NHS
Blood and Transplant

NHSBT Board

28th November 2019

Chief Executive's Report

Status: Official

While NHSBT must continue its vital work on a business as usual basis, any aspect of the plans outlined in the report that follows, on which a new Government might wish to take a view, are subject to the agreement of the new administration.

Operating Model Review

At the May Board, I reported that we would be undertaking a fundamental review of our operating model. As discussed then, there were two main drivers for this review. A recognition that:

- Looking backwards, NHSBT had experienced a number of issues in the previous 12-18 months, including the Core Systems Modernisation programme and a period of low blood stock levels. This led to our internal auditors giving us a limited opinion in last year's Annual Report and Accounts; and
- Looking forwards, NHSBT is operating in a rapidly changing external environment, from evolving clinical practice and new technologies to changing demographic and consumer trends. All of these will have huge implications on patient needs, our products and services and how these are delivered.

We have spent the last six months holding a series of conversations with staff, the Board and external stakeholders about the journey we have been on as an organisation, the things that make us great and the gaps between where we are today and our collective ambitions for the future. We took this input and distilled it into our design principles, which were included in my September report.

We used these principles to assess our current operating model and to develop a new model which, we believe, will set us up for the future. These changes are focused on how we organise to deliver at the most senior levels in the organisation and have led to a number of changes to our Executive Team. We announced these changes on 23 October; a copy of the all staff email is attached to this report, as is an update on the presentation I brought to the Board in May.

Inevitably, these changes have been welcomed by some and questioned by others; we continue to meet with people individually and in groups to explain the rationale and listen to their concerns. We will now work with the Assistant Director community to design the next layer of our organisation. Changes will be made in a phased and controlled way, recognising the need to continue meeting the demands of today whilst working to transform our organisation for the future. We will be working closely with

staffside colleagues, who have written to me with their concerns, to ensure that they and their members are formally consulted.

We have deliberately taken an iterative and emergent approach to developing our new operating model - one that draws on the skills, experiences and expertise of our people and stakeholders. The process has been designed not simply to work 'with' the organisation but to work 'on' the organisation, encouraging a new set of more collaborative leadership behaviours and a more open and inclusive culture.

Governance Review

Since the last Board meeting, the focus of the Governance review has been on:
(i) recruitment of a permanent Company Secretary; and
(ii) reviewing the structure and TORs of the Board and management-level committees.

The findings from the early stage of the Governance Review identified the need to consolidate the 'micro secretariats' supporting our various governance forums into a centralised team, headed by a professionally qualified Company Secretary. The post has now been advertised and interviews are scheduled for 6 December.

Having agreed our high level operating model and leadership changes, we are now in a position to streamline and strengthen our internal governance structures. A workshop has been planned with the full Executive Team on 11 December to review our management-level committees. We will be speaking to Non Executive Directors in parallel about the Board level committees and aim to bring an integrated proposal to the Board in January.

A 'good-governance toolkit' comprising a suite of essential standard templates, planners, trackers, databases and guidance has also been developed. At this stage, our plan is to hold off launching it until the permanent Company Secretary is in place and has an opportunity to review.

Risk Management

We continue to hold a series of discussions with Executive and Non Executive Directors to discuss the scope of the risk review, the proposed structure of our new risk register and a draft set of strategic risks. We are in the process of incorporating feedback and will be seeking Board approval in January for a new set of strategic risks.

We are developing risk management training for all staff and will be exploring a separate offer for Non Executives. Work has already started on aligning the NHSBT Risk Management system with ISO31000, with an aim to certify once the organisation is ready.

Work has already progressed with the Blood Donation Senior Management Team (SMT) to address the recommendations from the PwC limited assurance audit. The

SMT have received risk management training and have restructured their directorate-level risks. Work has now started with the Manufacturing and Logistics and Marketing and Communications directorates, with reviews of risks and risk registers underway.

As discussed at GAC, Blood Donation have escalated a risk in respect of Copper Sulphate - a critical component used on session to test donor iron levels. A recent audit of our sole supplier exposed a number of quality issues, leading to a decision to switch manufacturing sites. We have over four months of stock available and are monitoring the situation closely. A backup solution, which is used widely by other blood operators, is available should that be necessary.

