

NHSBT Board30th January 2020**Chief Executive's Report****Status: Official****Operating Model Review**

Since the November Board, we have moved to interim management arrangements under the new directorate structures announced in October. From 1 January, collection teams from Blood Donation came together with Manufacturing and Logistics to form Blood Supply, under Greg Methven. The remaining teams in Blood Donation came together with Marketing and Comms to form the Donor Experience team, under Mike Stredder on an interim basis. Tissue and Eye Services came together with ODT under Anthony Clarkson. And the remaining parts of DTS moved into the Clinical Services team, under Gail Miflin.

Directors have worked with their Assistant Director teams to discuss new ways of working and to help design the next layer of their structures in line with our agreed design principles. Our main focus to date has been on Blood Supply and Clinical Services where we hope to begin formal consultation with staff side in February.

Wendy Clark joined us on 6 January as our new Chief Digital and Information Officer (CDIO). Recruitment is underway for the new directors of Donor Experience and Strategy and Transformation, with final interviews planned for 28 January and 8 February, respectively. We will shortly start to turn our heads to Group Services where, apart from re-mapping our business partners to the new directorate structures, we want to identify if/where there are opportunities to improve user experience and become more modern and agile in delivery.

We continue to invest in leadership and organisational development interventions to develop a more open and collaborative culture. We have also made progress on our review of governance and risk management; an update is on the agenda for review and discussion.

We are working to consolidate and distil the various strands of this programme of work into a single document that we can use to inform internal and external communications. A very early draft is appended to this report for information and comment, along with our latest project report.

Infected Blood Inquiry ('IBI')

The IBI team continue to request additional boxes of historical information. We are working with Iron Mountain, our storage company, to get boxes released in a timely manner and, once scanned by the IBI, to agree redactions and comment on their use in the Inquiry. The first tranche of documents (around 3000) now been released; these are not new to us as they relate to a previous litigation case on HCV and to documents used in the Penrose inquiry. We are content for them to be released, other than where a previous legal ruling called for anonymity.

The next phase of the Inquiry will begin in the last week of February.

Quality Assurance and Regulation

The MHRA carried out two significant inspections in Birmingham and Manchester before Christmas. They raised three 'Majors' and three non-conformances at Birmingham and six non-conformances at Manchester. The major findings in Birmingham related to data integrity, incident management and irradiation. On the latter, it is worth noting that inspectors were at one point considering a Critical finding, however we were able to provide evidenced assurance that there was no risk to patient safety. We are working to address the issues raised.

December saw a 30% decrease in the number of overdue items in our quality management system. QA and operational teams are working closely to drive further improvements, with weekly oversight by the ET and wider leadership team.

A major non-conformity was identified in the BSI audit of our Business Continuity systems under ISO22301 in relation to the stand-by generator at Colindale. Specifically, it had not been regularly tested for several months following the appointment of our new Facilities Management provider, Mitie. This non-conformity potentially places our ISO certification at risk; the Assistant Director for Estates and Facilities is managing a corrective action plan ahead of a follow up visit by the auditor on 31 March.

Our scope of registration with the Care Quality Commission (CQC) has now been clarified. Therapeutic Apheresis Services (TAS) and Blood Collection are the only two operational areas which will be inspected. The leadership, management and governance of NHSBT will also be subject to a 'Well Led' inspection. The timing of these inspections is still to be confirmed.

IT Testing and Assurance

Following our discussion at the November Board into the IT-related Serious Incident in ODT, we immediately halted further code releases into the live environment pending an assurance review of our testing procedures on each of the 27 systems that directly impact patient safety. The framework we are using to walk through the full test lifecycle and process for each release has been independently verified by a specialist test

consultancy. Each review is being conducted by a team of senior ICT and Quality Assurance staff, with the process being co-ordinated by an independent consultant.

Seven reviews have been completed, with the remainder scheduled to complete in February. Follow up actions have been identified in the majority of the reviews to date. Evidence that these actions have been completed will be required before the release can continue its path to live.

It is too early to identify whether there are any systemic issues with our approach to testing and assurance, though there is variation in practice across the organisation, reflecting our hybrid operating model and the different methodologies used by different development teams. We will be looking to introduce a more consistent approach across the organisation, with improvements to tooling, automation, documentation and training likely to feature in our recommendations. Whilst we cannot eliminate all risk associated with releasing new code into a live environment, we are taking urgent action to learn from this Serious Incident.

Organ Donation and Transplantation

The moving annual total number of donors continues to improve, reaching 1,654 at the end of December 2018. This is 35 more (+2.2%) than the previous calendar year, though still 4.9% lower than our TOT2020 strategic target. Unfortunately, the number of transplants over the same period was slightly down (- 0.1%) at 3,949. This is 20% lower than our TOT2020 target. As we will discuss at the Board, we will need to turn our focus to organ utilisation and transplant as part of the next ODT strategy.

The 'Pass it on' public awareness programme is progressing as planned and will build in scale as we approach implementation later this Spring. Awareness of the new legislation across England has now reached 55% - up from 46% in 2018. This puts us on track to hit the 60% target by the end of March.

Unfortunately, awareness among the BAME community stands at only 44%; we are unlikely to bridge the gap to the 60% target over the next two months. Unfortunately, we continue to see spikes in opt out activity, driven mainly by 'fake news' on social media. We are implementing a range of counter measures to correct misinformation. The total number of opt outs has now reached 1.28m - still short of the anticipated 3.25m.

