

Business Plan - 2019/20

Including strategic summaries and five-year
financial projections

March 2019

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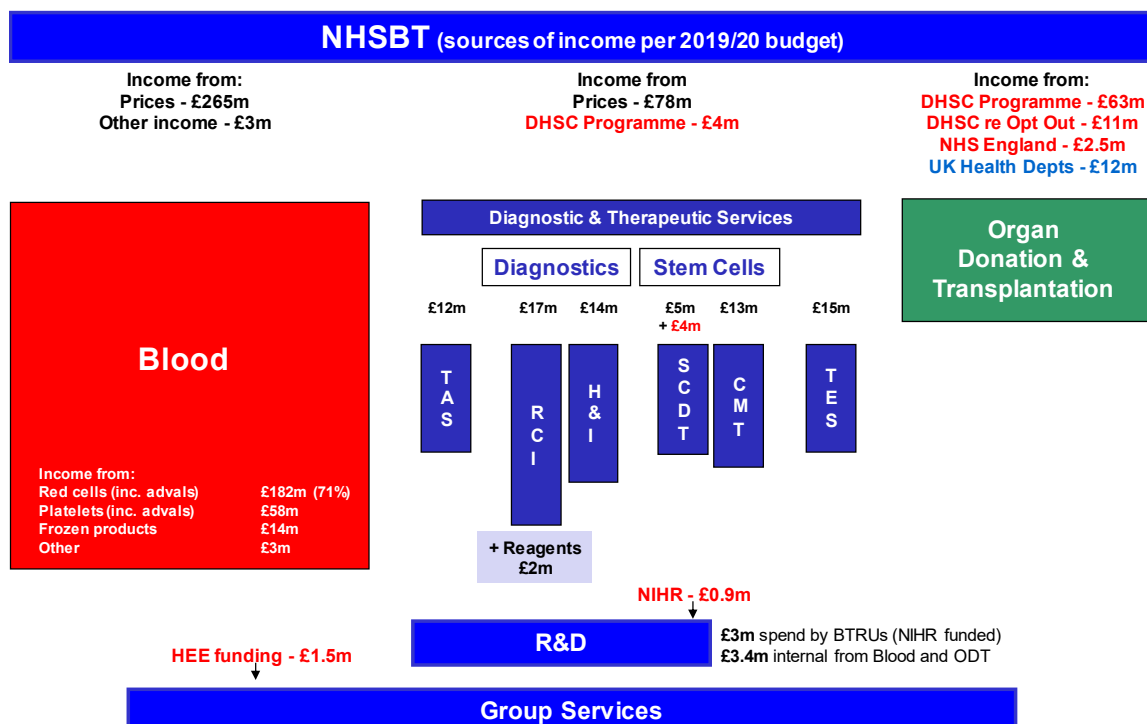
Section One: Introduction

NHS Blood & Transplant (NHSBT) is a Special Health Authority in England and Wales and is also accountable to the Scottish and Northern Ireland Health Departments for providing UK wide services in support of Organ Donation and Transplantation. Our core purpose is to **“Save and Improve Lives”** through providing a safe, reliable and efficient supply of blood components, solid organs, stem cells, tissues and related diagnostic services.

NHSBT is operationally unique and has characteristics that cannot be found anywhere else apart from similar services in other countries. Our ambition is simple, we aim to be recognised as **the best service of our type in the world**, and evidence this through appropriate benchmarking.

Even amongst our international peers NHSBT is unusual in that the supply of blood, organs, stem cells and tissues are provided by the one national organisation. In support of this NHSBT operates through a Divisional structure comprising:

- **Blood**
- **Organ Donation and Transplantation (ODT)**
- **Diagnostic and Therapeutic Services (DTS)**



The DTS Division is itself a group of distinct strategic business units (SBUs) comprising:

- **Tissue and Eye Services (TES)**
- **Stem Cell Donation & Transplant (SCDT)**
- **Cellular and Molecular Therapies (CMT)**
- **Red Cell Immunohematology (RCI) – including Reagents and the International Blood Group Reference Laboratory (IBGRL)**
- **Histocompatibility & Immunogenetics (H&I)**
- **Therapeutic Apheresis Services (TAS)**

The total income of NHSBT is £442m, with £10.5m of this being non-recurring income to deliver the Opt-Out Programme in England (2019/20 budget). £343m (80%) of our recurring income derives from the sale, at cost, of the biological products and associated services that are supplied, primarily to NHS hospitals, within the Blood and DTS divisions. In this regard the economic performance of much of NHSBT is highly transparent through the prices that are charged to the NHS.

£79m (18%) of our recurring income consists of programme funding provided by the four UK Health Departments. £75m of this is provided to ODT to fund its activities as the UK Organ Donor Organisation with £4m funding activities in stem cell donation & transplantation (in support of the UK Stem Cell strategy). The sources of our income and funding by SBU is summarised in the diagram on the previous page.

All the above strategic business units (Blood, ODT and the DTS SBUs) are underpinned by formal strategies that confirm their individual purpose and objectives and define their relevance to NHSBT's accountabilities and objectives.

The status of our business strategies is captured below. Strategically, NHSBT is at an unusual and uncertain point in time because of:

- The rapidly changing environment in Blood, as well as newly emerging risks regarding collection and plasma. A new ground up strategy is required.
- The existing strategy for ODT ("Taking Organ Donation to 2020") is coming to an end and hence there is the requirement for a new strategy to be developed with and agreed by our stakeholders.
- Within DTS, the strategic objectives of each business remain broadly appropriate, but there is a need to work with our stakeholders in stem cell transplantation to refresh the (hematopoietic) stem cell strategy for the UK.

SBU	Board Approval	Planned reapproval
Blood (Blood 2020)	January 2015	March 2020
ODT (TOT 2020)	June 2013*	July 2019
Tissue and Eye Services	May 2016	TBD
RCI	July 2013	Emerging "Diagnostics" strategy May 2019?
Reagents	January 2015	
IBGRL	N/A	
H&I	March 2013	
Stem Cells – SCDT	Sept 2016	2020/21
Stem Cells – CMT	July 2018	TBD
TAS	March 2012	July 2019

* Approved by the four UK Health Departments

The purpose of this document is to:

- Summarise each of the business strategies as they exist at March 2019
- Describe the business plans, targets and associated budgets for 2019/20
- Provide five-year financial projections for each of the Divisions

Section Two: Challenges and Key Priorities

BLOOD

Following the red cell stock shortages seen during 2018, collection performance, and adherence to collection plans, will continue to be the immediate focus. Actions will therefore be centred on ensuring that we have enough numbers of active donors (especially O negative and R_o donors), with re-balancing towards re-activating and retaining lapsed donors and less new recruitment. The aim is to ensure that our donor appointment grids (capacity) is effectively and consistently utilised.

A strong track record and reputation had been established in **Blood** for driving continual improvement in the safety, sufficiency, service quality and efficiency of the service. The challenges seen during 2018/19 reinforce the fact that we have now entered a much more challenging environment that is materially different from that anticipated by the original Blood 2020 strategy i.e.

- Much lower demand than was envisaged in the Blood 2020 strategy.
- The distraction generated by the CSM project.
- Differential demand trends for specific blood group / component types (most obviously R_o for patients with sickle cell disease).
- A donor base that requires re-building and re-balancing to reflect the demands at component/blood group level blood (e.g. R_o donors, O negative donors, CD platelet donors in total and for A negative).
- The impact of the need to better manage and protect donor iron levels.
- Much higher cost inflation both internal (head count in blood donation) and external (pay and consumables inflation).

In addition to the above there is the merging prospect that SaBTO may recommend that there is no longer a requirement to import plasma for patients born after 1995. If NHSBT is directed to do this, the impact will be significant, and a response plan will need to be fully worked through as a priority

During 2019/20 we will therefore need to fundamentally refresh and renew the strategy for Blood. This will implicitly assume, that the Pulse blood management system will continue to be used for the next 5 years, at least, and that we will need to invest in the renewal of some of its components to minimise any risk to the security of supply that any failure of Pulse would imply.

The priorities in 2019/20 will therefore be to:

- Respond to the requirements of the Infected Blood Inquiry.
- Generate greater consistency in marketing and collection performance to ensure stocks consistently remain at target levels and able to cope with demand fluctuation.
- Identify the critical process improvements needed in the short/medium term to support donor safety, donor recruitment and retention and the management of sessions, along with any IT tools that will be needed in support.
- Revisit the options for replacing the Pulse blood management system and, depending on the solution and timetable, identify and commence delivery of the risk mitigation steps that will be required to safely operate Pulse for as long as it remains in operation.
- Deliver the Logistics rationalisation programme (LRP).
- Generate a new strategy for Blood, that appropriately responds to the changing and developing environment, and especially the implications of any decision on the safety of plasma.

ODT

Following excellent growth in the number of deceased donors and deceased transplants during 2017/18 the trends have now flattened during 2018/19. In addition, although (to date) there are more deceased donors in 2018/19 versus last year, the number of deceased transplants has not increased, suggesting that we are seeing more marginal donors with fewer transplantable organ per donor. Despite overall growth, in overall terms ODT is now falling behind the final year targets of the TOT2020 strategy and hence it is timely that a new strategy for organ donation and transplant beyond 2020 is generated.

As with Blood the new strategy will need to reflect a very different environment than was anticipated by the preceding TOT2020 strategy. It will need to focus more on more marginal gains (no lost opportunity for donation), in a highly constrained funding environment, but also responding to the major investment and changes related to the introduction of opt out legislation, especially in England.

Alongside this, 2019/20 was due to be the final year of the ODT Hub programme. Excellent progress has been made to date, but requirements are becoming more complex as the programme moves beyond the delivery of solutions provided by the BPMS platform and needs to integrate with other platforms / applications.

The priorities in 2019/20 are therefore to:

- Review the way forward for the ODT Hub Programme and reconsider the plans, milestones and investments required to deliver the ODT Hub vision.
- Support delivery of the developing opt out legislation across the UK, and especially in England.
- Develop and obtain approval for a new UK strategy for organ donation and transplantation in the UK, considering the views of all stakeholders and incorporating the demands of opt out and a revised approach to delivery of the ODT Hub vision.