Quality and Compliance

Four external regulatory inspections were carried out during September and October: MHRA inspections in Cambridge, Filton and CBC, and an HTA inspection in Leeds. One major non-conformance was raised during the CBC inspection relating to incident management and investigation. This is a positive outcome overall given that two of the four inspections were of our IMP sites where we have had significant facilities issues in the past.

Planned inspections for November and December include blood establishment authorisations by the MHRA at our sites in Manchester and Birmingham. We are still awaiting the outcome from the HTA in relation to the previously reported license breach at Colindale. We have provided HTA with the details of our action plans and review of current licences.

The management of overdue items within the quality management system continues to be a priority. Unfortunately, the latest data show the overall numbers have remained around the 200 mark. This has been discussed by the Executive Team who have agreed to put more focus on reducing the numbers during November. The MHRA have reviewed our current overdue status at the Cambridge inspection and have said that they will continue to review during future inspections.

We have been working with our new Account Lead at the CQC to clarify their inspection regime. They have confirmed that:

- Therapeutic Apheresis Services (TAS) will be subject to inspection; this is the outcome we expected. Our six TAS units will be registered as locations. We expect to be inspected next year.
- Blood Donation activity will remain subject to inspection and, again, we expect to be inspected next year. All our fixed Donor Centres will be registered as locations, with Filton Blood Centre registered as our headquarters and the ‘umbrella’ location for our mobile teams.
- All Diagnostic activity has been confirmed as out of scope for CQC registration. We will now remove these locations from our registration.
- NHSBT will be subject to a ‘Well Led’ inspection next year. This is routine but requires significant preparatory work. Normally, 12 weeks’ notice is given ahead of the inspection.

Infected Blood Inquiry (IBI)

All of the original 2700+ boxes requested by the IBI have now been delivered. We have also completed the project to detail the contents of the additional 14k boxes that we're not labelled and have provided this information to the IBI. The next stage of disclosure is likely to be from NHSBT IT systems; discussions are ongoing with the IBI about this process.

The current phase of evidence from infected and affected witnesses has concluded, although further oral evidence from this group of core participants is expected at the end of the Inquiry. A week of expert evidence commences in February, which we will attend. It is understood that the evidence from NHSBT and other core participants will commence in June 2020, but detailed timings of this phase are not yet known. We have held an event for previous employees who may be called to give evidence.

Blood Supplies

Red cell stocks are currently healthy, with all groups at or above target levels. Based on our latest demand and collections forecasts, we do not anticipate any issues maintaining stock targets over the Christmas period and into the New Year.

Whilst O neg stocks have been sustained consistently since September, the increase in O neg demand continues to be a long term supply chain challenge. O neg now represents 12.8% of total demand (and 14.5% of total issues) versus a general population prevalence of around 8%.

We have revised our red cell demand forecast for the remainder of 2019-20 to reflect this level of O neg demand, as well as a slowdown in the overall decline in red cell demand; we have increased our collection plan accordingly. As reflected in our stock levels, O neg collection has been strong. September saw the launch of our 'First Responders' campaign, linking O neg blood to the emergency services and offering a unique proposition to our valuable O neg donors, including access to priority appointment slots and a dedicated appointment booking line.

Recruitment of new Ro donors increased by 20% this past quarter however demand continues to outstrip supply by c.50%. Based on current projections, we would need to increase Ro collections by c.40% next year to place ourselves on a trajectory to meet demand fully by 2022-23. We have now received DHSC approval to engage external consultants to help us achieve this target. We are reviewing the exact timing, resourcing and governance for this engagement given the senior leadership changes underway.

Logistics Review Programme (LRP)

The collective consultation period was extended to allow time to discuss a number of counter proposals from Staff side. Having considered these suggestions, we have

agreed to postpone the implementation of on-call rotas for Blue Light and TAS deliveries for 12 months. This allows for further dialogue and aligns with our plans for Barnsley.

This change reduces the forecast annual savings to £1.3m (from £1.8M) but establishes the principle of annual rota reviews and nationally agreed rota parameters, this addressing a number of local discrepancies.

