# NHS BLOOD AND TRANSPLANT

# THURSDAY 30 JULY 2015

# The Royal College of Obstetricians and Gynaecologists 27 Sussex Place, Regent's Park, London NW1 4RG in U6/7 the Novo Nordisk Suite

09.00	Public Board Meeting
10.20	Representation from colleagues from Sheffield
10.35	Tea/Coffee Break
10.50	Meeting continues
12.30	Lunch
13.00	Private Board Meeting
14.00	Seminar: The NHS 5 Year Plan
15.00	Close

# NHS BLOOD AND TRANSPLANT

### The Sixty-eighth Meeting of NHS Blood and Transplant will be held at 09.00 on Thursday 30 July 2015 in U6/7 the Novo Nordisk Suite at the Royal College of Obstetricians and Gynaecologists 27 Sussex Place, Regent's Park, London NW1 4RG

# AGENDA

1	Apologies and Announcements	
2	Declaration of Conflict of Interest	
3	Agreed ways of Operating following the Board Development Day (attached)	
4	Minutes of the last meeting (attached)	
5	Matters Arising (15/51 attached)	
	For Decision	
6	Response to NHS Scotland's Review of the Income Generation Agreement with NHSBT (15/52 attached)	09.05
7	Infrastructure Hosting Project – Due Diligence Stagegate Review (15/53 attached)	09.30
	For Discussion	
8	Triennial Review	09.40
9	Organisational Workforce Development Functional Review (15/55 attached)	09.50
	For Decision	
10	Modernisation of Manufacturing in NHSBT (15/56 attached)	10.55
	For Discussion	
11	Chief Executive's Report (15/57 attached)	11.25
12	Board Performance Report (15/58 attached)	11.40
13	Clinical Governance Report (15/59 attached) Francis Report Action Plan Update (15/60 attached) Penrose Inquiry: Points for Reflection (15/61 attached)	11.55
14	Minutes of the GAC 24.4.15 (15/62 attached)	12.15
	Continues overleaf	

15	Minutes of the Expenditure Controls Committee 27.4.15 (15/63 attached)	
16	Minutes of the R & D Committee 14.5.15 (15/64 attached)	
17	Summary of the meeting of the Remuneration Committee 25.6.15 (15/65 attached)	
18	Reports from the UK Health Departments (15/66 attached)	12.20
19	Any Other Business	12.30
20	Date of Next Meeting	
21	Resolution on Confidential Business (15/67 attached)	
	For information	
22	Annual Reports from the Board Committees (15/68 attached)	
23	2014/15 Annual Report and Accounts (15/69 attached)	
24	Register of Sealings (15/70 attached)	
25	Forward Agenda Plan (15/71 attached)	

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## NHS BLOOD AND TRANSPLANT

### AGREED WAYS OF OPERATING FOLLOWING THE BOARD DEVELOPMENT DAY

- (i) Operating with a customer perspective.
- (ii) Operating with a donor perspective.
- (iii) Approaching all issues with a positive and dynamic mindset.
- (iv) Working at all times with colleagues in a challenging but supportive manner.
- (v) Ensuring open and transparent communication channels between all members of the executive and non-executive team.
- (vi) Proactive development of relationships between and across all members of the group.

# Minutes of the Sixty-seventh Meeting of NHS Blood and Transplant held at 9.00am on Thursday 28 May 2015 at the Royal College of Obstetricians and Gynaecologists 27 Sussex Place, Regent's Park, London NW1 4RG

Present:	Mr J Pattullo Mr A Blakeman Mr R Bradburn Dr C Costello Ms L Fullwood Mr R Griffins Ms S Johnson	Mr J Monroe Mr K Rigg Dr C Ronaldson Mr I Trenholm Dr H Williams Mr S Williams Dr L Williamson
In attendance:	Ms L Austin Mr I Bateman Mr D Evans Mr A Powell	Mr G Brown Ms P Vernon Mr E Webb Ms J Minifie

15/59	APOLOGIES AND ANNOUNCEMENTS	
	Mr Pattullo welcomed Ted Webb, Deputy Director - Health Science & Bioethics Division of the DH, who had taken over day to day sponsorship responsibility for NHSBT from Dorian Kennedy. The Board recorded their thanks to Dr Kennedy for his very helpful contribution.	
	Apologies had been received from Mr Campbell and from Dr Jones who was represented by Ms Vernon.	
	Mr Pattullo summarised the output from the Development Day on 27 May which had comprised sessions on (I) Board Effectiveness and (ii) Risk.	
	A separate summary of the Board effectiveness follow-up items will be issued.	
	The Risk session had used the emergence of IT risk as a case study and consequently there had been significant discussions on this topic. These had raised some important issues and Mr Pattullo said he had asked Mr Trenholm to provide an overview paper for the July Board to serve to provide an overall perspective on the IT situation and thereby complete the discussion.	
	The Board agreed to conduct a further formal review of effectiveness in three years' time. Of course, there will also be ongoing opportunities to improve Board process and effectiveness.	

15/60	DECLARATION OF CONFLICT OF INTEREST	
	Mr Rigg asked the Board to note that he had a potential conflict of interest under item 7, the Organ Donation Behaviour Change Strategy – Allocation of Funding, because the Nottingham University Hospitals NHS Trust will be part of the hot house pilot. There were no other conflicts of interest.	
15/61	AGREED WAYS OF OPERATING FOLLOWING THE BOARD DEVELOPMENT DAY	
	The agreed ways of operating were noted.	
15/62	MINUTES OF THE LAST MEETING	
	The minutes of the previous meeting were agreed.	
15/63	MATTERS ARISING	
	Paper 15/35 was noted. In addition (I) Dr Williamson said she would be providing the Board with a paper on the issues raised in the report of the Penrose Inquiry at the July meeting; (ii) The Board had received the initial report on the IT outages on 22 May.	
15/64	PROGRESS REPORT: IMPLEMENTATION OF NHSBT PLANNING AND CONTROL SYSTEM AND HOSPITAL STOCK MANAGEMENT	
	Teresa Allen, Assistant Director Customer Services, attended to present paper 15/36 and this was well received. The Board noted the progress made with the PCS and hospital stock replenishment projects and approved the additional funding defined in the paper. The Board received assurances that the revised funding estimate was robust.	
15/65	ORGAN DONATION BEHAVIOUR CHANGE STRATEGY – ALLOCATION OF FUNDING	
	Ms Austin and Ms Johnson presented paper 15/37. The Board supported the recommendation to allocate £1.2m from Grant in Aid funding to deliver the behaviour change interventions in England in 2015-16.	
	The Board commended the paper as an exemplary example of their requirements for length and clarity.	