Our Opt Out Implementation Programme is progressing well. We have delivered the first training module - covering the principals of the change in law - to our Specialist Nurses for Organ Donation. The second module is now underway, providing interactive training in best practice on how to have the conversation with families. Last month, we provided advice and training about the change in legislation to over 2k delegates at the Intensive Care Society's annual conference. We received positive feedback that this is already impacting on practice in ICU wards and improving consent rates.

Blood Supply

Overall red cell stocks have fallen since the November Board, largely due to under collection. That said, we are only just under our target level of 5.5 days of stock (DOS), having built up stocks going into the winter period. Collection performance in January has improved and we have increased appointment numbers over the next few months to create more opportunities for donation.

O neg stock remains healthy at 5.5 DOS, thanks to the success of our First Responders campaign. However, we have seen demand increase by 4.3% over the last 12 months; O neg now represents 13% of total red cell demand (vs a 7% frequency in the general population). We have - again - written out to hospitals requesting their help to manage inappropriate use of O neg. However, it is clear that this approach only offers short term relief. Developing a new, sustainable strategy will be a priority for our Associate Medical Director for Transfusion, once appointed.

Demand for Ro has risen c11% in the last 12 months, which is in line with our demand forecast and driven by the expansion of red cell exchange programmes for increasing numbers of sickle cell patients. Whilst we have increased the size of our Ro donor base by c13% in the last 12 months, we are still only fulfilling c55% of demand. Following the Board's approval in September, McKinsey will shortly be starting their 12 week engagement with us to help address the challenge of Ro/black donor recruitment and, more widely, the need to manage the unit cost implications of an overall decline in red cell demand. We have delayed their work until now to ensure we can resource the project appropriately. Mike Stredder, Greg Methven and I will jointly sponsor the project, meeting with the team on a bi-weekly basis to review progress and emerging recommendations.

MSM

The Board will be aware of the high profile campaign being run by various LGBT groups to lobby for changes to the existing deferral guidelines in respect of Men who have Sex with Men ('MSM'). These guidelines are set by Government, based on advice from SaBTO. In 2017, the deferral period was reduced from 12 to 3 months.

As part of the FAIR (For the Assessment of Individualised Risk) project, we are working with other UK blood services, Public Health England, Nottingham University and a range of stakeholders (including the National AIDS Trust, Stonewall, Terrance Higgins Trust and Freedom to Donate) to explore if a more individualised donor risk assessment is possible, without compromising the safe supply of blood to patients. We hope to be in a position for this to be considered by SaBTO in September.

Imported Plasma

Our project to end the importation of plasma, in line with SABTO recommendations and DHSC instructions, remains on track. Increased donations from Group A and AB male donors are progressing well, with targets for AB already being met.

We have served notice to our supplier, Macopharma; the last delivery of imported plasma is expected at the end of March. From April, hospitals will begin to order generic FFP and Cryo, with NHSBT issuing a mix of UK and imported plasma components whilst stocks ramp down. The only risk to this timeline is if there are any further delays (beyond January) to PULSE releases, due to the ongoing assurance reviews mentioned above.

Logistics Review Programme (LRP)

At the requests of staffside, we temporarily paused collective consultation on the National Rota Review in order to discuss the wider organisational changes underway. Consultation has now recommenced and, subject to final agreement around the latest proposals, we hope to close collective consultation in February, followed by individual consultation and implementation.

The rest of the programme remains on track with recurring annual benefits now forecast at £3.8m (vs £4.8m at OBC), at a reduced cost of £4.5m (vs £5.7m at OBC).

Session Solution and Data Centre Programmes

Session Solution is progressing to plan. Key User Acceptance Testing is now complete, and Savant has fixed 41 defects which will enable us to move into UAT. BT has also delivered the full hardware stack that will be used in Donor Centres and Mobile sites (e.g. laptop, printer, Wifi device and cabinet).

Following approval by the Board and DHSC in November and December, respectively, we were able to place our order for new Itanium servers to support Pulse. These are due to arrive imminently. We are now working with Savant on a detailed implementation plan and remain on track for implementation in July. In parallel we have begun work on a business case to upgrade our VMWare and storage for Pulse.

Our data centre provider, SCC, has advised us that one of our two sites (Lyndon Place) is no longer part of their long-term strategy and have asked us to consider an alternative site. We are working with SCC to confirm that they will support Lyndon Place for another year whilst we build out our new hardware and undertake a procurement exercise for new hosting and migration services.

International Best Practice

As our visit to SNBTS in November illustrated, there is much to gain from visiting our international peer organisations and learning from their experience and approach. We continue to be active members in the European Blood Alliance (EBA) and Alliance of Blood Operators (ABO).

In May, we will be hosting the next ABO meeting in London and have invited the ABO Secretary, who leads on horizon scanning for the Australian blood service, to help

facilitate a workshop on innovation with our AD community ahead of the meeting. Between now and then, I will be visiting my Dutch and French counterparts to learn more about their national operations and to discuss the nature of our role in the EBA following the UK's exit from the European Union.

Further afield, a member of Manufacturing and Logistics team recently visited the Japanese Blood Service to learn more about their experience in automating testing, pooled platelets production, labelling and packaging. They have seen their investments pay off both in terms of efficiencies and reductions in human error. As previously reported, we are working in collaboration with ABO members on a proof of concept to automate labelling but it is fair to say that countries like Japan and Germany remain ahead of us in terms of automation and robotics. Equally, organisations such as the Canadian Blood Service have made greater strides in donor-facing digital improvements, such as paperless donor centres and electronic health questionnaires. As part of our Blood Tech Strategy, we will need to decide which investments we want to prioritise and the speed at which we can deliver.