affected by the IBI. Their claims will not be progressed until after the IBI reports and may be impacted Sir Robert's report and the Government's response.

Quality and Regulation

There have been no MHRA or HTA inspections since the last Board meeting. The HTA are planning to audit OTDT in Bristol and Liverpool on 9 and 10 June. Whilst no other MHRA and HTA inspections are currently planned, we are anticipating an increase in activity over the next 6 months as the regulators schedule audits which have been postponed due to Covid-19.

We are continuing our preparation efforts ahead of a possible CQC Well Led inspection later this year or next. Since the last Board, the project team has produced an information pack for Board members detailing compliance against each Key Line of Enquiry (KLOE); progress against the recommendations from the Good Governance Institute; and good practice case studies. Board members will be invited to attend a drop in session to discuss progress in more detail with each KLOE lead. In parallel, our Chief Nurses have taken the lead on engaging the wider organisation on the role of the CQC and what is required to become 'inspection ready'.

Blood Supply

The latest wave of the pandemic, which peaked in early April, has resulted in a sustained period of low collections. COVID-related absences, combined with annual leave and other sickness absence, has resulted in total absence levels of approximately 20% in our front-line collection workforce, and adversely impacted donor responsiveness. Demand, on the other hand, has remained strong. As such, overall red cell stocks have been running below our 5.5 – 7 day target, with some blood groups (including O negative) approaching 3 days at their lowest points.

Many of our international colleagues in the Alliance of Blood Operators (ABO) and European Blood Alliance (EBA) have reported similar stock challenges. We have continued to support our closest neighbours, providing units of blood to the UK services and Republic of Ireland.

Our operational teams are now well rehearsed in coping with periodic stock shortages. Consistent with previous periods over the last two years, a National Emergency Team (NET) has been stood-up and is providing regular oversight of recovery activity, supported at Executive level by the Blood Operations Leadership Team (BOLT). BOLT recently reviewed plans to recover stocks to target levels over the coming weeks. These plans include increasing appointment capacity to approximately 50k per week (vs 44k-45k previously) and mobilising more existing and new donors through a combination of direct marketing, local press and national campaigns.

Whilst blood stocks should now begin to grow, more work is required to ensure that we avoid the need for such 'recovery' efforts, which prove exhausting for the people involved and take

time and resources away from delivering on our longer term strategic priorities. As the Board can see from our new performance report, for example, we are behind target in terms of growing and diversifying our donor base, which has been impacted by the cap on new donors.

We have made good progress, however, on developing a new Blood Service Strategy, including a multi-year programme of associated transformation and change. With input from Blood Supply, Donor Experience and Clinical Services, this service line strategy fleshes out the high level priorities set out in the overarching NHSBT strategy – making them specific to blood and integrating key themes from associated strategies, such as Transfusion 2024. This strategy is coming to the May Board for approval.

Plasma for Medicine

Gerry Gogarty recently attended a plasma conference organised by the Italian National Blood Centre in collaboration with the International Federation of Blood Donor Organisations. This was an opportunity to connect with European stakeholders and industry partners and to build support for UK plasma. A positive development in this respect was the recent decision by the Australian government to lift the ban on blood and plasma donors who have previously lived in the UK. We hope that the EMA will take note of their risk assessment and that the MHRA will also approve the use of UK plasma for the production of albumin and other plasma derived medicines.

In the meantime, the need to increase worldwide plasma collection becomes ever starker as the growth in immunoglobulin demand is forecast to increase 55% by 2026, compared to 2020 levels. Across Europe, there is intense pressure from the private sector to allow paid for plasma donations, with many blood services rightly worried about the impact that would have on voluntary, non-renumerated blood donation and, ultimately, security of blood supply.

The procurement process to appoint a fractionator, led by NHSE/I, is progressing to schedule. We have reached an in-principle agreement with them on future funding for ongoing collection. In the short term, the focus in NHSBT is on addressing operational challenges which have impacted YTD source and recovered plasma volumes – both of which are currently behind plan. We are still confident that we can recover the position by year end.

We continue to support the new arm of the REMAP-CAP trial, which is exploring the benefit of convalescent plasma for immuno-compromised patients. First trial patients have been recruited.

Organ and Tissue Donation and Transplantation

Deceased organ donors fell in the last three months of 2021/22 vs the previous quarter, following a further reduction in the pool of eligible donors and a reversal of the upturn in consent / authorisation seen during autumn 2021. The UK's system continues to experience variability and it is not yet clear whether a reduction in the pool of eligible deceased donors (-25% since March 2020) is permanent. An increase in transplants per donor was not enough to offset the reduction in deceased donors, so transplants also decreased in Q4.