DTS

Progress across the DTS portfolio is strong (in terms of patients treated and income/contribution) except for changing technology and trends in cord blood and bone marrow donation (in SCDT). Although many of the strategies are some 5 years old, SCDT aside, there is, in general, no requirement to change their fundamental objectives but rather a need to update plans for execution and delivery (against the background of a changing NHS).

The new plan will, therefore, mostly consist of updates to refresh targets and supporting action plans. The most significant development of strategic importance is in Cellular and Molecular Therapies and is reflected in the planned investment in the Clinical Biotechnology Centre extension at Filton and clean room capacity in the new Barnsley Centre. The priorities in 2019/20 are therefore to be:

- Develop the 'Eyes' portfolio within Tissue and Eye Services, maximising the number of corneas available for transplantation and developing a closer partnership with the Moorfields Eye Hospital.
- Facilitate a meeting of stakeholders to re-visit the UK (hematopoietic) Stem Cell strategy, considering the very different trends now being seen in cord blood/bone marrow transplantation and re-setting NHSBT activities, plans and funding in support.
- Further develop NHSBT's role, contribution and processes in support of advanced cell therapies; the delivery of the project to relocate and expand the Clinical Biotechnology Centre (CBC) within an extension of the Filton site and utilisation of new capacity in Barnsley.

CORPORATE

At a corporate level NHSBT will continue to develop the capability and capacity needed to support the delivery of the SBU strategies and develop NHSBT as an attractive place to work. Key to this will be:

- Our commitment to safety, availability and compliance and particularly our ongoing aspiration for:
 - Zero Serious Incidents
 - Zero critical or major findings from any regulatory inspection
- Working with DHSC and its arm's-length bodies to manage the consequences of EU Exit on the health and care system as well as leading on the contingency planning to ensure the continued supply of blood, blood components and plasma and the continued supply of organs for transplantation. In addition, ensuring that the appropriate governance and accountability structures are in place to monitor and assess the impacts of EU Exit and collaborating with the DHSC Operational Response Centre by providing information, advice and data on matters related to EU Exit.
- Developing and delivering the significant programme of work required to re-new, protect and improve the performance of our IT infrastructure, including the need to transfer the hosting of our data centres, improving cyber security and ensuring Pulse can operate safely for at least the next 5 years.
- Developing the relevant workforce models and capabilities required by our strategies, especially regarding blood donation and advanced cell therapies and to the recruitment and retention of nurses across NHSBT.
- Delivering on key estates projects with priority on delivering the new Barnsley Centre, the CBC extension at Filton and a 2nd blood donor centre in London. In respect of the development of the existing estate our priority will be on refurbishing Hospital Services in Tooting and making progress with the Colindale master plan.

Section Three: Blood

Strategic Objectives, Themes and Action Plans

STRATEGIC OBJECTIVE - Blood 2020

To ensure for all patients, including patients with complex needs, that the right blood components are available at the right time, and are supplied via an integrated, cost efficient and best in class supply chain and service.

The Blood 2020 strategy was approved by the NHBST Board in January 2015 and was based on the following **four pillars**, with the **safety of our service to patients and donors** presumed:

Blood Collection

We will ensure a sustainable donor base underpinned by flexible collection and donor invitation processes; a modern donor service, an excellent session experience and high levels of collection productivity.

Supply Chain

Our supply chain will be hospital focused with high levels of safety, productivity, regulatory compliance and order fulfilment.

Customer Service

We will provide excellent customer service with a tailored, cost-effective offering and a modern interface with hospitals.

Integration

Integration of NHBST's supply chain with key hospitals, and any related networks, to drive improved patient outcomes and reduce system costs through integration of blood supply from "vein to vein".

Although the pillars remain broadly relevant there is a need to develop a new strategy for Blood.

PLAN – 2019/20

The plan below therefore focuses on the short-term plan, following on from the collection challenges that were encountered during 2018/19, plus a "plan to plan" for development of a new strategy over the course of 2019/20.

To this end the short-term plan builds on the actions taken to stabilise the stock position over the latter half of 2018/19 and assumes that stocks will remain stable, and at target levels, through the course of the year. The key elements of the plan for 2019/20 involve:

- Red cell demand of 1.372 million units, 3.0% lower than 2018/19 forecast, but with the plan assuming capacity to increase collection by around 30k given current uncertainty around demand trends.
- 13% increase in the demand for R_o.
- Increasing the O neg, B neg and R_o donor base.
- Rebalancing away from recruitment towards reactivation and retention as a more effective way of delivering the necessary donor base and to significantly reduce the pressure that high numbers of new recruits generate on session.
- Ensuring there is the capacity to manage the roll out of capillary HemoCue, the introduction of nurse breaks and the implementation of Session Solution.
- Resulting in the following planning assumptions for blood donation in 2019/20 (*but excluding any impact from potential changes to decisions on plasma safety*):

Operational Targets – Blood Collection 2019/20.

Blood collection targets	2018/19 Fcast	2019/20 Budget	Change
Whole Blood Collection (units)	1,508k	1,456k	-3.5%
Productivity – Blood Donation	1,393	1,325	-4.9%
% of donors scoring \geq 9/10 for satisfaction	77.3%*	79%	
Complaints as % of whole blood donations	0.46%*	0.41%	
New Donors Donating - DCs	46,078	44,706	-3.0%
New Donors Donating – Mobiles	113,790	89,054	-21.7%
Active total donors - end March	832k	827k	-0.6%
Active O neg donors - end March	111k	116k	+4.5%
Active B neg donors -end March	20,992	22,700	+8.1%
Active R ₀ Kell neg donors - end March	20,679	23,675	+14.5%
WB collection – DCs (units)	348k (23.1%)	361k (24.8%)	+3.7%
Capacity utilisation - DCs	66.1%	68.6%	+3.8%
WB collection - Mobiles	1,144k	1,095k	-4.3%
WB capacity utilisation - Mobiles	82.1%	78.4%	-4.5%

**As reported for January 2019 month*

The targets for the O negative and R₀ donor base are set at a level that assumes:

- There is ongoing gap between R₀ demand and supply but with the number of donors ensuring that the gap does not increase any further
- There are sufficient O negative donors to meet demand and provide capacity for R₀ substitution.

The assumptions for manufacturing and logistics are captured within the other supply chain targets below. They are broadly flat overall but with waste and expiries re-set to reflect being at target stock levels through 2019/20. Although work will continue towards reducing red cell waste, expiries will inevitably increase because of being at target stock levels (rather than the low levels suffered during 2018).

Operational Targets – other supply chain 2019/20 (excluding any impact on change to decision on plasma safety)

Other Blood supply chain targets	2018/19 Fcast	2019/20 Budget	Change
OTIF - excluding R ₀ substitutions	98.0%	98.0%	-
% hospitals scoring \geq 9/10 for satisfaction	78%*	70%	na
Productivity – processing	10,644**	10,700	~flat
Productivity - testing	36,471**	33,700	-7.6%
Productivity – hospital services	36,369**	36,000	-1.1%
Red cell waste	4.8%**	3.9%	+18.8%
Red cell expiries	0.44%**	2.0%	+400%
Platelet waste	2.77%**	3.2%	+15.5%
Platelet expiries	5.76%**	5.5%	+4.5%
% platelet issues from apheresis	49.0%**	48.0%	

**As at September 2018 (note - 66% in March 2018 and varies widely with the sample surveyed).*

***Year to date as at January 2019.*

BUDGET 2019/20

The income budget for Blood has been set according to the volumes and prices agreed with NCG in September 2018 as below.

Income	2018/19			2019/20		
	Vol '000	Price £/unit	Value £m	Vol '000	Price £/unit	Value £m
Red Cells	1,386	128.99	182.4	1,371	133.44	185.0
CD Platelets	79	231.50	18.7	67.6	240.14	15.7
Pooled Platelets	180	185.86	33.4	185.3	193.40	35.8
FFP / Other			25.6			28.0
TOTAL			258.7			264.5

The direct cost budget for 2019/20 results in significant increases, more than those that were agreed in the 2018 NCG pricing round for (2019/20 prices). The budget for blood donation includes an £8m increase in budget to budget costs driven by:

- An increase in headcount of around 150 WTEs. Recruitment to this level commenced in November 2018, and is expected to complete by March 2019, although 66 of the increase derives from the cancellation of the reductions that were budgeted for the CCM project.
- Maintaining the additional marketing and call centre resource that was also put in place during the year (paid for via transformation in 2018/9 but included in recurring baseline costs for 2019/20).

The cost increases reflect the response to the collection and stock challenges seen during 2018 but results in blood donation productivity falling below that recorded in 2014/15 (and around 25% lower than EBA top quartile) and lower overall capacity utilisation. It is acknowledged that in response to falling demand, headcount should be reduced later in the year, and only once the roll out of capillary HemoCue, the introduction of nurse breaks and the implementation of Session Solution has been completed. There are no plans for this at present.

Costs are also increasing in manufacturing and logistics (with a budget to budget increase in processing, testing and issue of £3.2m). This also reflects the challenges seen during 2018 crystallising in the new budget, but also:

- Increased headcount in Manchester to reflect new shift patterns required post the consolidation of processing from Newcastle and Sheffield.
- An increase in headcount to process waste plasma in Manchester and Colindale for non-component income (and hence is offset by increased income).
- A contingency in overtime and transport cost of ca £0.5m in case that collections in the first quarter are less than planned and action is needed to manage WIP and move stock between SHUs.

Although this has an adverse effect on productivity, this happens against a backdrop where NHSBT is at or above EBA top quartile productivity in these areas and remains one of the best performers globally. The plan assumes a reduction in WTEs in logistics, as a result of the LRP project, although this occurs towards the end of 2019/20 and has a limited impact on in-year costs. Note that the timing of LRP benefits are currently at risk pending a decision on when the project will commence.