15/66	ODT NATIONAL HUB & ASSOCIATED IT – OUTLINE BUSINESS CASE FOR YEAR ONE	
	Ben Hume, Assistant Director Transplantation Support Services, attended to present paper 15/38. The Board approved the year one Outline Business Case which would enable the delivery of the three Heart Pathway Prototypes in 2015/16.	
	The Board were clear that they would not normally be prepared to receive a stage one business case of this kind until after they had given approval in principle to a programme in its entirety. They agreed to the sequencing of this business case as an exception because they were assured that the heart pathway prototype would deliver significant, much needed benefits on a stand alone basis in the event that the programme as a whole was not approved.	
	Commenting on the standard of the paper the Board agreed that it was too lengthy, partly because of duplication. Also it would have been beneficial had some of the issues discussed been drawn out in the paper.	
15/67	2015-2020 R&D STRATEGY	
	Dr Nick Watkins, Assistant Director R&D, attended to present paper 15/39. This was well received and the 2015-2020 R&D Strategy was approved.	
15/68	NHSBT ICT – STRATEGY, OVERVIEW AND RISK	
	Mr Powell was supported by James Fishwick, Assistant Director Solutions Architecture; Anthony Snape, Head of Service Management; and Karen Packham, Performance & Business Manager, in presenting paper 15/40 and this was extremely well received.	
	The Board noted the progress towards the implementation of the Strategic Framework and noted the updated structure of ICT and how Service Management, benchmarking and performance monitoring will inform its future. They also considered the key risks facing ICT in NHSBT and confirmed their support for the mitigation strategies being applied.	
	Re Pulse replacement Mr Bradburn asked whether a full risk analysis has been produced on the "platform" approach versus implementing an existing blood management system such as ePROGESA.	
	Mr Monroe observed that the same level of analysis to underpin the Pulse replacement project had not been conducted to the extent	

	seen in the earlier ODT business case approval and asked what the plans were for this.	
	It was agreed that the Board would receive a paper on the approach being taken to replace the Pulse system in light of the platform approach at the September meeting. The Chairman asked that this includes answers to the questions posed by Mr Bradburn and Mr Monroe.	
	The Board was informed that standard IT performance metrics such as downtime are now being put in place. Mr Bradburn was asked to include the key measures from the IT balanced scorecard in the Board performance report.	RB
15/69	NHSBT'S ENGAGEMENT PROGRAMME - ANNUAL UPDATE	
	Ms Austin presented paper 15/41. The Board noted progress with our stakeholder engagement and public facing partnership programmes. They also confirmed their support for the future focus for senior level engagement.	
	It was agreed that future reports would incorporate a discrete section on international stakeholders.	
15/70	MANAGEMENT QUALITY REVIEW ANNUAL REPORT APRIL 2014 to MARCH 2015	
	Mr Bateman presented paper 15/42. The Board noted the current levels of regulatory performance across NHSBT and supported the actions being taken to achieve quality improvements and address the weaknesses and issues identified.	
	The Board agreed in future to receive the Management Quality Review Annual Report offline and to receive a short paper containing comment from Mr Bateman at their formal meeting.	
15/71	CHIEF EXECUTIVE'S REPORT	
	The Board received paper 15/43 and Mr Trenholm drew attention to the key issues.	
15/72	BOARD PERFORMANCE REPORT	
	Mr Bradburn presented the report 15/44 the main points from which had been highlighted by Mr Trenholm.	
	Mr Bradburn drew attention to the possibility of recording a technical deficit in 2015/16 as a result of using our cash balances to fund the transformation plan. In response to concern raised that the Government might ask for funds to be returned to them, Mr	

	Trenholm said he had emphasised the fact that our plans would deliver reduced costs to the NHS at his recent meeting with the Permanent Secretary.	
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15/73	CLINICAL GOVERNANCE REPORT	
	Dr Williamson presented paper 15/45. The Board noted that they would receive a report on the potential introduction of Hepatitis E testing at the next meeting.	
15/74	MINUTES OF THE GAC MEETING 27.02.15	
	The minutes were noted. Mr Blakeman confirmed that in future he would provide the Board with a short paper on key points.	
15/75	SUMMARY OF THE MEETING OF THE REMUNERATION COMMITTEE 25.03.15	
	The summary was noted.	
15/76	MINUTES OF THE NATIONAL ADMINISTRATIONS COMMITTEE MEETING 24.04.15	
	The minutes were noted.	
15/77	REPORTS FROM THE UK HEALTH DEPARTMENTS	
	Paper 15/49 was noted.	
15/78	ANY OTHER BUSINESS	
	Mr Pattullo reminded the Board that two new NEDs would be recruited in 2016 and he hoped that the composition of the Board could in future better reflect the BAME mix of society in general. He asked Directors to let him know of any high calibre individuals of who might be interested in applying for the vacancies.	
	There was no other business.	
15/79	DATE OF NEXT MEETING	
	The next meeting will be held on Thursday 30 July at the Royal College of Obstetricians & Gynaecologists in London.	
15/80	RESOLUTION ON CONFIDENTIAL BUSINESS	
	The resolution, 15/50 was agreed.	

15/81	FORWARD AGENDA PLAN	
	Paper 15/51 was noted.	

# Matters Arising from meeting held on Thursday 28 May 2015

Agenda item no.	Issue	Lead	Action Taken
10	NHSBT ICT – STRATEGY, OVERVIEW AND RISK		
	The Board was informed that standard IT performance metrics such as downtime are now being put in place and Mr Bradburn was asked to determine which of these metrics should be included in the Board performance report.	RB	Additional metrics are included in the July Board report for review at the July meeting.

1	Date / title of meeting	NHSBT Board July 2015	
2	Title of paper	Response to NHS Scotland's Review of the Income Generation Agreement with NHSBT	
3	Status	Official and discloseable	
4	Tweet (max 140 characters)	NHSBT rejects proposals to change commissioning for Scottish Organ Retrieval service	
5	Executive Summary		
	Generation Agreement with management of the Specialis	ation NHSBT responds to the review of the Income Scotland. Whilst supporting the recommendation that st Nursing team remains unchanged, NHSBT rejects the the commissioning arrangements for the Scottish Organ	
6	Action requested of the Boa	ard	
		change the commissioning arrangements for SORT to retain operational management of the Specialist Nurses	
7	Background and customer promise		
	The Minister for Public Health in Scotland requested a formal review of Scotland's Income Generation Agreement with NHSBT. The review, independently chaired by Prof Rudge, has recommended that consideration should be given to moving the commissioning of the SORT team from NHSBT to National Services Division (NSD), Scotland but that management of the Specialist Nursing team should remain with NHSBT. The Scottish Government has asked for comments on the scope, omissions in assumptions, methodology and recommendations. NHSBT consulted widely with representatives from the donation and transplantation community. It should be noted that was no consultation with the ODT Organ Donation team in Scotland during the Review itself; the OD team feel strongly that this was a serious omission.		
	Proposal to transfer the commissioning of SORT to NSD Scotland		
	<ul> <li>Extensive consultation with the clinical community has highlighted concerns about the proposal to change the commissioning of SORT. Concerns were raised about the about lack of clarity in the following areas: performance management; financial impact; clinical governance; training and development. Specifically:</li> <li>Lack of consideration of the financial implications of the proposed change. Within the current financial constraints the main reasons for moving the commissioning to NSD would be a higher quality service for the same cost; or an equivalent/higher quality service for lower cost. There is no evidence that this would be the case and the weighting of the option scoring does not appear</li> </ul>		

to reflect these key priorities.

•	Clinical Governance is out of scope. Accountability for clinical governance of
	the SORT team is already complex and the proposed change will does not
	address how Clinical Governance structures and support will be accessed.
	Incidents will need to continue to be reported to NHSBT as part of their assisted
	function under the EUODD so there will be duplication and greater complexity.