Despite these challenges, we achieved 90% of pre-pandemic activity in 2021/22, with deceased donation and transplantation up 18% and 16%, respectively, vs the previous year. Living donation was also up over 100%.

Whilst the UK's recovery has been amongst the strongest internationally, we have nonetheless seen a significant increase in the transplant waiting list. This makes it vital to drive improvements in consent and organ utilisation, as set out in our strategy. The Organ Utilisation Group, chaired by Prof Stephen Powis, is now in the final stages of completing their report and making recommendations to Ministers. Our funding settlement for 22/23 is just starting to become clear. We are working through the operational impacts and will provide the Board with a fuller report during the meeting.

20 May will mark two years since Max and Keira's law was implemented in England. We continue to monitor the impact of this law change. Based on the Welsh experience, it is anticipated to take some time to realise the full benefits. Our media release for the anniversary will lead with the story of an organ donor who donated under deemed consent, with the aim of educating the public on the role of the family in organ donation to encourage people to record and share their decision. This will be supported by content on our own social channels and amplified via stakeholders to address some of the common misconceptions we see about the law change and organ donation in general.

Northern Ireland has entered the implementation phase of their legislation change programme. We are liaising with our colleagues in NI Government to understand how the recent election may impact implementation, with the aim for Dáithí's Law to go live in Spring 2023. The Isle of Man continue with their planned activity of work to develop regulations and clinical guidance before entering their implementation phase in 2023.

A significant recovery effort is underway in Tissue and Eye Services to increase ocular donation which has fallen during the pandemic. More details on our effort to meet clinical demand are included in an appendix.

Clinical Services

We are working with the UK Stem Cell Strategic Forum to finalise a report for Ministers on improving the supply and provision of stem cells in the UK. This follows on from previous reports in 2010 and 2014, which led to the creation of the UK Aligned Registry, a national cord blood inventory, the establishment of IMPACT (to drive clinical trials) and ultimately an increase in the number of patients receiving transplants from unrelated donors. This latest policy report comes at a time of huge change in the sector, and will help inform our own Cell, Apheresis and Gene Therapy strategy.

Our Board seminar this month will explore some of the key issues and considerations raised in this report, including the decrease in national self-sufficiency and difficulty finding appropriately matched stem cells for people of Black, Asian and mixed ethnic backgrounds. In anticipation of our new strategy, we have relaunched our Stem Cell donor recruitment campaign with new material. This is sent to priority donors ahead of their blood donation appointment to prepare them for recruitment on-session. Recruitment criteria is focused on increasing the number of young, male donors and those of Black, Asian or mixed heritage.

Having identified genomics as a key opportunity to improve patient outcomes, we have set up an overarching programme to oversee and drive progress in this important area of innovation. Our work includes:

- A 3-year collaboration with Oxford Nanopore Technologies (ONT) to jointly develop a full gene, allelic resolution HLA typing technique. This collaboration has the potential to transform HLA typing for transplantation by addressing the limitations of currently available techniques and supporting improved matching strategies for

transplant recipients – particularly those with rare HLA types who are more likely to be from BAME backgrounds;
- Validation of a new DNA-based array as part of the Blood Consortium Group Collaboration. Our H&I lab in Colindale recently completed the first phase of the validation, genotyping 2,400 samples; and
- Support to Our Future Health through the recruitment of 500k blood donors to this ambitious research programme.

Our five new NIHR Blood and Transplant Research Units (BTRUs) have commenced work and are busy setting up new workstreams and making appointments. The R&D Committee meeting on 13 June will be an opportunity for Board members to hear from Principal Investigators about their plans.

People and Culture

We are currently reviewing the results of our recent Our Voice survey which indicated an overall engagement score of 7.5. As with all averages, this masks significant variations between and within directorates, which we are in the process of analysing. Once the ET has the opportunity to review, we will bring a fuller update to the People Committee for discussion.

Staff turnover continues to be a major challenge across the organisation, increasing from 11% pre pandemic to 15% in 2021 and over 17% in March 2022. Across the wider NHS, turnover varies between 11% and 20+%, depending on the organisation. The nursing profession is particularly affected with an overall rate of 17%. The turnover rate of staff new to role is even higher, at 37%.

Within our own organisation, Blood Donation is particularly affected with annual turnover currently sitting at 27% - largely driven by departures of new staff in their first year. The impact on operational delivery, as well as the increased workload for the recruitment team, is not sustainable. Work is underway to understand and address the root causes.