Blood – Direct Costs	WTEs			Cost (£m)		
	2018/19 Budget	2018/19 Fcast	2019/20 Budget	2018/19 Budget	2018/19 Fcast	2019/20 Budget
Blood Donation	1,340	1,489	1,489	69.7	73.6	78.4
Process, Test, Issue	711	745	751	65.3	66.9	68.4
Logistics	336	333	298	19.9	20.6	20.4
Cost of Sales Mvmt	-	-	-	-	-1.7	-
TOTAL	2,387	2,567	2,538	154.9	159.4	167.2
Cost / red cell (£/unit)				110.80	112.73	121.87

On a budget to budget basis (the reference point for NCG pricing discussions) total direct costs increase by £12.3m (+7.9%) with the (notional) total direct cost / red cell increasing by £11.07 (+10.0%).

The plan assumes that we aspire to zero occurrences in the:

- **Number of critical and major non-compliances from external inspection**
- **Number of days when red cell stocks are below 4.5 days for any blood group, excluding AB**
- **Number of days where opening stock of platelets (any blood group) is below average daily demand, excluding AB** i.e. in respect to stocks it implicitly assumes that we return to the stable stock position that was consistently established prior to 2018.

FIVE YEAR PROJECTION (AND PRICING IMPLICATIONS)

Reduction in demand for red cells continues to be assumed as below. The long-term demand plan will be reviewed in May 2019. It is anticipated that this may see an upward revision to red cell demand, albeit platelet demand may be revised downwards.

	2018/19 Fcast	2019/20 Budget	2020/21 Plan	2021/22 Plan	2022/23 Plan	2023/24 Plan
Red cell demand	1.414m	1.372m	1.282m	1.230m	1.230m	1.230m
Change (cum.)	-3.6%	-3.0%	-12.3%	-15.8%	-15.8%	-15.8%
Platelet demand	259k	260k	260k	260k	260k	260k
Change (cum.)	-0.2%	+0.3%	nil	nil	nil	nil

Assuming the demand assumptions above, flat pricing after 2019/20 (i.e. an ongoing red cell price of £133.44), and a cost model that assumes:

- Baseline costs re-set to 2019/20 budget
- Limited future productivity savings other than LRP (and Barnsley)
- Pay inflation as per AfC award plus 2% pa in 2021/22 onwards
- The existing employers pension contribution (14.3%)
- Non-pay costs as per the NHS inflator (+1.7%)

Blood / Group would fall into an ongoing operational deficit in 2020/21 with cash running out in 2021/22.

Theoretically NHSBT has the cash reserves that would allow it to navigate through 2019/20 without a price increase (for 2020/21). However, a 6% price increase would then need to be imposed in 2020/21 (for 2021/22), plus price increases of around 3% pa in the following years.

	2019/20	2020/21	2021/22	2022/23	2023/24
Operating surplus / deficit	£8m	£5m	£6m	£6m	£11m
Transformation Spend	-£19m	-£11m	-£7m	-£3m	-£2m
Surplus / deficit	-£11m	-£6m	-£1m	£3m	£9m
Closing cash position	£25m	£20m	£19m	£22m	£31m

% price increase (RC)	+3.5%	+8.3%	+6.0%	+5.0%	+5.0%
Red Cell price	£133/unit	£144/unit	£152/unit	£160/unit	£168/unit

To smooth the 6% impact in 2021/22, and to avoid an operating deficit in 2020/21, Blood should plan for annual price increases of around 3% pa from 2020/21 onwards. Given demand decline of ca 3.5% pa this would result in broadly flat costs to the NHS. It would also result in an ongoing cash balance of around £20m.

In addition to this, however, the employers pension contribution will increase from 14.3% to 20.6% from 1 April 2020 (the increase in 2019/20 was funded by NHS England). This cost increase will, however, roll into prices from 2020/21 onwards. This would require overall prices to increase by 5% (with red cell prices increasing by 8%) in 2020/21 and increases of ca 5% pa thereafter. The table above summarises the financial projections based on these pricing assumptions.

To mitigate against this level of price increases it is anticipated that, assuming collection is demonstrably robust through April to June 2019, NHSBT will be seeking opportunities to improve productivity later in the year, with a focus on the operating model in blood donation and opportunities to recover performance.

None of the above considers the impact of any changing decisions regarding the safety of plasma.

KEY SHORT TERM MILETONES

These reflect the need to plan for a new Blood strategy and to allow time for appropriate Board engagement with the key issues and challenges. The potential for SaBTO to revise its advice regarding the safety of plasma in the UK is a new and highly significant issue and will generate both massive opportunity and risk for the Blood supply chain. Further background to this will be provided to the Board in the May 2019 meeting.

New Blood strategy	Outline plan - March 2019
Plasma sub strategy (as part of the above and driven by the pending SaBTO decision)	Data pack / issue definition - May 2019 Board discussion / outline plans – July 2019
Logistics Rationalisation Project	Start date to be confirmed – delay due to Brexit. A revised approach with a reduced scope may be adopted in response (decision – May 2019)
Session Solution	Business case – May 2019 (plus outline plan for subsequent phases)
2 nd London Donor Centre	Outline Business Case – May 2019 Implementation – start June 2020

Blood donation – future operating model and productivity plans	September 2019
Future of BOLT / Blood management structure	September 2019
Sustainable donor base / collection footprint	September 2019
Hospital service offer	November 2019
Blood donation – operating model	November 2019
Blood – key IT applications strategy / Pulse risk mitigation	November 2019
SHU strategy	January 2020
New Blood strategy	March 2020

Section Four: Organ Donation and Transplantation

Strategic Objectives, Themes and Action Plans

Strategic Objective – Organ Donation and Transplantation

“Taking Organ Transplantation to 2020” seeks to build on the excellent progress of the last five years and aims to match world class performance in organ donation and transplantation.

Following the publication of the Organ Donation Task Force (ODTF) report in 2008 significant progress was made in increasing the level of organ donation and transplantation in the UK. In March 2013 the ODTF target to deliver a 50% increase in deceased organ donation (versus a 2007/8 baseline) was achieved. Following completion of the ODTF plan the four UK Governments, supported and facilitated by NHSBT, published a new strategy aiming to match world class performance in donation and transplantation by 2020. The strategy was published in June 2013 and aims to achieve the following outcomes for organ donation and transplantation in 2020:

Outcome 1

Action by society and individuals will mean that the UK’s organ donation record is amongst the best in the world and people can donate when and if they can.

To deliver this outcome, the UK should:

- Develop national strategies to promote a shift in behaviour and increase consent.
- Ensure that it is easy to pledge support for organ donation and once a pledge has been given, to honour the individual’s decision
- Increase Black, Asian and Minority Community awareness of the need for donation, to benefit their own communities and provide better support for people in these communities to donate
- Learn from the experience of legislative change in Wales

Outcome 2

Action by NHS hospitals and staff will mean that the NHS routinely provides excellent care in support of organ donation and every effort is made to ensure that each donor can give as many organs as possible.

To deliver this outcome, the UK should:

- Increase adherence to national standards and guidance
- Increase the number of people who can donate following circulatory death and learn from the Scottish pilot on donation after failed resuscitation
- Provide hospital staff with the support, training, resources and information they need to provide an excellent organ donation service
- Ensure every donor’s care, prior to retrieval, optimises organ quality

Outcome 3

Action by hospitals and staff means that more organs are usable, and surgeons are better supported to transplant organs safely into the most appropriate recipient.

To deliver this outcome, the UK should:

- Increase the number of organs that are retrieved from both DBD and DCD donors.
- Increase the number of organs that can be transplanted safely, providing surgeons with the information and guidance to make decisions about organ suitability
- Improve transplant recipient survival by improving understanding of the donor organ/ recipient compatibility

Outcome 4

Action by NHSBT and Commissioners means that better support systems and processes will be in place to enable more donations and transplant operations to happen.

To deliver this outcome, the UK should:

- Support Regional Collaboratives to lead local improvement in organ donation, retrieval and transplant practice and promote organ donation
- Review and improve the workforce, IT, systems and processes which operate throughout the donation and transplant pathway
- Build a sustainable training and development programme which can be tailored to meet local needs, to support organ donation and retrieval

In support of these four strategic targets were established:

- A consent / authorisation rate more than 80% (currently at 67%).
- 26 deceased donors per million population (currently 24.6 pmp).
- An aim to transplant 5% more of the organs offered from consented, actual donors.
- A deceased donor transplant rate of 74 per million population (currently 61.8 pmp).

In addition to the above (and monitored alongside the other actions in the TOT2020 plan):

- A supplementary action plan was established by the 2020 Oversight Group and publicised under the strapline '**no missed opportunities**'. The Oversight Group reaffirmed that the aim to match world class performance remained a reasonable ambition but there were concerns that this might take longer than expected without additional actions. It was agreed that the key measurement was the number of **transplants** but that all elements of the system needed to be optimised to increase transplant numbers.
- In addition, although there has been significant progress in increasing the number of transplants from deceased donors, more needs to be done to maximise the numbers of organs accepted for transplantation. A new strategy for improving organ utilisation was therefore also developed in November 2016.