- No consideration is given to participation in future initiatives to support robust operational management and clinical governance, for example the National Hub, arrangements for research into novel technologies etc.
- Given the extensive organ sharing, particularly of hearts and lungs, an environment of trust and reciprocity must exist. This is underwritten by strong governance arrangements; the two cannot be separated.
- The review does not make clear that DCD lung retrieval is out of scope and that DCD lung retrieval in Scotland is undertaken by Newcastle. If this continues, additional funding will need to be identified to cover the cost of these retrievals and the governance clarified.
- There is no assurance that SORT will still work to the same clinical standards as rest of the UK; divergence in clinical standards may, over time, erode confidence in the organs retrieved by SORT.
- There is lack of clarity and transparency around how the option assessment criteria weighting was agreed; this makes it difficult to fully understand the process and therefore support the recommendations.
- There does not appear to be any consideration given to the impact these changes may have on other UK countries, for example, how can we be assured that reciprocal retreival will continue.
- The NORS Review did not highlight a need to change the commissioning pathway between retrieval and transplantation and this further fragmentation of the pathway would be detrimental to a high quality service across the UK.

Moving the commissioning of the SORT team to NSD Scotland, has the potential to dilute recommendation 10 of the Organ Donation Taskforce Report which stated, 'A UK-wide network of dedicated organ retrieval teams should be established to ensure timely, high-quality organ removal from all heartbeating and non-heartbeating donors. The Organ Donation Organisation (NHSBT) should be responsible for commissioning the retrieval teams and for audit and performance management.'

The NORS Review also considered the option of a single commissioner across the UK for retrieval and transplantation, but concluded ' in a system, where the NHS is organised differently in the four countries of the UK, it was difficult to see benefit in a change here'. More important was the need to work together to implement TOT 2020, which is a four nation strategy.

Questions were raised about some of the statements in the report:

	<ul> <li>the report states "cardiothoracic retrievals led by NHS National Waiting Times Centre Board". This centre currently retrieves hearts and DBD lungs. Any DCD lungs are retrieved by the next available CT centre (usually Newcastle). As such it is not strictly true that "SORT provides continuous coverage for organ retrieval throughout Scotland"</li> <li>it also states that organ retrieval rates have undergone greater changes in Scotland: this statement does not reflect that this is due to the fact they were starting from a lower baseline.</li> <li>NHSBT fund a 24/7 service: there is no limitation on increased retrieval activity as there is currently significant excess capacity, particularly within the SORT team which currently has the lowest number of retrievals per annum.</li> <li>The benefits described in the report suggest there may be some financial efficiencies but these are not quantified and may not be realised.</li> <li>On the basis of advice received from the clinical community, NHSBT strongly rejects the recommendation for NSD to commission SORT.Operational management and professional development of SN-ODs</li> </ul>							
	The clinical community supported the proposal for NHSBT to retain the operational management and professional development of the Specialist Nursing team in Scotland, particularly as the workforce strategy for role redesign is implemented. The benefits have already been clearly articulated in the report and arguably some, such as the provision of 24/7/365 expert organ donation, retrieval and transplantation clinical expertise, can only be provided by NHSBT. The report did not consider the employment of the CL-ODs which is a significant oversight: the powerful combination of the SN-OD and CL-OD collaborative working has been one of the keys to success in increasing donation rates across the UK. Maintaining these links is vital to achieving the Taking Organ Transplantation to 2020 strategy.							
	arrangements for the Specialist Nursing Team.							
8	Why is this important?							
	The proposed change would alter the arrangements for commissioning retrieval services established following by the Organ Donor Task Force and may have implications for the NORS review implementation.							
9	Who else has been involved so far?							
	The Review report has been discussed by: the National Retrieval Group, the National Organ Donation Committee, Chairs of the Advisory Groups, Heads of UK Transplant Units, OD Regional Team in Scotland, the ODT Commissioning Team and the ODT Senior Management Team.							
10	Costs and benefits							
	In 2014/15 Scotland provided £5.8m to cover the Scottish Government's share of ODT's activities. The funding value is based on the proportional population basis of 8.4% of the total UK budget. If commissioning responsibility for SORT transfers, then the funding expected to be returned to Scotland is £2,224,996 leaving a shortfall of £626,916 against the estimated funding requirement of £2,851,912.							

11	Significant next Actions					
	This response to the IGA review will be given to the Scottish Government and a final decision awaited. Should the decision still be to press ahead with changing the commissioning arrangements for SORT, then NHSBT will work with the National Service Division (NSD) to manage the transfer and the implementation of the NORS review as smoothly as possible.					
12	How does this impact on Equality and Diversity?No impact: only affects the commissioning arrangements for SORT					
13	What is the impact on sustainability?No impact: only affects the commissioning arrangements for SORT					
14	Employee impact?					
	-	arrangements change, NHSBT's commissioning team will NSD if an effective UK wide service is to be maintained.				
15	Donor/Patient/Customer im	pact?				
	Feedback from the transplant community has highlighted concerns that the proposed fragmentation of NORS commissioning may, over time, erode confidence in the SORT team's capability. If this should happen, it may reduce usage of organs retrieved by SORT.					
16	Taxpayer impact?					
	The cost to Scotland of commissioning the service directly is expected to be higher than commissioning via NHSBT given the 'insurance' type funding arrangement for ODT across the UK.					
17	Author         Karen Quinn, Assistant Director: UK Commissioning           GRO-C					
18	Responsible Director         Sally Johnson, Director of Organ Donation &           Transplantation         Transplantation					
19	NED input	Keith Rigg was part of the IGA Review Group together with Sally Johnson: both made it clear as part of the review that they could not support the recommendation to change the SORT commissioning arrangements.				
20	Additional Documentation Available on Request	Review of Income Generation Agreement Report by National Services Division Scotland available on request.				

IGA review response final.docx Page Page 5 of of 5

### 1 Date / title of meeting

30th July 2015 - NHSBT Board

2 Title of paper

### Infrastructure Hosting Project – Due Diligence Stagegate Review

#### 3 Status

Official

### 4 Tweet (max 140 characters)

SCC confirmed as migration and hosting partner, costs are within budget and BPL exit planned for February 2016.

### 5 Executive Summary – Output of Due diligence

In November 2014, the Board approved the award of a contract for data centre migration and hosting to SCC. The Board requested a further report following the completion of the due diligence phase of the contract to confirm the final costs, and the evaluation of alternative options.

BPL rejected any lease extension beyond 3 months thus removing the option of remaining in the current data centres.

SCC completed their migration due diligence, the resultant "data centre at a time" migration strategy is recommended as providing the best balance of risk, timescales and costs. This strategy maximises service availability but with a loss of geographic resilience for up to one month during the migration events scheduled for February 2016. The location of the SCC second data centre has been changed to minimise latency and operational risks to Pulse.

The SCC fixed price for migration is within budget, and the forecast project budget has reduced by c. £1.1m, largely due to VAT being confirmed as recoverable on SCC costs, greater use of in-house resources, and lower temporary circuit costs.