Fortunately, we are starting to see a general reduction in sickness absence. As at the end of April, we were at 5.5% compared to 6.85% the previous month. Though the trend is positive, we are not yet down to pre pandemic levels.

Following a review of Government guidance on COVID, we have relaxed social distancing across our organisation, effective from 9 May. The change provides additional flexibility in scheduling collection sessions and general service delivery across NHSBT, which is helping to offset some of the impacts of staff turnover. We are taking a measured approach and facial coverings will continue to be mandatory in CQC-regulated areas such as Blood Donation, Therapeutic Apheresis Services (TAS) and Organ Donation. Colleagues can continue to wear facial coverings at their own discretion in all areas.

Finance

An early draft of the Annual Report of Accounts for 2021/22 has been provided to DHSC and our external auditors Mazars, on behalf of the NAO. We will continue to develop the narrative and disclosures, with the objective of laying the report before Parliament on 7 July. This will be overseen by the ARGC with a review of the final draft, supported by the external audit report and opinion, at their meeting on 28 June. The management accounts for March 2022, which provide the financial results that are captured in the annual report, were reviewed by the Finance & Performance Committee on 26 April.

The financial result for April 2022 is a surplus of £1.5m versus a budgeted surplus of £0.2m. The primary drivers for the positive variance are Clinical Services (higher income and vacancies), ODT (lower activity than plan) and Group Services (mostly phasing differences). The cash balance on 30 April was £72m; capital expenditure incurred in April was £0.8m.

Planning is underway to prepare for the 2023/24 pricing and budgeting cycle. This will involve generating an indicative budget for 2023/24, alongside reporting the 2022/23 forecast in July. Although this is a normal part of the annual cycle, greater attention will be made to this early first iteration given inflationary risks and a need to improve our productivity and cost base.

Digital, Data and Technology Services

On the agenda is a regular progress update on our Blood Tech Modernisation programme to upgrade Pulse. This multi-year, complex programme rightly merits regular Board oversight and assurance. It is also worth noting that, behind the scenes, DDTS have also been modernising their ways of working, leading to significant improvements in performance and user experience. For example, improvements to processes, monitoring capabilities and technology have resulted in a 45% decrease in the number of major incidents raised and a 34% decrease in the time to resolve. In the past, changes were a common cause of major incidents. Over the last year, 99.25% of changes were implemented successfully.

Automating repeatable tasks to improve quality and reduce effort has also been a key area of focus. At the start of the year, 97% of requests to the service desk were fulfilled manually. Today, 33% of requests are automated, releasing the time to attend to higher value tasks. In May, an important upgrade was made to the National Transplant Database to digitise the urgent heart and lung pathway. This was a 7 month piece of development work that removes the need for current manual activities, reducing the risk of human error.

On the agenda is the first NHSBT-wide Technology strategy, which has been developed with input from across NHSBT and industry partners. The strategy is being presented to the Board for approval.