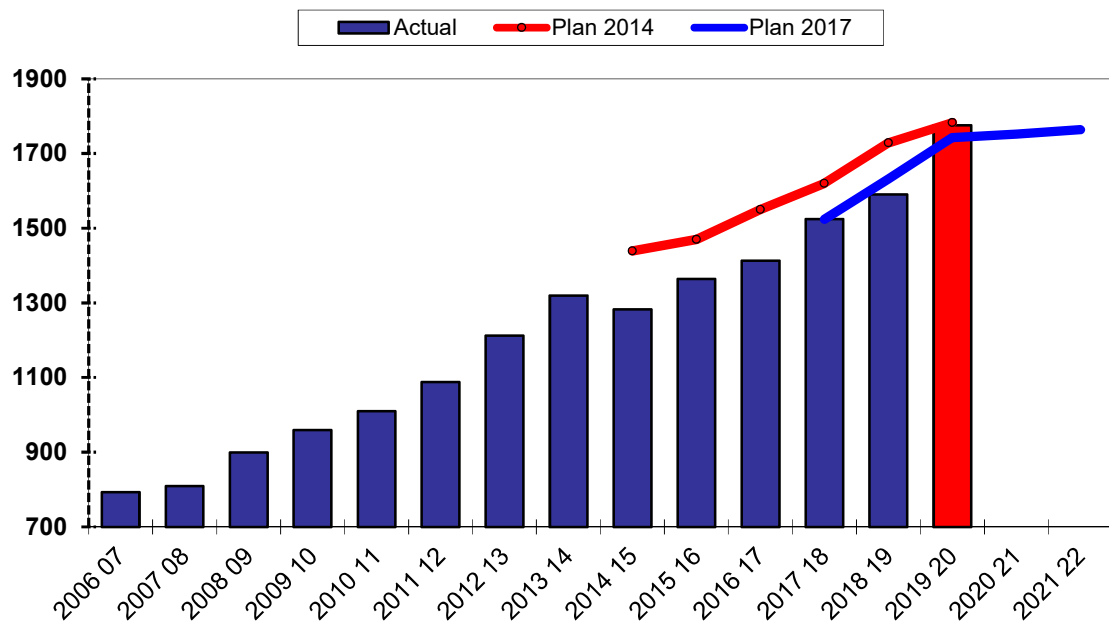
Status in 2018/19

Growth in deceased donors has flattened during 2018/19 with the trend in deceased transplants declining. In 2018/19 another new record for deceased donation in the UK has been delivered with growth of 1.7% over 2017/18. A target of 1,628 deceased donors has been set for 2019/20 (further growth of ca 2.5%) but that will be around 150 donors (-8.3%) below the original TOT2020 target (1,776).

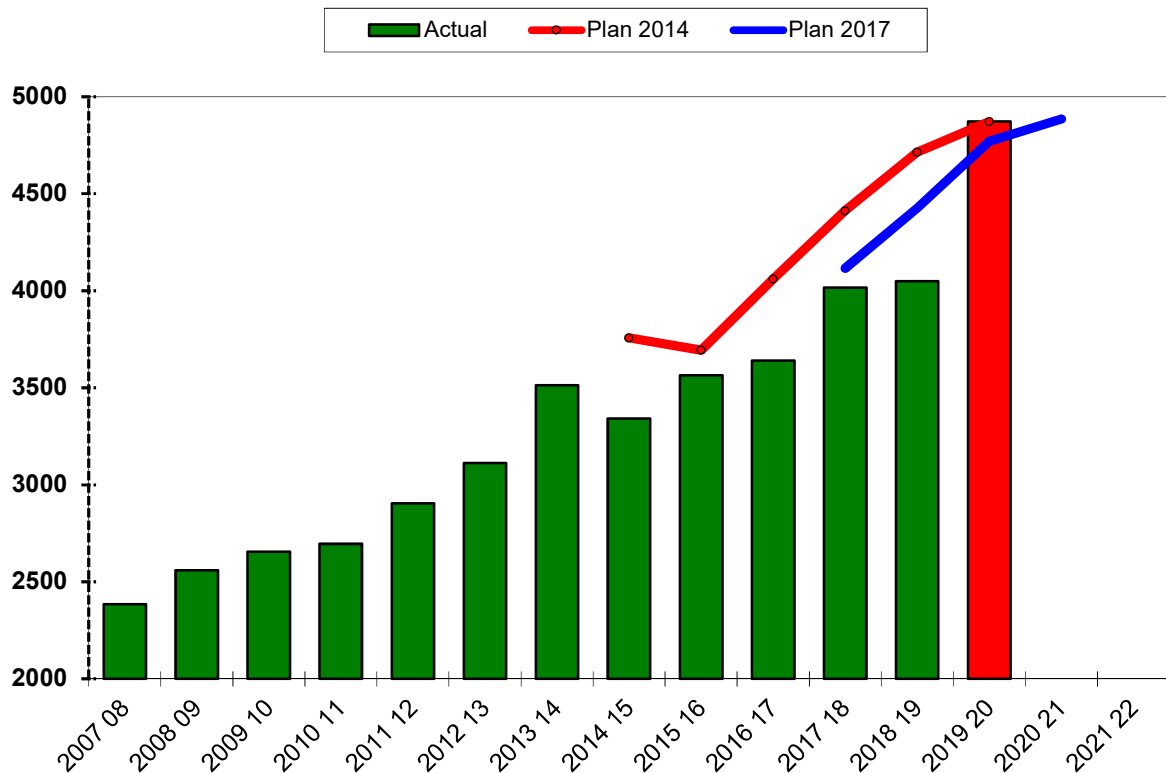
The number of deceased transplants in 2018/9 was, however, 2.2% below 2017/18. Given there has been an increase in donors it suggests that that we are seeing more marginal donors with both fewer transplantable and fewer transplanted organs per donor. The adverse trend in transplanted organs per donor will hence be a key theme in the new strategy. A target of 4,214 deceased transplants has been set for 2019/20 (+4%) although this will be 659 less than the TOT2020 target (-13.5%).

The living donor target for 2018/19 was set at 1,524 donors. Progress continues to be difficult with a current moving annual total of around 1,037 donors, marginally lower than last year and 32% lower than plan. It is not unusual to see living donor numbers increase in the latter part of the financial year, but it is anticipated that the outturn for 2018/19 will again be well below expectations.

Number of deceased donors



Number of deceased donors



2019/20 Budget

Excluding funding for Opt-Out in England, income for ODT continues to assume broadly flat funding from all four UK Health Services. Increased funding of £1m in 2019/20 is assumed from DHSC for the cumulative (2nd year) impact of the 2018 NHS pay settlement (although £0.6m of this is at risk)

Income – ODT (£m)	2018/19 Budget	2018/19 Forecast	2019/20 Budget
DHSC	61.9	62.3	63.0
Scotland	6.1	6.1	6.1
Wales	3.8	3.5	3.5
Northern Ireland	2.1	2.1	2.5
Other	0.1	0.1	0.1
TOTAL	73.9	74.1	74.8

Although ODT has operated with flat funding over recent years, certain expenditure during this time has been re-directed to fund increases in the operating costs (both inflation and activity) and to provide financial headroom for investment in the ODT Hub and other non-recurring investments. This included diverting support for living donation (which went into the NHS tariff) of £3.0m and reducing the level of donor recognition payments by ca £2.2m (so re-directing total funding of £5.2m to baseline costs and transformation). That financial head room has now come to an end, especially due to sharp increases in operating costs in 2019/20 as per the budget summary below.

Budget costs for 2019/20 are summarised below (excluding Opt-Out in England):

Expenditure – ODT (£m)	2018/19 Budget	2018/19 Forecast	2019/20 Budget
Director / Medical	1.4	1.3	1.5
Education & Governance	2.0	1.9	2.1
Commissioning	27.5	27.1	28.6
Organ Donation and Nursing	25.6	24.8	26.6
Transplant Support Services	3.8	3.9	4.2
Direct group services	7.9	7.9	7.9
TOTAL Operational Costs	68.2	66.8	70.9
Costs funded from cash	-	0.8	-
Transformation Spend	5.7	5.9	3.9
TOTAL EXPENDITURE	73.9	73.5	74.8
SURPLUS / (DEFICIT)	-	0.6	-
WTEs	423.5	446.2	457.7

**non-recurring spend funded from brought forward 2017/18 surplus (cash reserve) in respect of ODT Hub timing, Wales and BAME initiative.*

The primary drivers for the increased costs are:

- 26 WTES (additional requestors) to support 24 hour working (£0.8m - part year effect)
- Increased NORS team capacity, following the review in 2018 (£0.9m - part year effect)
- 6 WTEs to support Hub operations and the ocular business case

In 2019/20 ODT is therefore at break even. As such there is no capacity for any other initiatives, such as NRP without additional funding from the four UK Health Services.

Regarding transformation activity, 2019/20 is due to be the final year of the ODT Hub business case. The successes to date have been based on delivery through the BPMS platform. In 2019/20 the programme

becomes more complex through dependency on the CRM platform and the need for integration with it and other systems. Progress is now being hindered due to a lack of supporting IT capacity and capability and the programme is now reporting at red status. The business case for 2019/20 is therefore being reviewed and a smaller proposal may now be brought pending a review of alternative approaches for delivering the Hub vision. A smaller proposal will reduce the financial pressures in 2019/20 but the next steps would need to form part of "Hub 2" type programme, including integration with other applications and replacement of NTxD (as intended by the original Hub business case). The scope of such a transformation programme has not been developed yet, however, the cost has not yet been profiled and there would be no funding for it unless provided by the four UK Health Services.

Transformation – ODT (£m)	2018/19 Budget	2018/19 Forecast	2019/20 Budget
ODT Hub	2.3	2.3	1.7
ODT Hub – recurring costs	0.5	0.5	0.3
Release Train	0.6	0.5	0.2
Behaviour Change	1.2	1.2	-
Donorpath	0.6	0.6	0.6
Ipad replacement	0.3	0.3	0.2
NHS App	-	0.4	-
Other	0.2	0.1	0.9
TOTAL	5.7	5.9	3.9

The above analysis also excludes two new initiatives that have now been agreed with NHS England and which will be funded by them ie:

- Donor characterisation – it is intended that NHSBT will in future commission this service (microbiology and HLA typing of donor organs) which has been estimated as costing the NHS £2.5m pa. NHS England is therefore providing funding of £2.5m pa, with 2019/20 considered to be a transitional year for establishing the process and procedures for commissioning the service in 2020/21. The budget therefore includes £2.5m of income, offset by matching costs of £2.5m.
- DCD Hearts – a joint fund of £5m has been established to support DCD heart retrieval in the UK, over the next 3 years from 2019/20, with NHS England providing £2.5m matched by £2.5m provided from NHSBT cash reserves. The budget for 2019/20 assumes that costs for the first year will be met from NHSBT cash reserves with any income received from NHS England during 2019/20 carried forward against the costs of year 2 and 3.

Opt-Out

The Government is supporting a change in the law on organ and tissue donation to move to an opt-out system in England. The Government's ambition is that the change in the law will lead to 700 additional transplants per year. The Organ Donation (Deemed Consent) legislation, known as Max and Keira's Law, received Royal Assent on March 15th 2019 and is anticipated to come into effect in Spring 2020. The Department of Health and Social Care (DHSC), NHSBT, NHS England and the Human Tissue Authority (HTA) are leading a set of workstreams that will implement the legislation.