The rest of the programme continues to be on track delivering significant benefits from warehouse consolidation, reduced inter-centre couriers and reduced fleet costs.

Session Solution

Sessions Solution continues to track on time and to budget against plan. We completed a major milestone in November: the handheld software (Genaro) has now been installed and configured on the target infrastructure (Public Cloud Azure). This work was completed in partnership with our key suppliers, Savant and BT. Having the Infrastructure and Application in place has allowed us to move the project into Key User Acceptance Testing. This phase allows the team to complete full end to end tests of the system and gives the User Acceptance Test (UAT) team familiarisation of the system and an environment to conclude the production of the UAT test scripts and plan.

Moving into the new year, the team will focus efforts on UAT, along with our Non-Functional Testing (performance and penetration). Completion of these phases will allow us to start our pilot of the system in May for both mobile and fixed blood donor centres.

Plasma

Following the Ministerial decision that UK plasma can be used to treat patients born after 1995, we have initiated the transition to 100% UK sourced plasma. Our contract with Macopharma will be terminated on 1st December 2019, with the last consignment of imported plasma expected in March 2020.

The initial implementation plan has been reviewed to reflect JPAC's decision that pathogen inactivation of UK plasma is not required for neonates/infants. This will bring forward delivery of 100% UK sourced plasma for all components to September 2020.

We continue to ramp up Group A and AB male whole blood (WB) collections to meet future forecast demand. At the moment, the target for AB males is broadly being met, with A male donations now at 47.5% (up from 45%) and moving towards the required target of c50%.

Required IT changes to enable the transition to all UK plasma are all on track.

Organ Donation and Transplantation

Following a disappointing start to the year, with donation and transplant numbers down on the previous year, we have seen an increase in proceeding donors, thanks to higher

consent rates. Donations are now up 3% vs this time last year. Whilst the number of organs transplanted is broadly flat, at just over 2000, we are working with the transplant community to identify and address the key constraints to higher transplant volumes. These include:

- Delays in the donor process;
- Poor communication in the offering process;
- Unwarranted variation in risk assessment and consent; and
- Resource in the transplantation pathway.

Our Opt Out campaign is on track, with public awareness across England now at 53% and BAME awareness at 35%, up from 27%. Unfortunately, we experienced another spike in opt out activity this month following further 'fake news' circulating on social media. Total opt-out registrations rose slightly to 833k - though still well short of the final anticipated number of 3.25m. Opt-in registrations now stand at 25.7m.

Diagnostic and Therapeutic Services

Financial performance in DTS is strong with income and I&E ahead of plan. In Tissue and Eye Services (TES), cornea stocks are 20% higher than plan (322 vs 270). Since taking over the eye banks in 2016, TES has more than doubled the number of corneas available for transplantation. We are currently pursuing a partnership with SNBTS which will expand the pool of potential eye donors further.

Unfortunately, we had to declare a Serious Incident in November following the failure of equipment used for pre-cutting corneas. Of 76 pre-cut corneas issued since the transfer of the service to the Filton Eye Bank, we have been informed of 8 cases of primary graft failure. In addition, 4 patients have reduced visual acuity and 7 patients have required additional interventions to reattach the corneal graft. Though these are recognised complications of corneal transplantation, we have seen more complications than would have been expected. A root cause analysis has been undertaken and corrective actions put in place. This has been reported separately to the Board in more detail.

DHSC approved the business case for the expanded Clinical Biotechnology Centre in November, following Board approval in September. The main contractor, Kier, is mobilising resources so that construction can begin at Filton in January. Completion is expected in September 2021, with parallel decommissioning of the current facility at Langford. CBC continues to perform well in financial terms, with a significant number of high-profile academic and commercial contracts.

The primary issue in DTS continues to be the trend in cord blood / BBMR and the need to reset the UK haematopoietic stem cell strategy. A revised strategy is in development and will be shared with the Board in the new year. In addition, H&I hospital referrals for solid organ transplantation and stem cell investigations continue to decline. This appears to be linked to the increased prevalence of next-generation sequencing among global donor registries, and the impact of haploidentical ("half-matched") transplantation in certain stem cell transplant units, thereby reducing the number of potential unrelated donors needing to be typed.