Appendix - **Ocular Donation:**

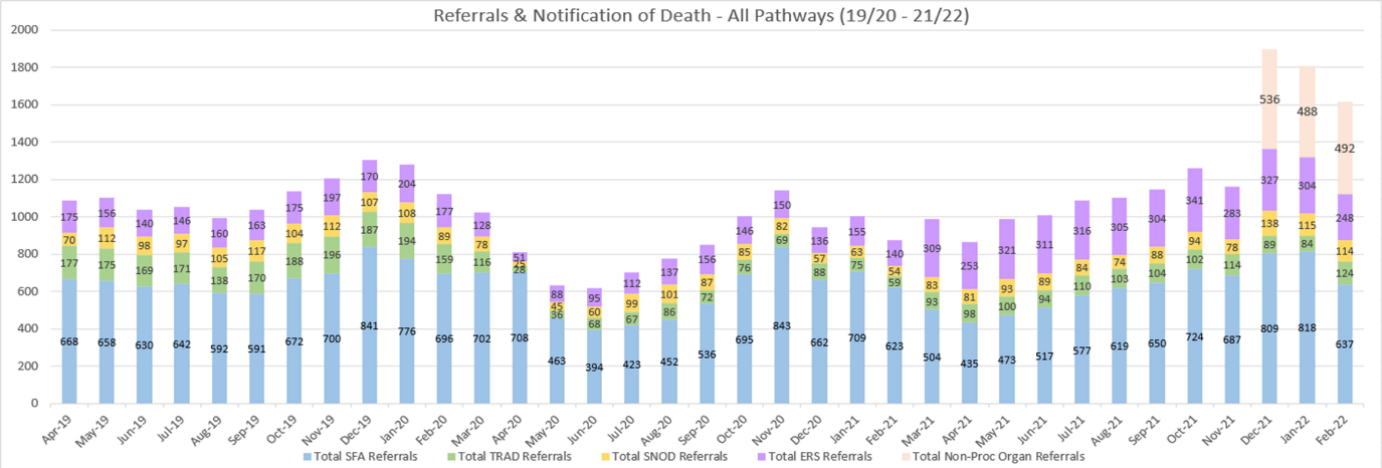
Background

We estimate that c.10-15 donations per day are needed to fully meet demand and reduce the backlog in the UK for cornea transplants.

Today's performance is in the range of 6-7 donations per day (44 per week). Failing to meet all demand is a long-term position exacerbated by the backlog created by the pandemic. We have not achieved the required level of donation since comparable data were available in 2016:

	2016/17	2017/18	2018/19	2019/20	2020/21	2021/22
Average Ocular Donations Per Week	54.0	54.8	56.9	53.6	34.6	43.9

Prior to the pandemic, ocular donation was a restricting factor to cornea transplantation. This remains the position today, though an emerging and important driver is a developing set of trends in potential donor referral:



Referral routes for ocular donation appeared to have recovered since the lows of 2020. Indeed, the table above appears to show an increase in referrals, notably since December 2021 when we introduced electronic referrals via our new digital TissuePath system. These comprise:

Traditional referrals (where people contact us as the person has shown an interest in donation), **Specialist Family Approach** (SFA – where we receive notification of death from a partner, some of whom ensure that donation is part of the end of life pathway via contractual arrangements), **Eye Retrieval Schemes** (ERS) and **Specialist Nurses in Organ Donation** (SN-OD).

However – while total referrals have recovered and indeed increased recently, we have uncovered new challenges within this overall picture:

- **Traditional referral** routes, which generally have a good conversion rate to donation, have not recovered to pre-2020 levels. This may be a permanent change.
- **ERS partners** are sending more referrals in. However, the increase is due to electronic notification being introduced into some schemes which this is giving us

more notifications of death, though they often have limited information about the potential donor and mean that our teams are contacting families for key details.
- **SFA** routes have recovered, however these are electronic notification of death and again contain limited information about the potential donor; meaning that the team supporting this method takes a lot of time to proceed with low conversion rates.
- **SN-OD** consented donors have recovered. We have set ambitious targets to increase these high-quality referrals during the coming months.

In summary: the gross number of referrals have recovered, but the net number of higher quality referrals appears to have reduced. This is possibly a structural development and, if we change nothing else in our operating model, it means that colleagues will undertake more work per proceeding donor.

Interim actions & outcomes to date

Our action planning is focused on 3 areas: immediate action, those with a 90-day delivery timeframe and longer-term changes. The number of ocular donations recovered strongly from mid-March and into April. The benefits of these donations was not seen in April's ocular issues data, as there is a 10-20 day product processing timeline.

This developing position was supported by immediate actions:

- We have overcome sickness absence that was impacting operations, especially in the National Referral Centre (NRC) and Retrieval teams. This has been achieved by increasing resilience through merging the NRC into our Organ Donation team, giving a larger pool of Nurses trained in consent to pull upon.
- Director and Senior Management Team support to the Operations team has been achieved by introducing daily and weekly calls. These have concentrated on escalating the short-term issues, such as staffing, access issues within some hospitals, and building-up alternative retrieval capacity from partners in areas with sickness.

There have been two further SMT resolution meetings to devise 90-day and longer term turnaround plans, and these have concentrated on:

1. Expediting the current project to increase referrals from hospices (known to have high consent rates);
2. Maximising integration benefits by deploying organ donation networks and infrastructure to increase referrals from hospitals where we have retrieval capacity, including building on the benefits of having integration between our TissuePath and DonorPath IT systems and;
3. Improving the communication and relationships with Eye Retrieval Schemes.

Our update to the Board in July will detail the projected impact of these and longer-term changes to referral, donation, retrieval and supporting pathways. In the meantime, demand (expressed by orders) remains high for corneas. We are now growing in confidence that our Q1 target for ocular donation is achievable. During the coming weeks, we will undertake more detailed planning to explain how we will reach the ocular donation levels required to achieve long-term sustainability. We are examining all options – including further reform of our operating model, product standards and potential imports from partners in Europe and the US.