Detailed implementation planning is in progress and funding arrangements have been confirmed by DHSC for the operational implementation and communications campaign. However, it falls short of NHSBT funding requirements and the programme is therefore assessing options to undertake the implementation activity within the allocated funding envelope.

The funding confirmed includes £11.5m over 2 years for the communications campaign plus £4.7m in 2019/20 for operational implementation. The budget in 2019/20 therefore includes income of £5.8m re the first year of the communications exercise, plus £4.7m for the operations funding, and an additional £0.5m that was provided by DHSC in March 2019 to support programme management in 2019/20. The budget assumes matching costs of £10.5m with a net zero impact on the income and expenditure position. The

income and costs will be separately identified within NHSBT's accounting systems and the overall position will be closely monitored and reported as we go through the year.

Opt-Out legislation in Scotland has also progressed. Our planning in support of implementing the legislation in Scottish therefore anticipates that the Bill will be enacted later this year and that we will be working with the Scottish Government's implementation team from May 2019 onwards.

Jersey has already introduced legislation and we are working with them to agree an implementation date which could potentially be summer 2019. The Isle of Man is progressing legislation and may also wish to implement in 2019. We are assuming that Guernsey is unlikely to introduce legislation before 2020.

FIVE YEAR PROJECTION (AND FUNDING IMPLICATIONS)

A five- year milestone plan will need to be developed early in 2019/20, considering:

- The need for a new post TOT2020 strategy, and especially the need to improve the numbers of transplants
- The requirement to revisit the options for delivering the final stage of the ODT Hub vision
- Delivery of opt out legislation, especially in England, and its various work streams
- A renewed funding commitment to support all of the above given that funding is now fully committed and ODT will otherwise fall into persistent deficit through activity and inflation alone (ie excluding any new transformational initiatives) as demonstrated below.

ODT	2019/20 Budget	2020/21 Plan	2021/22 Plan	2022/23 Plan	2023/24 Plan
Deceased Donors	1,628	1,668	1,710	1,753	1,797
	£m	£m	£m	£m	
Total Income	74.8	75.2	75.2	75.2	75.2
Baseline operating costs	70.9	74.2	75.6	76.9	78.4
Available for transformation	3.9	1.0	(0.4)	(1.7)	(3.2)

The above excludes income and costs for Opt-Out in England, assuming that these will offset and have a net zero impact overall (in total and within any one year).

However, it does not take account of

- DHSC **not** funding the NHS pay award in 2019/20 and beyond.
- Increased pension contribution costs with a further £1m risk in 2019/20 if the four UK Health Services do not provide funding to cover it.
- A review of the NHSBT direct group services contribution to ODT.
- The transformation programme (including "ODT Hub 2") that will be required post 2019/20.
- Any other initiatives, especially regarding new perfusion technologies, that are not within the scope of the Opt-Out programme.

ODT can offset this in the short term by reducing the donor recognition payments to Trusts to zero (£2m opportunity) and could generate some limited efficiency saving through a review of costs throughout the Division (and supporting services). In broad terms, it suggests that the four UK Health Services will need to increase their funding to ODT on a recurrent and increasing basis from 2020/21 onwards.

In the interim, and pending a new strategy, plan and associated funding settlement, the following targets apply for 2019/20.

Organ Donation and Transplantation – Strategic Targets	2018/19 Budget	2018/19 Actual		2019/20 Budget
Overall consent/authorisation rate (%)	69%	67.0% ¹	Red	72%
DBD consent/authorisation rate (%)	80%	72.7% ¹	Yellow	85%
DCD consent/authorisation rate (%)	60%	61.9% ¹	Red	62%
Number of Deceased Organ Donors	1,632	1,606 ²	Red	1,626
Deceased Organ Donors per million population	24.3	24.6 ³	Green	25.5
Number of Living Organ Donors (for info)	1,524	1,037 ²	Red	1,740
Living organ donors per million population (for info)	23.0	15.7 ³	Red	26.0
% of the population who have had a conversation about their donation decision	49%	49%	Green	51%
Deceased donor organ transplants	4,423	4,026 ²	Red	4,770
Deceased donor transplants per million population	66.5	61.8 ³	Red	71.3
NHSBT cost per transplant (£k)	16.4	16.3k ⁴	Green	16.3

¹ Year to date at January 2019

² MAT at January 2019

³ As at Q3 2018/19 (green versus in year targets, red versus TOT2020 targets)

⁴ As at mid-year 2018/9

NB. The living donor targets are the targets that the signatories of the Living Donor Kidney Transplantation 2020 Strategy signed up to and that the four commissioners are therefore committing to deliver. Transplant commissioners are now accountable for the target while NHSBT supports innovation and best practice through our professional lead.

Section Five: Diagnostic and Therapeutic Services (DTS)

Strategic Objectives, Themes and Action Plans

The DTS Division comprises the following strategic business units (SBUs):

- **Tissue and Eye Services (TES)**
- **Stem Cell Donation and Transplant (SCDT)**
- **Cellular and Molecular Therapies (CMT)**
- **Red Cell Immunohaematology (RCI) - including Reagents & IBGRL**
- **Histocompatibility & Immunogenetics (H&I)**
- **Therapeutic Apheresis Services (TAS)**

The products and services provided by DTS are mostly supplied to NHS hospital, and are sold at prices to recover costs via prices agreed with the National Commissioning Group for Blood. Any sales to the private sector include a margin that is appropriate to the external market. SCDT also receives £4.1m of programme funding in support of our operation of the NHS Cord Blood Bank.

Strategic plans have been developed for each SBU including individual objectives, themes, plans and targets for each. A common theme across of all the plans within DTS is the opportunity for NHSBT to leverage its unique national footprint and capabilities to consolidate services across the NHS. The primary objective is to leverage scale across low volume specialist products and services in support of higher safety, consistent quality, lower costs and better availability of specialist therapies for NHS patients.

In this regard, the strategic objectives of TES, TES and CMT are well established with little need to review other than focus on the plans for execution. This also applies to RCI and H&I, although there is a developing overarching “diagnostics” strategy that will be brought for consideration to the NHBST Board during 2019/20. At present, however, there are few materially new plans, that would otherwise appear in the individual RCI and H&I strategies. Given the trends in cord blood and bone marrow transplant, there is, however, a need to fundamentally review the SCDT strategy. To this end the stakeholders in UK stem cell transplantation will be brought together during 2019/20 to commence this review. The individual SBU strategies and plans are summarised on the following pages.

The table below summarises the income targets by SBU and overall DTS contribution. This excludes non-component income (sales driven by the DTS team but reported under Blood).

Income by SBU (£m)	2018/19 Budget	2018/19 Fcast	2019/20 Plan	2019/20 Growth
TES	13.8	14.7	15.1	+2.7%
RCI / Reagents / IBGRL	17.5	18.7	19.0	+1.6%
H&I	13.6	13.8	13.6	-1.4%
SCDT – income	5.0	5.1	5.2	+2.0%
SCDT – funding	4.7	4.7	4.2	-10.6%
CMT	12.3	12.2	13.3	+9.0%
TAS	10.0	11.4	11.7	+2.6%
Other	0.2	0.2	0.1	
Total Income	77.2	80.8	82.2	+1.8%
Direct Costs	64.7	66.9	68.1	+1.8%
Gross Margin	12.5	13.5	14.1	+4.4%

STRATEGIC OBJECTIVE – Tissue and Eye Services

To be recognised by the NHS as the preferred provider of high quality, ethically sourced and cost-effective tissue allografts in England, Wales and Northern Ireland.

NHSBT is the sole supplier of certain critical tissues (particularly skin) to the NHS. The strategy therefore builds on NHSBT's unique capabilities to provide bespoke services, especially in support of unmet clinical needs and which can be provided both ethically and cost effectively. NHSBT is ideally positioned to work with surgeons due to our access to deceased donor tissue and the dedicated donation facility in Speke under a “**for the NHS, by the NHS**” theme. This provides an opportunity to consolidate supply across the NHS and hence generate efficiencies of scale that can be re-invested in new and improved tissue allografts and/or lower prices for the NHS. The strategy was refreshed to incorporate “eye services” following acquisition of the Bristol and Manchester eye banks and approved by the Board in May 2016. It identifies the following five strategic goals:

To provide high quality care for donors, their families and patients

Across both organ donation and tissue donation there should be a consistent and ethically led approach to consent from donor families so that NHSBT Tissues is a credible and, trusted “brand” built on compassion for donor families and ethical supply from within the NHS.

To reinforce NHSBT Tissue Services as the preferred provider for tissue allografts in England, Wales and Northern Ireland (and including corneas in Scotland)

We aim to consolidate supply of tissue allografts across the NHS and hence leverage the capacity and capability of the Speke tissue bank, deliver cost benefits through scale and support delivery of cost-effective solutions for unmet clinical needs where appropriate.

To implement new systems in support of the core business processes

Core business processes will be implemented to support the implementation of greater sales and marketing capability and move NHSBT from being a passive to a proactive supplier to the NHS. This will be supported by improvements to customer and product coding processes and the provision of real time management information.

To pursue a focused, high potential and strategically relevant product development strategy

NHSBT will collaborate with innovative SMEs in the UK that are developing new products and therapies. In return for the providing access to their R&D and innovation capability we will provide them with supporting infrastructure and a route to the clinic for novel products.

And ultimately to:

To deliver financial surpluses that can be reinvested into further product development and / or lower prices for customers

Milestone plans are described below followed by the strategic targets. All activities are funded within the income envelope established by the plan. A price increase of 1.1% was agreed with the NCG for all products in 2019/20.

The plan assumes that we continue to aspire to zero occurrences in the number of critical and major non-compliances from external inspection (**zero in 2018/19**).