The review of a Crown Hosting (CH) solution concluded that while the hosting costs were less than the current SCC costs, the service offering was not as comprehensive and the Elstree exit timescale would be put at risk. Using Crown Hosting would necessitate procuring a new migration partner and a repeat of the migration due diligence process. In addition, CH would offer no geographic resilience as it can only meet the latency requirements for Pulse by using adjacent data halls in the same building. This would not meet our specification and introduces additional risk. The decision to proceed with SCC has been communicated to GDS.

#### 6 Action requested

- Agreement to proceed with SCC for the supply of migration and data centre co-location hosting services.
- Agreement to SCC Lyndon Place as the second data centre in order to mitigate Pulse operational risks.
- Acceptance of the recommended "data centre at a time" migration approach which maximises service availability but involves managed periods of loss of geographical resilience.

Infrastructure Hosting\_SG Final\_v1 2.docx Page 1 of 6

### 7 Background and customer promise

### Options reviewed from the November 2014 Board Paper

The November 2014 Board paper identified three options for ongoing data centre provision to be explored – proceeding with SCC after confirmation of migration costs; moving the data centres to the Crown Hosting locations if they became available; and seeking to remain in the current locations while moving applications to the new cloud-hosted platforms.

BPL rejected any lease extension beyond 3 months thus removing the option of remaining in the current data centres.

Crown Hosting was evaluated against three criteria – cost, the achievability of migration within before March 2016, and its technical compliance with our original specification. Discussions with Crown Hosting identified indicative like for like hosting costs to be 40% less than those offered by SCC. However, this represents less than 10% of the overall project budget since the bulk of the cost arises from moving the data centres. CH confirmed that they do not offer migration services and have no approved migration partner. The evaluation suggests that it is not possible to procure a new migration partner, complete due diligence, plan and safely implement the migration before the end of March 2016. In addition, CH cannot meet NHSBT latency and geographical resilience requirements other than by locating both data centres in the same building. The CH option is therefore not recommended. The SCC contract is for 2 years, with two 1 year extension options. NHSBT will review moving to CH at an appropriate point in our cloud hosting strategy.

Due diligence has been completed by SCC following their selection in the OJEU restricted tender process. The SCC due diligence entailed a series of workshops attended by a range of NHSBT teams and suppliers, together with data centre audits. SCC have confirmed that all NHSBT requirements can be met and confirmed their fixed price for this stage of the project at £586,929 which is within the project budget. This is therefore the recommended option to safely exit our existing data centres by March 2016.

#### Migration strategy options

A range of migration strategy options were considered by SCC and NHSBT teams.

- Migrating both the BPL and Colindale data centres in one movement was not recommended as it would require extended service outages and was considered too high risk.
- A complete build ahead of all IT services was not recommended. It would require high "throw-away" capital costs for hardware and licences, was not within budget, and cannot be delivered within the BPL exit timescales.
- Migrating service by service (i.e., moving Desktop services, then Pulse, then file storage etc.) from both data centres simultaneously was not recommended as it would require multiple migration events and extended service outages. The multiple migration events required would leave no contingency in the event of any unanticipated delays and could challenge the required Elstree exit date of 31 March 2016.
- "Data centre at a time" migration is recommended by SCC and represents the best balance of risks, budget and timescales. This involves switching all operational services

Infrastructure Hosting\_SG Final\_v1 2.docx Page 2 of 6

from Elstree to Colindale; moving the Elstree data centre to SCC's primary data centre in Birmingham; progressively activating the services in Birmingham until Colindale is running only as a backup location and then moving the Colindale equipment to SCC's secondary data centre. This offers the greatest continuity of service. However for a period of 3-4 weeks there will be loss of geographic resilience with Colindale running as a single point of failure. The strategy also includes a build ahead of key network components to mitigate risk. PTS Consulting has independently reviewed and endorsed the SCC recommendation on migration strategy.

#### Data centre location options

Due diligence identified an operational risk on Pulse latency i.e. the time it takes for data in one data centre to be replicated in the second data centre. Our existing data centres are 4.6 miles apart (0.2 milliseconds latency), whilst the target SCC data centres in the original proposal are 43.2 miles apart (1.8 milliseconds latency). The suppliers supporting Pulse are unable to warrant that operational performance will not be impacted by this increase in latency. Existing limitations on our ability to performance test Pulse under full operational load are such that we cannot definitively prove in advance of the migration that Pulse will not be impacted by the increase in latency.

The option of re-engineering Pulse to run asynchronously was rejected as it cannot be achieved within the required timescales. It would also be a backwards step in resilience.

A complete build ahead of Pulse was not considered viable due to high costs and the challenging timescales. Also, it would not resolve the limitations on full load testing thus there would remain an operational risk at go-live.

The option of accepting the latency risk was considered. It is not recommended as the impact on Pulse of increased latency will not be known until the final stages of migration, with no timely solutions available which will maintain current resilience if there was an issue.

The recommended option is to change the location of the SCC secondary data centre from Northampton to Lyndon Place, Birmingham (0.16 milliseconds latency). NHSBT teams have visited and reviewed Lyndon Place. It is a high resilience tier 3 data centre, using a different power sub-station to the SCC Primary DC. It complies with our tender requirements, and the costs are £55k cheaper than SCC Northampton. It is however 2.7 miles from the SCC Primary DC, and whilst this creates some geographic risk, it is more resilient than the current NHSBT DC's and the SCC DC's can be remotely operated for a period of time in the event of an incident affecting all of south Birmingham. The risk of operational loss from reduced geographic resilience is therefore recommended over a risk of performance issues with Pulse at go-live which would have no "quick fix" resolution.

In summary, the SCC "data centre at a time" migration strategy, utilising Lyndon Place as the secondary data centre, is recommended as representing the lowest operational risk to services whilst meeting the timescale constraints imposed by the March 2016 exit date.

#### Risk Rating

As advised in the DBC, the risk rating of the project remains "high", due to its complexity. A wide range of mitigations will be employed to minimise risk: engaging migration partners, SCC, who have experience of leading data centre migrations; the migration strategy is designed to minimise risk of service outages; build ahead and testing of networks in advance; introduction

Infrastructure Hosting\_SG Final\_v1 2.docx Page 3 of 6

of change freezes to establish a firm baseline configuration; engagement of specialist contractors; test failover pre-migration; enhanced supplier support planned during migration events; pilot and dry run migration events. External specialist Quality Assurance has also been engaged.

#### 8 Why is this important?

We must migrate the Elstree data centre by 31<sup>st</sup> March 2016 or risk running for an extended period with the Colindale data centre as a Single Point of Failure (SPoF). This is not recommended from a Business Continuity perspective and the risk this represents to services and patients.

### 9 Who else has been involved so far?

- NHSBT Board approved DBC in November 2014
- Department of Health approved DBC in December 2014
- Cabinet Office / GDS approved DBC in January 2015
- Savant, Xdelta, HP and NHSBT Technical and QA teams reviewed potential latency impacts on Pulse April – June 2015.
- Independent Quality Assurance review of due diligence process and recommendations by PTS Consulting Ltd April – June 2015.
- Infrastructure Hosting Steering Group approved the SCC recommended migration strategy – 26<sup>th</sup> June 2015.
- NHSBT Executive Team approved Due Diligence Stagegate Board paper on 8th July 2015.