TES - Milestone plans

Goals / Theme - Tissue & Eye Services	Key Action Plans	2019/20	2020/21	2021/22	2022/23	2023/24
Modernisation of the Ocular Supply Chain	Introduce the DMEK pre-cutting service	Q1				
	Moorfields Collaboration Project		Q1			
	Manchester Eye Bank relocation	Q3				
	Newcastle Islets	TBC				
Modernisation of the TES Supply Chain	Introduce an improved distribution service for Serum Eye drops to reduce cost	Q1				
	Donor Path	Q2				
	TES ERP		Q1			
Increase Direct Sales	Research Tissue Bank	Q2				
Optimise the Donation Pathway	National Institute for Health Research grant to improve donations from hospices			Q4		
New Product Development	Complete clinical trial of dCELL dermis for diabetic foot ulcers				Q1	

TES - Strategic Targets	2018/19 Plan	2018/19 Actual		2019/20 Budget
Sales income (£m)	13.8	14.4 ¹		15.1
% of customers scoring >= 9 /10 for satisfaction	70%	85.7% ²		70%
Products issued on time (OTIF)	98%	99.5% ³		98%
Number of Corneas in stock (month end)	250	>300 ³		250

¹ Forecast 2018/19

² September 2018

³ January 2018

STRATEGIC OBJECTIVES – Stem Cells

Stem Cell Donation and Transplant (SCDT)

To maximise the number of patients offered a potentially curative stem cell transplant by providing an effective, affordable and financially sustainable supply of well-matched unrelated donor stem cells.

Cellular & Molecular Therapies (CMT)

To establish NHSBT as the preferred provider of established cell therapies to the NHS, and of innovative cellular and DNA-based therapies for academic and commercial organisations.

Hematopoietic stem cell transplantation (HSCT) or “bone marrow transplantation” is firmly established worldwide as the only curative option for many patients with inherited and malignant bone marrow disorders. SCDT’s core purpose is to provide stem cells from unrelated adult donors and cord blood. It directly supports around 50% of all stem cell transplants in the NHS through collection, processing and cryopreservation of donated stem cells.

The BBMR lists blood donors as potential stem cell donors. Because young male donors are preferentially selected for stem cell donation, the BBMR recruits donors under 40 years of age. BAME donors of either gender are recruited whilst only male Caucasian donors are recruited (referred to as “fit panel” donors). Fit panel donors are around six times more likely to be selected to donate than other donors. All newly recruited donors are HLA typed at an allelic level using NGS.

The NHS-CBB collects cord blood from six maternity units in London. Donations are triaged at Colindale, and clinical donations (those containing over 14×10^8 total nucleated cells) are transported to Filton where they are processed and stored.

Because of our support for HSCT, NHSBT has developed a unique national footprint and capability. This provides NHSBT with the opportunity to support the development of the next generation of stem cell therapies that are using stem cells and bioactive molecules to regenerate tissues (‘regenerative medicine’) and to selectively destroy cancerous cells (‘cancer vaccines’) and viruses. In support of this NHSBT can provide the donor stem cells and bring strengths in specialist manufacturing, regulatory expertise, distribution and R&D in support of this developing industry. This includes the operation of the Clinical Biotechnology Centre (CBC) in Bristol that has unique capabilities in the manufacture of plasmids / gene therapy vectors in small volumes to support early stage clinical trials.

Within Stem Cells we therefore recognise two distinct strategic objectives for

- **Stem Cell Donation and Transplant**, and
- **Cellular & Molecular Therapies**

Within [Stem Cell Donation and Transplant \(SCDT\)](#) the strategic objective described above is supported by the following three goals:

Goal 1. To improve the quality of the adult donor registry and cord blood inventory by:

- Recruiting around 10,000 young male Caucasian donors to the BBMR each year
- Banking around 2,300 high quality cord blood donations until 2019 (with BAME at 40%)

Goal 2. To improve the selection of precisely matched donors and donations by:

- Typing all new donors and cord blood donations at an allelic level using NGS

Goal 3. To improve the visibility and promote the selection of donors and donations by:

- Completing the implementation of EMDIS-cord
- Migrating adult donor data to the US stem cell registry (NMDP)

Over the last four years, activity levels have not progressed in line with the expectations of the UK stem cell strategy. The emergence of haplo transplants and increased competition from overseas registries have contributed to the shortfall. As such there is a fundamental need to review the strategy with the UK transplantation community and this will be facilitated during 2019/20. In the interim a conservative activity budget has been set (consistent with 2018/19 levels) and the CBB collection team has been restructured (-19 WTEs) to limit capacity for collection and maintaining a bank of 20,000 units. Price increases of 2.3% were proposed to, and accepted by, the NCG for 2018/19. The plan assumes that we continue to aspire to zero occurrences in the number of critical and major non-compliances from external inspection (zero in 2018/19).

SCDT – Milestone Plans

Goals / Theme - SCDT	Key Action Plans	2019/20	2020/21	2021/22	2022/23	2023/24
Cord Blood Banking	Bring forward a new cord blood bank operating model to substantially reduce operating costs	Q3				
	Implement revised operating model		Q2			
BBMR	Maximise donor collections performed at NHSBT clinics	Q2				
	Deploy machine learning approach to support donor engagement	Q4				

SCDT - Strategic Targets	2018/19 Budget	2018/19 Fcast		2019/20 Budget
Sales income (£m)	9.6	9.9 ¹		9.5
Clinical bank size of searchable units (A, B & C)	19,525	19,785		20,068
Banked donations (incremental)	1,404	847 ²		972
Number of Cords Issued	63	39 ²		79
Adult Donor Provisions	240	185 ²		277
Donors recruited to fit panel	20,000	13,063 ²		20,000

Within [Cellular & Molecular Therapies \(CMT\)](#) the strategic objective above is also supported by three goals:

Goal 1. To meet customer demand for increasingly sophisticated haemopoietic stem cell therapies by:

- Providing complex processes and products to existing customers and promoting these to new customers lacking the capability for in house production
- Improving safety through continuous improvement initiatives and the electronic transfer of data from laboratory analysers to Hematos
- Reviewing processes and establishing an appropriate laboratory / clean room footprint

Goal 2. To more than double the provision of innovative cell therapies for regenerative medicine by 2020 by:

- Producing a range of advanced cell therapy products for early phase clinical trials
- Close collaboration with NIHR BTRUs and other academic and biotechnology enterprises

- Developing close and effective links with the Cell Therapy Catapult, Centres of Excellence for regenerative medicine, and UK regenerative medicine networks
- Establish the planned CBC/Filton expansion to provide additional capacity and capability for the manufacture of advanced cell therapies

Goal 3. To more than double the provision DNA-based therapies by 2020 by:

- Producing a range of advanced molecular therapy products intended for early phase clinical trials
- Close collaboration with NIHR BTRUs and other academic and biotechnology enterprises
- Utilising the planned CBC/Filton expansion to provide additional capacity and capability

£3.7m of CMT income derives from the storage of stem cells post-transplant. A price increase of 2.3% to the NHS was proposed to, and accepted by, the NCG for 2019/20 for these services.

The plan continues to aspire for zero occurrences in the number of critical and major non-compliances from external inspection - five in 2018/19 (ATU Birmingham).

CMT – Milestone Plans

Goals / Theme - CMT	Key Action Plans	2019/20	2020/21	2021/22	2022/23	2023/24
Create Additional Capacity for Cellular and Molecular Therapies	Support detailed design for new CBC facility at Filton	Q2				
	Develop project/change control plan to relocate and upscale cell therapies to consolidated site	Q2				
	Through continuous improvement, create additional capacity at CBC for production of DNA plasmids and QC	Ongoing				
	Support construction /commissioning of CBC facility at Filton		Q4			
	CBC facility operational			Q1		
	Additional clean room at Filton operational	Q1				
Business and Operating models	Develop project/change control plan to relocate services to Barnsley	Q1				
	Consolidate services to Barnsley		Q1			
Drive improved quality and safety	Remediate data integrity risks via "automated results transfer"	Q2				
Remediate Deficiencies in SCI Clean Rooms	Initiate programme to remediate regulatory and operational deficiencies	Q3				
Product Development Pipeline	Offer GMP-grade MSC for treatment of GvHD	Q2				
	Develop GMP-compliant process for viral vector production		Q4			
Secure new business opportunities	Develop a web site to promote NHSBT's offer in advanced cell and gene therapies	Q4				

CMT - Strategic Targets	2018/19 Budget	2018/19 Fcast		2019/20 Budget
Sales income (£m)	12.3	12.4 ¹		13.3
CBC income (£m)	1.74	2.28 ¹		2.32
% of hospitals scoring >= 9/10 for satisfaction	62%	62%		63%
Stem cell provision - OTIF	100%	100%		100%

¹ Forecast 2018/19, ² MAT as at January 2019, ³ January 2018

STRATEGIC OBJECTIVE – RCI

To position RCI as an innovative, integrated, technologically-enabled service saving patients' lives by ensuring they have access to precisely matched blood when needed.

Red Cell Immunohaematology (RCI) ensures the safety and clinical efficacy of red cell transfusion by providing expert diagnostic and donation selection activities which are beyond the capability of hospital transfusion laboratories. The workload in our RCI laboratories has been increasing over time driven by deskilling and downsizing in hospital laboratories. In response to this NHSBT developed a long-term blueprint for a hub and spoke "Integrated Transfusion Services" model, based on models used in other countries, but with a long-term low risk approach based on the following three discrete phases:

Optimise - Build the competencies required to meet changing customer needs and the challenges of future integration.

Extend through integrating patient care pathways - Prospectively genotype patients (e.g. multi-transfused patients) with the aim of optimising transfusion therapy.

Integrate red cell diagnostics - Work with hospitals to extend services and form transfusion networks to drive higher standards at lower cost.

In 2017 the International Blood Group Laboratory was extracted from R&D and positioned with DTS/RCI, to address its loss-making position. Establishing break-even for IBGRL via growing income opportunities and re-pricing/rationalising activities is an additional theme in the RCI strategy.

In 2019/20 prices per test for Red cell reference, and per request for Reagents, increase by 2.1%. There were zero occurrences in the number of critical and major non-compliances from external inspection in 2018/19 and we expect the same in 2019/20.

RCI - Strategic Targets	2018/19 Plan	2018/19 Actual		2019/20 Budget
Sales income (£m)	16.0	16.6 ¹		17.2
% of hospitals scoring \geq 9/10 for satisfaction	62%	73%		63%
Turnaround Time vs SLA	95%	96.3%		95%

¹ Forecast 2018/19, ² Year to date at January 2019

RCI – Milestone Plans

Goals / Theme - RCI	Key Action Plans	2019/20	2020/21	2021/22	2022/23	2023/24
Service Development	Introduce NGS-based patient typing - pre-transfusion diagnostics				Q2	
	Review benefits of antenatal screening offer		Q4			
	Market confirmatory typing offer		Q2			
Business and Operating Models	Develop project/change control plan to relocate	Q1				
	Consolidate services to Barnsley		Q1			
	Establish RCI Assist pilots at Barnsley and Newcastle	Q3				
	Complete RCI Assist pilots at Barnsley and Newcastle		Q3			
	Procure core laboratory platform		Q2			

Goals / Theme - IBGRL	Key Action Plans	2019/20	2020/21	2021/22	2022/23	2023/24
IBGRL	Develop business case for genotyping black blood donors	Q4				
	Genotype black blood donors		Q4			
	Deploy NGS in support of reference investigations			Q2		
	Reduce repeat rate of molecular diagnostics testing	Q2				
	Modernise International Rare Donor Panel	Q4				

STRATEGIC OBJECTIVE – H&I

To maintain our position as the UK's largest provider of H&I services through delivering an innovative, integrated and technologically enabled service which will save more patients' lives by ensuring they have access to precisely matched blood, stem cells and organs when needed.

Histocompatibility and Immunogenetics (H&I) provides genetic testing and matching of solid organ donors and stem cell donors and matching of HLA platelets. NHSBT is by far the single largest provider of H&I services to the NHS with a market share of approximately 40%. Continued growth is anticipated in stem cell and solid organ transplantation, with limited short-term threat from alternative providers, and with emerging opportunities in the developing field of pharmacogenetics. Rapid advances in genetic testing are likely to change the way in which H&I services are delivered with NHSBT intending to be an early adopter of 'next generation sequencing' technology for high throughput, high quality, low cost donor and patient typing.

Three strategic themes have been identified:

Grow services - by offering additional services to existing customers, improving productivity and developing new business.

Improve patient outcomes - through better matching of blood components and transplants to the needs of patients.

Increase the repertoire of testing services - by leveraging our core capabilities in HLA-related testing and diagnostics to undertake a wider range of pharmacogenetics tests

Flat prices were proposed to, and accepted by, the NCG for 2019/20. We saw zero occurrences in the number of critical and major non-compliances from external inspection and target zero in 2019/20.

H&I – Milestone Plans

Goals / Theme - H&I	Key Action Plans	2019/20	2020/21	2021/22	2022/23	2023/24
Service Development	Introduce NGS-based patient typing - stem cells	Q1				
	Introduce NGS-based patient typing - platelets	Q3				
	Introduce NGS-based patient typing - immunogenetics		Q4			
	Introduce NGS-based patient typing - organs				Q4	
Business & Operating Models	Develop project/change control plan to relocate services to Barnsley	Q1				
	Consolidate services to Barnsley		Q1			
	Review donor typing by NGS to reduce operating costs	Q3		Q1		

Strategic Targets – H&I	2018/19 Budget	2018/19 Actual		2019/20 Budget
Sales income (£m)	13.6	13.8 ¹		13.6
% of hospitals scoring \geq 9/10 for satisfaction	70%	71% ²		70%
% of patients receiving A or B1 Platelets	75%	74.8% ²		75%
Time to type deceased organ donors	80%	84% ²		80%
Turnaround time for SLA	95%	97.2% ²		95%

¹ Forecast 2018/19, ² Year to date at January 2019

STRATEGIC OBJECTIVE – TAS

To become the NHS preferred provider of high quality, cost effective therapeutic apheresis services.

NHSBT has a long history of providing therapeutic apheresis services within the NHS and has built the largest installed therapeutic apheresis equipment base in the NHS. TAS provides access to a portfolio of therapies using technology that exchanges, removes, or collects certain components within the blood. It is the only area where NHSBT provides treatment directly to NHS patients. The main therapeutic apheresis procedures offered by TAS are:

- Extracorporeal Photopheresis (ECP)
- Plasma Exchange
- Peripheral Blood Stem Cell Collection

The strategy for TAS is underpinned by the following three themes:

Become the preferred provider of therapeutic apheresis services

- Deliver 6000 patient treatments per annum (40% market share)
- Meet unmet patient demand for specialised therapies

Deliver high quality acute services from 6 NHS Trusts

- Regional service provision for adults and children integrated with Trust clinical teams
- Meet the highest standards of safety and regulatory compliance

Ensure leadership in therapeutic technology

- Largest number of machine platforms in the NHS
- Wide portfolio of therapies covering a broad range of clinical specialities
- Lead introduction of new therapies e.g. immunoadsorption

The service is delivered from eight units that are based within NHS Trusts and which operate an outpatient model for non-acute patient procedures. Delivering services from within an acute setting also enables TAS to offer a peripatetic outreach model for paediatrics and acutely unwell patients. Units are located at the following NHS Trusts Each with each unit operating as a regional service provider as part of a national infrastructure:

- The Christie NHS Foundation Trust
- Oxford University Hospitals NHS Foundation Trust
- Sheffield Teaching Hospitals NHS Foundation Trust
- Leeds Teaching Hospitals NHS Trust
- University Hospitals Bristol NHS Foundation Trust
- Royal Liverpool and Broadgreen University Hospitals NHS Trust
- Great Ormond Street Hospital for Children NHS Trust
- Birmingham City Hospital

Flat prices were proposed to, and accepted by, the NCG for 2019/20.

TAS - Strategic Targets	2018/19 Budget	2018/19 Actual		2019/20 Budget
Sales income (£m's)	10.1	11.3 ¹		11.7
Number of 'critical' and "major" regulatory non-compliances	0	0 ¹		0
Percentage of Patients rating patient experience $\geq 9/10$ with the service from TAS	90%	97% ³		90%
% of hospitals scoring $\geq 9/10$ for satisfaction	68%	74% ⁴		68%

¹ Forecast 2018/19, ² YTD January 2019

³ As at September 2018, ⁴ As at December 2017

TAS - Milestone Plans

Goals / Theme - TAS	Key Action Plans	2019/20	2020/21	2021/22	2022/23	2023/24
Review Strategic Plan	Refresh TAS strategy to define opportunities for new therapies and opportunities to further meet unmet patient demand	Q1				
Review Unit Locations	Relocate Liverpool unit into hub and spoke in new Royal Liverpool and Clatterbridge Cancer hospitals		Q4			
	Review options for relocation of Leeds Service prior to lease renewal		Q3			
Explore service expansion opportunities to increase patient access to treatments	Continue to explore options for TAS service expansion in the London region and increase activity in the region by a minimum of 30%.	Q4				
	Continue to explore options for expansion of TAS service provision in Birmingham to a) meet unmet regional demand for therapies and b) strengthen the existing TAS Birmingham infrastructure.	Q4				
	Review apheresis offering in the East of England to understand gaps in patient access and potential for NHSBT to support this.		Q1			
Use LEAN principles to optimise costs and efficiencies	Introduction of electronic referral pathway for service users	Q1				
	Introduce (following an RIE) a system for nurse led patient referrals	Q4				
	Routinely operate 6-day (Monday - Saturday) service provision TAS sites to offer more flexibility to patients and clinical teams			Q4		
NHS England Collaboration	Continue to work with NHSE to expand ECP services to patients across England e.g. East of England.	Q1				
	Continue to engage in the consolidation and review of haemoglobinopathies across England to identify gaps in patient service provision.	Q4				
	Establish links with NHSE neurology commissioners to engage NHSBT with the neurosciences review	Q4				
	Support consolidation of TTP services across England (NHSE led)	Q3				
Increase collection centre services for bone marrow registries	Anthony Nolan - establish a second collection site		Q1			
	Provide collection services for DKMS UK from Sheffield	Q1				
Support delivery of Advanced Therapies for patients	Work with Innovate as part the SAMPLE project to standardise patient cell collection		Q4			
	Establish a healthy volunteer donor panel to support pre clinical trial activity in the UK	Q4				

Section Six: NHSBT Corporate

The following objectives are managed at **corporate** level within NHSBT:

- Developing **organisational capacity** and **capability** in support of our objectives.
- Supporting our Operating Divisions with an **effective programme of research and development** and provide them with an **efficient estate** and **effective group services**.
- Modernising our **IT infrastructure and business applications**.
- Championing a culture of **sustainability** across all our activities.

NHSBT has established a highly recognised set of corporate values; **Caring, Quality** and **Expert**, supported by a behavioural framework used throughout the organisation to support staff engagement. Staff engagement is a priority for NHSBT and progress is measured through our employee surveys.

Research & Development

NHSBT conducts a world-leading research and development (R&D) programme to underpin our strategic objectives in transfusion, transplantation and regenerative medicine. The R&D programme is founded on eight goals:

Goal 1: To establish and ensure delivery of NIHR Blood and Transplant Research Unit objectives through partnership working

Goal 2: To enhance our programme of research in transfusion/transplantation microbiology and virology to maintain blood, tissue and organ safety

Goal 3: To deliver clinical trials to support patient blood management

Goal 4: To strengthen our position in the development, assessment and clinical delivery of regenerative medicine-based therapies

Goal 5: To establish a Behavioural Research programme to identify behavioural change interventions which significantly increase donation and consent rates

Goal 6: To establish a Translational Data Science programme to build and exploit big data resources that deliver improvements to our services

Goal 7: To provide facilities and resources to support an innovative research programme

Goal 8: To ensure that our workforce have the skills and expertise to deliver the R&D Programme

Total spend on R&D is budgeted at £6.4m for 2019/20 with £2.8m of this spend conducted by the four BTRUs, funded by NIHR. The NIHR provide funding of £0.26m directly to NHSBT (a sum that is decreasing over time). The balance of the funding for R&D is provided by an internal levy on blood prices (£3.1m) and from ODT funding (£0.4m). NHSBT is aiming to increase the levy on blood prices where possible to maintain R&D capacity and replace the reduced funding from NIHR.