# 10 Costs and benefits

Forecast capital funding costs have reduced by £70k and are expected to reduce further once SCC detailed migration planning and network designs are completed. The current forecast includes £492k of hardware contingency.

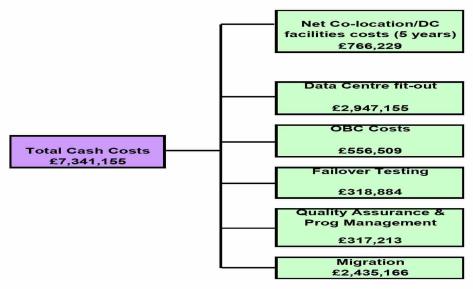
Forecast non-recurring revenue costs have reduced by £1.3m, largely as a result of SCC migration costs being confirmed as VAT recoverable, greater use of in-house resources, and lower temporary circuit costs between Colindale and CV1. The forecast includes £424k in contingency costs, which would include any business backfill required.

Forecast recurring costs are £1.299m which is an increase of £231k over the DBC. This is because the DBC only included costs for the first 2 years of hosting rather than the full five year cost should the extension options be pursued. The Finance team have advised that, for transparency, the full 5 year cost should be shown – an increase of £779k. On a like for like comparison, recurring costs have reduced by £548k from the DBC due to VAT now confirmed as recoverable on co-location costs, plus lower hardware maintenance as a result of lower forecast capital spend.

	DBC	Forecast
Capital funding	£2.005m	£1.935m
Non recurring costs	£5.421m	£4.103m
Recurring costs	£1.068m	£1.299m
Cash Costs	£8.494m	£7.341m

Infrastructure Hosting\_SG Final\_v1 2.docx Page 4 of 6

A summary breakdown of cash costs is detailed below.



# 11 Significant next Actions

- Network Build ahead in SCC data centres November 2015
- Detailed migration plan November 2015
- Migration execution planning and migration pilot completed January 2016
- o Migration to new hosted facility completed February 2016
- o Completion of failover testing between SCC data centres May 2016
- Project Closure June 2016

### 12 How does this impact on Equality and Diversity?

There is no expected impact on equality and diversity.

#### 13 What is the impact on sustainability?

Power savings will be realised from the move to more energy-efficient data centres.

#### 14 Employee impact?

Legal advice has been received that TUPE provisions will not apply to this project.

#### 15 Donor/Patient/Customer impact?

Donors will notice little direct impact. Service disruptions during transition will be scheduled to minimise impact and will be widely trailed.

#### 16 Taxpayer impact?

Costs and benefits outlined above

### 17 Author

Graeme Buchanan, Programme Manager

### 18 Responsible Director

Aaron Powell, Interim Director of ICT

#### 19 NED input

Jeremy Monroe and Shaun Williams reviewed the DBC Board paper. Jeremy Monroe and Shaun Williams reviewed the due diligence stagegate Board paper.

### 20 Additional Documentation Available on Request

- o Crown Hosting analysis and recommendation Bernie Allsopp
- o Risk analysis of migration strategies considered Graeme Buchanan
- o Risk analysis of latency options considered Graeme Buchanan
- SCC Migration strategy paper Graeme Buchanan
- o DBC approvals from NHSBT Board, DoH & Cabinet Office Graeme Buchanan
- Detailed cost breakdowns Graeme Buchanan

1	Date / title of meeting					
	30 <sup>th</sup> July 2015 NHSBT Board Meeting					
2	Title of paper					
	OWD Functional Review					
3	Status					
	Official and discloseable					
4	Tweet (max 140 characters)					
	OWD — enabling our people's potential - from engagement to succession management, facilitated through leadership, management, core & specialist development					
5	Executive Summary					
	<ul> <li>This paper and presentation provides an overview of the Organisation an Workforce Development (OWD) function which was established as a su directorate of Workforce in 2011. OWD has been evolving from a traditional trainin and development department towards a function that provides organisational development (OD) consultancy, talent and succession management together wit core and specialist training and development. Since 2011 it has reduced it headcount by a third, whilst increasing delivery and the range of intervention offered.</li> <li>Return on investment can be seen in the number of programme delegates wh have achieved a promotion or a change in role since participating in leadership programmes such as SLDP and Hubbub. Participation rates in performanc appraisals and staff surveys have increased over the last five years and th development offering through Shine has been highly valued by employees an managers (Annex A). Talent management and succession planning processe have been successfully implemented. These include leadership development programmes for people with high potential and successors identified for busines critical posts.</li> </ul>					
	The focus now is improving managerial competence and capability for operational managers, equipping them with core skills through a Managers Passport underpinned by The NHSBT Way, a leadership charter for all managers. With the launch of the Shine Academy in July employees will be able to take more direct ownership of their personal development and more responsibility for maintaining their own Mandatory Training compliance. This will support a cultural shift over the coming months and years as more people are able to realise their potential and better plan for their future career.					

6	Action requested						
0	The Board are asked to review the report and supporting presentation and to endorse the direction of travel of the OWD function.						
7	Background and customer promise						
	OWD has evolved from a traditional training team, through a learning and development department into an Organisational Development function which benchmarks well against the NHS and the wider public sector. From being a reactive, transactional function, delivering basic core personal development, the department has matured in its ability to deliver more planned and structured transformational initiatives which are linked to specific organisational objectives. In addition OWD manages the Single Equality Scheme action plan process, ensuring that NHSBT is compliant with equality and diversity legislation, and supporting its commitment to delivering fair and accessible services to donors, customers and staff.						
	OWD continues to support the organisation as it drives culture change throughout all directorates. Performance management, the routine use of the PDPR process to review performance and to establish development plans, more robust systems to ensure succession planning (eg Shine Secure and Shine Accelerate) and the management of talent across the whole of NHSBT all support the organisation in its ambition to be the best organisation of its type in the world and a great place to work.						
	The function is able to demonstrate significant return on investment through a range of financial and other measures, such as recruitment costs saved through promotion of internal candidates or income generated through delegate places on programmes sold to other organisations.						
	OWD leads the organisation in its planning for the future in terms of career development, diversity and inclusion, talent management and succession planning, thereby enabling NHSBT to be robust in the face of future recruitment needs, particularly in specialist and core areas.						
	The OWD team ensures the embedding of NHSBT's core values of Caring, Expert and Quality through PDPRs and all Shine programmes. The breadth and depth of the OD offering enables employees to better equip themselves for change, whether externally or internally driven, and supports the drive for continuous improvement.						
8	Why is this important?						
	<ul> <li>Continuous improvement of the OWD function, ensuring OD interventions are linked to and will support the achievement of organisational objectives.</li> </ul>						