Corporate - Strategic Targets	2018/19 Plan	2018/19 Actual		2019/20 Budget
Number of BAME employees at AfC Band 8a or above.	52	56		54
Number of Accidents (Level 1&2) MAT 1 month in arrears	18	19		18
% response rate to the Your Voice Staff Survey	85%	69%		85%
Engagement Score for NHSBT (max score is 5)	3.85	3.80		3.90
Reduce the number of servers (physical and virtual) hosted and managed directly in an NHSBT data centre	925	1,107		893
Reduce the number of obsolete or end of life software products used across NHSBT	15	16		14
Reduction of CO2 emissions (tonnes) from 2014/15 baseline (estate-based emissions as per the CRC)	15%	24.7% ¹		20%

¹ Forecast 2018/19, to be confirmed April 2019.

Corporate – Milestone Plans						
Goal / Theme - Corporate	Key Action Plans	2019/20	2020/21	2021/22	2022/23	2023/24
IT Infrastructure	Develop the business case and plan for data centre hosting	Q2				
	Implement the printer management contract	Q1				
	Develop the outline plan for Pulse risk mitigation	Q2				
Utilisation of NHSBT Estate	Newcastle Islet process supporting the University, including the building of clean room facilities	Q2-4				
	Consolidate Stoke Gifford to Filton		Q3	Q3		
	Complete Leeds/Sheffield consolidation to Barnsley and closure of the existing sites		Q2-3			
Finance	Agree with IT the road map for Oracle upgrade/replacement	Ongoing				

Section Seven: Budget Summary

NHSBT normally set its budgets (and financial projections) based on delivering a balanced income / expenditure position, with prices set accordingly, in total and for each Division.

However, to finance the CSM project and IT infrastructure renewal blood prices were recently set at levels that enabled NHSBT to accumulate cash in its balance sheet to fund the investments (in effect we retained flat, or recently increased prices, rather than lowering them further). We therefore anticipated **planned** deficits (in Blood/Group) **funded from accumulated cash reserves**. Within this ODT and DTS would normally set a balanced budget with the large deficits in Blood/Group driving NHSBT into an overall planned deficit.

Due to the halting of CSM, and other projects not commencing to plan, however, NHSBT will make a surplus of more than £11m in 2018/19 and will end the year with substantial cash reserves of ca £30m. As described in the section on Blood, this masks a significant adverse shift in the underlying operating position in Blood, because of the sharp increase in headcount/operating costs, especially in Blood Donation.

BUDGET

Income (£m)	2017/18 Actual	2018/19 Budget	2018/19 Actual	2019/20 Budget	2018/19 Actual vs 2019/20 Budget
Programme Funding - Organ Donation & Transplantation	61.9	62.1	62.3	73.0	10.6
Programme Funding - Diagnostic and Therapeutic Services	4.2	4.7	4.7	4.2	-0.5
Programme Funding - Blood & Blood Components - National	0.0	2.2	2.2	0.0	-2.2
Blood & Components Income	256.9	258.7	261.2	264.5	3.3
Diagnostic and Therapeutic Services Income	71.0	72.5	76.6	78.0	1.5
Research & Development	1.7	1.0	1.9	0.9	-1.0
Organ Donation & Transplantation Other Income	12.0	11.8	12.0	14.4	2.4
Blood Supply Other Income	4.7	3.4	3.5	3.3	-0.2
Group Services Other Income	2.5	1.8	3.0	2.6	-0.4
Total Income	414.9	418.1	427.4	440.9	13.5
Total Operating Costs	-396.1	-391.8	-404.0	-415.0	-10.9
Transformation Fund Blood / Group	-24.2	-20.3	-9.1	-19.0	-9.9
Transformation Fund ODT	-4.8	-5.7	-5.5	-17.3	-11.7
Transformation Fund DTS	0.0	-1.0	-0.3	-1.0	-0.6
Net I&E Position	-10.2	-0.6	8.4	-11.3	-19.8

This includes DHSC funding of £10.5m for Opt-Out and NHS England income of £2.5m for donor characterisation (both within "ODT Other Income").

Within the 2019/20 budget this is matched by offsetting expenditure. This is excluded from the expenditure table below to provide like for like comparability.

Expenditure (£m)	2017/18 Actual	2018/19 Budget	2018/19 Forecast	2019/20 Budget	Forecast to Budget Movement
Cost of Sales - Blood Component Stock Movement	-1.3	0.0	1.7	0.0	-1.7
Cost of Sales - Tissues Stock Movement	-0.1	0.0	-0.2	0.0	0.2
Organ Donation & Transplantation: Operational Expenditure	-60.1	-60.3	-59.7	-63.2	-3.5
Organ Donation & Transplantation: Change Programme	-4.8	-5.7	-5.9	-3.8	2.1
Blood Supply: Manufacturing, Testing & Issue	-68.1	-65.7	-66.9	-68.4	-1.5
Blood Supply: Blood Donation	-72.1	-70.5	-73.6	-78.2	-4.6
Blood Supply: Logistics	-21.0	-20.0	-20.6	-20.4	0.2
Diagnostic and Therapeutic Services: Operational Expenditure	-62.2	-64.7	-66.9	-68.1	-1.2
Diagnostic and Therapeutic Services: Change Programme	0.0	-1.0	-0.3	-1.0	-0.6
Quality	-5.0	-4.9	-4.8	-5.5	-0.7
Chief Executive and Board	-0.6	-0.6	-0.6	-0.7	-0.1
Communications	-7.4	-6.6	-6.8	-6.9	-0.0
Estates & Facilities	-39.6	-38.9	-39.7	-39.9	-0.3
Finance	-5.4	-5.0	-5.4	-5.4	-0.1
Business Transformation Services	-1.4	-1.6	-1.5	-1.7	-0.2
People	-7.4	-7.4	-7.2	-8.1	-0.9
Information Communication Technology	-23.7	-24.8	-25.3	-26.9	-1.6
Clinical Directorate	-13.8	-13.9	-14.1	-14.6	-0.6
Research & Development	-5.1	-4.2	-4.8	-4.3	0.5
Change Programme (Blood & Corporate)	-24.2	-20.3	-9.9	-19.0	-9.1
Miscellaneous and Capital Charges	-1.7	-2.5	-2.6	-3.5	-0.9
Total Expenditure	-425.1	-418.7	-415.4	-439.7	-24.3

Summarising the above into the net Divisional recurring / non-recurring position (pre-ABC allocations), excluding the net zero impact of Opt-Out and NHS England funding, and then extending this into 2020/21.

Divisional I&E position	2018/19 Budget	2018/19 Fcast	2019/20 Budget	2020/21 Indicative
	£m	£m	£m	£m
Blood / Group - Operating Position¹	8.2	7.2	(5.4)	(11)
Blood / Group - Transformation	(20.3)	(9.9)	(19.0)	(11)
Blood / Group - Total	(12.1)	(2.7)	(24.4)	(22)
DTS – Operating Gross Margin²	12.5	13.6	14.1	15
DTS - Transformation	(1.0)	(0.3)	(1.0)	(1)
DTS – Total Gross Margin	11.5	13.3	13.1	14
ODT – Operating I&E³	5.7	6.5	3.9	1
ODT - Transformation	(5.7)	(5.9)	(3.9)	(1)
ODT – Total I&E	-	0.6	-	-
NHSBT Surplus / (Deficit)	(0.6)	11.2	(11.3)	(8)

¹ All group services costs allocated into Blood / Group (except the ODT services contribution)

² Excludes any group services allocation

³ Includes the ODT services contribution only

The increased costs in Blood see the Blood/Group (pre-ABC allocation) operating position sinking to a deficit of £5.6m in 2019/20 and is projected to fall further to a ca £11m deficit in 2020/21. To drive a reasonable operating surplus blood price increases of 3-4% will be required in 2020/21 (to be agreed with NCG in September 2019) and in future years. This excludes the impact of the pension contribution increase which, when rolled into prices in 2020/21 would require a total price increase of around 5% (with red cell prices increasing by 8%).

The table above also demonstrates a deteriorating operating position in ODT. On current assumptions, without a funding increase, ODT would be in operating deficit in 2021/22.

Headcount Development

WTEs	2018/19 Budget	2018/19 Fcast	2019/20 Budget	Change vs 2018/19	% change
Blood Donation	1,340	1,496	1,487	147	+11%
M&L	1,047	1,077	1,050	3	0%
DTS	848	836	871	23	+3%
ODT	416	447	451	35	+8%
Group	855	862	888	33	+4%
Total	4,506	4,718	4,746	240	+5%

Capital Investment

During 2019/2020, we are planning to deliver a capital investment programme of £27.8m. This is significantly larger than the normal spend of £6-9m and is driven by the large projects underway (Barnsley and CBC) and an estimation for the capital cost of the data centre hosting project (as below).

Around £0.8m (to be confirmed) of this plan will be related to a carry forward of projects started in 2017/18 and projects already authorised in year.

Subject to DHSC re-approval, the full capital cost of the CBC expansion is £8.5m, phased £1.0m in 2018/19, £2.5m in 2019/20 and £5.0m to complete the build in 2020/21. The full capital cost of the Barnsley Centre is £15.8m, phased £1.5m in 2018/19, £13.5m in 2019/20 and £0.8m in early 2020/21. The Data Centre Hosting project capital cost is estimated at £4.8m. Subject to DHSC approval this is scheduled to complete in 2019/20.

Summary Capital Investment Plan 2019/2020

	2018/19 Budget	2018/19 Fcast	2019/20 Plan
	£m	£m	£m
Estates Investment Programme	2.0	2.9	2.5
IT and System Development Projects (exc. DHC)	0.5	0.5	0.8
Minor Capital Programme – asset replacement	4.5	3.1	3.7
Sub-total	7.7	6.5	7.0

CBC Filton¹	1.8	1.0	2.5
Barnsley Centre²	5.0	1.5	13.5
Data Centre Hosting³	-	-	4.8
Total	13.0	9.0	27.8

¹ CBC Filton cumulative spend to end 2019/20 £3.5m. Remaining £5m to complete in 2020/21

² Barnsley Centre cumulative spend to end 2019/20 £15m. Remaining £0.8m to complete in 2020/21

³ Data Centre Hosting cumulative spend to end 2019/20 £4.8m. Project complete 2019/20