	<ul> <li>Greater efficiencies across the function.</li> </ul>						
	<ul> <li>Enabling personal ownership of personal development and career</li> </ul>						
9	planning. Who else has been involved so far?						
5							
	<ul> <li>OWD team members</li> </ul>						
	<ul> <li>Leadership Team</li> <li>HR colleagues</li> </ul>						
	<ul> <li>HR colleagues</li> <li>Staff side colleagues</li> </ul>						
10	Costs and benefits						
	Staffing costs have reduced from £2,246k in 2011/12 to £1,940 in 2015/2016						
	WTE has reduced from 62.44 in 2011 to 43.05 in 2015, returning £306k.						
11	Significant next Actions						
	<ul> <li>Launch of Shine Academy</li> </ul>						
	<ul> <li>Launch of the Leadership Charter for managers – The NHSBT Way</li> </ul>						
	<ul> <li>Implementation of the Managers' Passport</li> </ul>						
	<ul> <li>Leadership Summit for Managers – 14<sup>th</sup>/15<sup>th</sup> October</li> </ul>						
	<ul> <li>Your Voice 'temperature checks'</li> </ul>						
12	How does this impact on Equality and Diversity?						
	<ul> <li>The Shine Framework is an inclusive and accessible programme of learning and development for everyone. Through the work of specific interventions, such as the formation of the BAME network, employees will have a greater voice and the workforce, particularly at the more senior level, will be more representative of the general population.</li> </ul>						
13	What is the impact on sustainability?						
	Further developments with succession planning will help NHSBT to be more future-						
	proof, particularly with workforce planning and development planning.						
14	Employee impact?						
15	<ul> <li>Employees will be able to take greater ownership of their own development.</li> <li>Improved opportunities for career planning</li> <li>Better workforce development planning across the whole organisation leading to greater efficiencies and better ROI for OD interventions</li> <li>Improved capabilities at operational manager level leading to greater motivation of staff which will impact positively on performance and productivity. This in turn will lead to improved outcomes in future Your Voice surveys.</li> <li>All of this will support NHSBT in its ambition to be a great place to work and will aid the recruitment and retention of the highest calibre staff.</li> </ul>						
10	Donor/Patient/Customer impact?						
	<ul> <li>All the points indicated in the Employee Impact section above will lead to better motivated staff who will give an improved service to donors, thereby</li> </ul>						

	<ul> <li>ensuring greater retention of donors and fewer complaints</li> <li>Better productivity means an improved service to hospitals, ensuring that patients get the right products they need at the right time.</li> </ul>
16	Taxpayer impact?
	See financial impact in Section 10.
17	Author
	Sue Hopgood – Associate Director of Workforce – Organisation & Workforce
	Development 8 3005
18	Responsible Director
	David Evans
19	NED input
	N/A
20	Additional Documentation Available on Request
	<ul> <li>Appendix A – Shine framework</li> </ul>
	<ul> <li>Appendix B – Supporting Presentation</li> </ul>

1	Date / title of meeting						
	30 July 2015 / NHSBT Board						
2	Title of paper						
	Modernisation of Manufacturing in NHSBT						
3	Status						
	Official						
4	Tweet (max 140 characters)						
	NHSBT will invest in modernising and consolidating manufacturing onto three sites in Manchester, Filton and Colindale by July 2017.						
5	Executive Summary (max 200 words)						
	The NHSBT Blood Supply 2020 Strategy commits to modernising manufacturing. Following a number of option appraisals it is recommended that manufacturing is consolidated on three sites in Colindale, Filton and Manchester. Operations at all sites will be based on the Filton model, providing a 24/7 service.						
	The proposed option will result in an overall reduction of 38 wte. There will be 94 staff (86 wte) impacted in Newcastle and Sheffield and the project will involve the recruitment of 48 wte across operations. Consultation, where required, will also take place with staff in Manchester; the aim of this will be to adopt new shift patterns and lean systems of working.						
	The non-recurring cost of the proposed option will be £6.1m with a recurring annual saving from July 2017 of £1.42m. Refurbishment costs will be £3.9m and payback will be in 4.75 years. The avoided capital costs over 10 years will be £2.8m.						
	The proposal reflects our ambition to be the best organisation of our type in the world, delivering a modern, flexible facility capable of providing future resilience for increased volumes and operational or regulatory requirements.						
	It is intended that pre-construction work will begin in Manchester as soon as possible, with construction planned to begin in January 2016 following initial consultation. Construction is planned to be completed in Q1 2017/18 and will be followed by consolidation of activity from Newcastle and Sheffield into Manchester during 2017.						
6	Action requested						
	To improve current operational performance and future proof operations, it is recommended that the Board supports work to invest in, and further consolidate, manufacturing operations including:						
	<ul> <li>closing manufacturing departments in Sheffield and Newcastle and transfer of the activity to Manchester</li> <li>investing in the modernisation of manufacturing facilities and operations in Manchester</li> <li>moving to 24/7 working in the Manchester manufacturing department</li> <li>changes within Hospital Services in Manchester, Sheffield and Newcastle to support the new operating model ensuring we continue to meet patient need.</li> </ul>						

7	Background and customer promise						
	The NHSBT Blood 2020 Strategy identified a number of challenges for the development of manufacturing. This paper proposes modernisation to improve operations and future proof the service for emerging technologies and process developments. These include pathogen inactivation, additional testing requirements and changes in the platelet supply chain. Key challenges for NHSBT's manufacturing operation include over capacity exacerbated by the fall in demand for red cells, poorly configured and inflexible estate and the need to update staffing structures and systems of work to better meet hospital needs. These structures are currently costly and do not make the best use of every donation due to current shift patterns.						
	Options analyses were conducted to determine the optimum number and location of manufacturing sites. It is proposed that these sites will be:						
	<ul> <li>Filton (because the estate and working practices are a model for other sites)</li> <li>Colindale (because of its location close to large London hospitals)</li> <li>Manchester (because the estate can be developed more cost effectively than other sites).</li> </ul>						
	Removing manufacturing from Sheffield will enable better opportunities for the development of the estate in the East of Pennines.						
	Three options were considered for Manchester:						
	<ul> <li>Minimum refurbishment</li> <li>Modernisation to create a smaller "Filton standard" site</li> <li>Creation of a Filton sized facility.</li> </ul>						
	The proposed solution is to create a smaller "Filton standard" site in Manchester by Q1 2017/18. The Colindale site is already earmarked for development in 2015/16. The operating model on these sites will standardise staffing structures and ways of operating (with a productivity improvement of 17%). Full shift working will be introduced to ensure the best use is made of every donation and that a full 24/7 service can be provided to hospitals. Some changes in activity will also be required in Hospital Services departments.						
	Red cell manufacturing volumes will increase at Manchester from 240,000 units to 670,000. Volumes at Filton and Colindale will be largely unchanged.						
	For routine components and most specialist components, the current service levels to hospitals across the north of England will remain unchanged as these components will be stored in local stock holding units (SHUs) as they are today. For a small number of specialist components, such as those for intra-uterine transfusion and washed red cells and platelets, specific arrangements will be put into place to ensure supply to meet the requirements of hospitals. This may include routine storage of some short shelf life components to provide emergency cover. Additionally, a reduction in work in progress (WIP) will result in hospitals receiving red cells with a longer shelf life.						

Page 2 of 24

8	Why is this important?											
	<ul> <li>Modernisation will provide flexibility, regulatory compliance and future- proofing for new technologies and developments.</li> </ul>											
	<ul> <li>New work patterns and staff grading will ensure cost effective and efficient working and make the best use of every donation.</li> </ul>											
	<ul> <li>It will provid standard.</li> </ul>	it tim provide the integrated to bring maneneous spite the time.										
9	Who else has be	en ir	nvolv	ed so	far?							
-	Who else has been involved so far? Review and support from:											
	Clive Rona	Idsoi	n. Dir	ector.	Blood S	Supply						
	Blood Supp							ications	s. Esta	ates ai	nd Fin	ance.
	Review at I				-	•			-,			
	Also early engage and local authoritie		nt wit	h staff	and st	takeho	lders	such a	s hosp	oitals,	union	s, MPs
10	Costs and benefi	its										
		_	2015/	2016/	2016/	2016/	2016/	2017/	2018/	2019/	2020/	2021/
			16	17	17	17	17	18	19	2019/	2020/ 21	2021/ 22
	THEORY	-	Q4	Q1	Q2	Q3	Q4	01000	01000	01000	01000	01000
	Total Costs Non Recurring Constructi		£'000	£'000	£'000	£'000	£'000	£'000	£'000	£'000	£'000	£'000
	costs Non Recurring Redundan	псу	-650	-650	-650	-650	-650	-646	0	0	0	0
Costs -1950												
	(double running & project) Total Recurring Revenue					-35	-90	-125				
	Costs (Transport)							-135	-180	-180	-180	-180
	Recurring Staff Savings Recurring Equipment							794	1323	1323	1323	1323
	Savings							135	272	272	272	272
	Total Cost Impact		-650	-650	-650	-685	-740	-1,927	1,415	1,415	1,415	1,415
11	Significant next	Actio	ons									
	Target Date	Hea	adline	e Activi	ty			Delive	ry / Be	enefits	;	
	August 2015	Early collective consultation to consult on overall proposal, prior to initiating estates work. Early and satisfactory consultation with stakeholders will enable the refurbishment work to start without undue delay.										
	August 2015	serv Lee bod	Engage with individual hospitals served by Newcastle, Sheffield and Leeds and hospital representative bodies (such as Regional Transfusion Committees).Respond to initial feedback received to date and ensure clarity on the proposals and identify delivery options for specific issues raised by customers.									

Page 3 of 24

			1					
	December 2015	Commence consultation with staff impacted by changes to Manufacturing and Hospital Services in Manchester.	Individual consultation with Manchester staff to deliver new grades and 24/7 working.					
	Q4 2015/16	Commence refurbishment in Manchester.	This will deliver a modern open plan manufacturing facility in Manchester, capable of operating 24/7 and increasing productivity through lean practices.					
	February 2016	Begin training of new staff, initially for new Manchester night shift. Will continue until May 2017.	This will deliver a well trained and capable workforce.					
	April – July 2016	Implement new shifts and working practices in Manchester.	Begin to deliver new lean systems and improve use of donations.					
	November 2016	Commence consultation with staff impacted by changes to Manufacturing and Hospital Services in Newcastle and Sheffield.	Individual consultation with those staff in impacted areas.					
	May /June 2017	Complete refurbishment in Manchester and commence transfer.	The estate upgrade will be commissioned and validated against the specification. Detail systems will have been put into place and tested to ensure that Hospitals see no change to service delivery.					
	July 2017	Closure of Sheffield and Newcastle manufacturing sites.	Aim to redeploy staff where possible. Every effort will be made to minimise the number of compulsory redundancies. This change will deliver the main benefits such as modernising for the future, maximising every donation, improving cost efficiencies.					
	August 2017	Project close.	This process will include a tracking and audit process to ensure benefits are measured.					
12	How does this im	How does this impact on Equality and Diversity?						
	An initial Equality Impact Assessment has been completed and shows the introduction of this change will not have a direct impact on equality or diversity. The assessment will be developed further as the project evolves and engages more closely with staff.							

Page 4 of 24

<ul> <li>there will be a requirement for additional transport between centres. We will adapt the established logistics network for the transportation of stock and testing samples in the Leeds, Sheffield and Newcastle areas to move blood components.</li> <li><b>14 Employee impact?</b> <ul> <li>There will be an impact on staff in the three affected centres with some redundancies in Newcastle and Sheffield.</li> <li>The proposed option will result in an overall reduction of 38 wte. There will be 94 staff (86 wte) impacted in Newcastle and Sheffield and Sheffield and an increase of 48 wte across operations in Manchester.</li> </ul> </li> <li><b>15 Donor/Patient/Customer impact?</b> <ul> <li>Customer impact will be focused on arrangements required to ensure timely delivery</li> </ul> </li> </ul>	13	What is the impact on sustainability?	
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<ul> <li>There will be an impact on staff in the three affected centres with some redundancies in Newcastle and Sheffield.</li> <li>The proposed option will result in an overall reduction of 38 wte. There will be 94 staff (86 wte) impacted in Newcastle and Sheffield and an increase of 48 wte across operations in Manchester.</li> <li><b>15 Donor/Patient/Customer impact?</b> <ul> <li>Customer impact will be focused on arrangements required to ensure timely delivery of bespoke specialist components. The project has reviewed all current customer agreements and is developing processes to ensure customers receive components to agreed timescales.</li> </ul> </li> <li><b>16 Taxpayer impact?</b> <ul> <li>Recurring savings of £1.42m <i>per annum</i> will contribute to maintaining or lowering the price of blood to the NHS.</li> <li><b>17 Author</b> <ul> <li>Stuart Penny / Assistant Director for National Operations</li> <li><b>18 Responsible Director</b></li> <li>Clive Ronaldson / Director of Blood Supply</li> <li><b>19 NED input</b></li> <li>Christine Costello and Roy Griffins</li> </ul> </li> <li><b>20 Additional Documentation Available on Request</b></li> </ul></li></ul>	14	Employee impact?	
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18       Responsible Director         Clive Ronaldson / Director of Blood Supply         19       NED input         Christine Costello and Roy Griffins         20       Additional Documentation Available on Request	17	Author	
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Christine Costello and Roy Griffins         20 Additional Documentation Available on Request		Clive Ronaldson / Director of Blood Supply	
20 Additional Documentation Available on Request	19	NED input	
		Christine Costello and Roy Griffins	
Detailed Business Case	20	Additional Documentation Available on Request	
		Detailed Business Case	

Page 5 of 24

# NHS BLOOD AND TRANSPLANT

### 30 JULY 2015

### MODERNISATION OF MANUFACTURING IN NHSBT

### 1. EXECUTIVE SUMMARY

The NHSBT Blood 2020 Strategy identifies a number of challenges for manufacturing operations. This paper proposes modernisation to improve operations and future proof the service for emerging technologies and process developments. These include pathogen inactivation, additional donor testing and changes in the platelet supply chain. The level of investment in Manchester will provide consistency across manufacturing facilities and support our continued high levels of regulatory compliance in the future.

**1.1** Manufacturing faces key challenges including excess capacity, unsuitable estate and sub-optimal working arrangements.

**1.2** The proposal is to consolidate manufacturing from five to three sites at:

- Filton the estate and working practices are the model for other sites
- Colindale strategically important location, close to large London hospitals
- Manchester the estate can be developed more cost effectively than the other two sites in the Northern Region. Testing and donor records activities are already consolidated here and removing manufacturing from Sheffield enables opportunities for the development of the estate in the Leeds and Sheffield areas. This could include the consolidation of activities in Leeds and Sheffield.

**1.3** The proposed solution will include the development of the Manchester site to a smaller "Filton standard" by Q2 2017/18. The Colindale site is already earmarked for the development required to implement 24/7 working during 2015/16, and the cost for this work is outside this project. Should there be competition for these funds as a result of this proposal, then the refurbishment of Manchester will take precedence.

**1.4** The operating model on the three sites will standardise staffing structures and lean ways of working (with a productivity improvement from 9,840 to 11,548 equivalent units per person per year, a 17% increase). Introduction of full shift working in Manchester will ensure the best use is made of every donation and a full 24/7 service can be provided to hospitals. The design and manufacturing approach at Manchester will use lean methodologies and principles.

**1.5** The Colindale manufacturing department is currently developing a separate initiative that will introduce 24/7 working, to ensure we provide a standardised service to all NHSBT customers.

**1.6** Red cell manufacturing volumes will increase at Manchester from 240,000 to 670,000. Volumes at Filton and Colindale will be largely unchanged.

Page 6 of 24

**1.7** For routine and most specialist components, the current service levels to hospitals across the region will remain unchanged. These components will be stored in the stock holding units in Newcastle and Sheffield as they are today. For a small number of specialist components such as those for intra-uterine transfusion and washed red cells and platelets, specific arrangements will be put into place to ensure supply to meet the requirements of hospitals. This may include routine storage of some short shelf life components to provide emergency cover.

1.8 The financial impact of the preferred option is:

Non recurring cost:	£6.1m
Recurring savings:	£1.42m
Avoided capital costs:	£2.8m.

This results in a simple pay back of 4.75 years, a positive NPV at year 10 of £4.5m.

The proposed option will result in an overall net reduction of circa 38 wte. There will be 94 staff (86 wte) impacted in Newcastle and Sheffield manufacturing and an increase of 48 wte in Manchester. Every effort will be made to minimise the number of compulsory redundancies.

It is intended that pre-construction work will begin in Manchester as soon as possible to allow construction to begin during January 2016, following initial consultation. Construction will be completed in Q1 2017/18 and will be followed by consolidation of activity into Manchester during 2017. The proposed timetable is contingent on NHSBT Information and Communications Technology (ICT) resource being available during Q4 2015/16. These resource requirements are currently being discussed with ICT.

### 2. RECOMMENDATION

To improve current operational performance and future proof operations it is recommended that the Board supports work to invest in and further consolidate manufacturing operations including:

- closing manufacturing departments in Sheffield and Newcastle and transfer of the activity to Manchester
- investing in the modernisation of manufacturing facilities and operations in Manchester
- moving to 24/7 working in the Manchester manufacturing department
- changes within Hospital Services in Manchester, Sheffield and Newcastle to support the new operating model ensuring we continue to meet patient need.

### 3. BACKGROUND

The NHSBT Blood 2020 Strategy identifies four key challenges within manufacturing:

- Sufficiency of supply
- Modernisation
- Organisation/workforce
- Efficiency.

Page 7 of 24

**3.1** The aim of this project is to modernise our facilities and working practices and to develop lean, efficient, flexible and compliant operations. These facilities will enable the development of automated systems and future-proof the organisation to accelerate and facilitate the implementation of new developments and technologies.

**3.2** In 2006 NHSBT performed manufacturing on eleven sites and testing on ten. Following a series of successful consolidations manufacturing (including quality monitoring) is now undertaken on five sites (Colindale, Filton, Manchester, Newcastle and Sheffield) and testing on two sites (Filton and Manchester). The supply of blood via the Hospital Services function is performed from 15 stock holding units and the recent consolidation of Donor Records has moved this activity from five sites to two (Filton and Manchester). Filton currently manufactures approximately 43% of the blood supply, Colindale 21%, Sheffield 14%, Manchester 13% and Newcastle 9%. There are no plans to further consolidate Hospital Services, Testing or Donor Records.

### 4. THE VISION FOR MANUFACTURING IN 2020

The Blood 2020 Strategy sets out the foundation for manufacturing for the future. The ambition is to provide the best possible service to hospital customers, to respond to decreasing demand for red cells and to increasing demand for other components. To meet the challenges outlined above the focus is on two key developments:

4.1.1 Creating a "Filton-like" environment (described in section 6) at all sites to:

- embed lean methodologies and systems of work
- maximise flexibility and optimise workflow
- future proof for new developments, safety measures and automation
- support our Quality systems and future regulatory demands.

4.1.2 Create systems of work which:

- provide the best possible service to the customer
- maximise the use of every donation (through 24/7 working)
- reduce the flow time for components and work in progress (WIP)
- improve scheduling of activity and workforce
- improve development and progression of staff.
- **4.2** Achieving this ambition is not viable with the current five site structure as:
  - the cost would be prohibitive to modernise all facilities
  - it continues the current over capacity and low equipment utilisation rates, there would be a duplication of equipment across sites
  - low volumes would not achieve economies of scale
  - fixed costs would not be removed as demand declines
  - workforce structures and planning are not optimal.

Page 8 of 24

### 5. CHALLENGES IN MANUFACTURING IN NHSBT

In order to meet the challenges of the 2020 strategy the primary issues facing manufacturing are:

### 5.1 Capacity utilisation and productivity

Falling demand (9.5% in the last three years) has increased excess capacity and even in the busiest areas equipment utilisation reaches only c40%. Additionally, significant variances in productivity are achieved in different sites. Lean working and successive consolidations have increased manufacturing productivity by c75% since 2008/09.

Although all sites continue to improve against a background of falling activity, significant future improvement now depends on maximising economies of scale. This will be achieved through consolidation, improved scheduling and workforce planning and developing facilities which will allow for the most effective implementation of lean methodologies, new technologies and automation.

### 5.2 Condition of the estate and modernisation

Filton is the only site with the flexibility to develop its processes to meet future demands and rapidly deploy new processes without major refurbishment. Future potential developments such as pathogen inactivation, additional testing requirements or automated systems may require more space and will require changes in the way space is utilised. The increasing demand for non-red cell components will also require more space and Manchester, Sheffield and Newcastle would each require refurbishment to support optimum performance and emerging requirements.

NHSBT has an excellent reputation for regulatory compliance. Manufacturing departments comply with the Blood Safety and Quality Regulations with regular inspections carried out by the Medicines and Healthcare products Regulatory Agency (MHRA). The MHRA expect consistency in operations and standards across facilities. There is inconsistency today between Filton and other sites. It is critical that NHSBT continues to develop its facilities and processes to ensure compliance is maintained.

#### 5.3 Standardising workforce practices and scheduling

Filton is the most cost efficient manufacturing site, setting record productivity levels for NHSBT in 2014/15. This is primarily because lean working and activity scheduling is more mature and the staff grading mix is the most cost effective. Whilst some activity scheduling has taken place within the four other manufacturing sites, historic working patterns and grading structures are in need of revision to maximise operational effectiveness.

#### 5.4 The requirement for 24/7 working

All hospitals receive a 24/7 service through NHSBT's 15 stock holding units. The provision of specialised (made to order) components is covered by a mixture of 24/7 operations at Filton and on call cover at other sites. As hospitals move further towards a 24/7 service, NHSBT must also adopt 24/7 working across all sites.

Page 9 of 24

The move towards an increase in pooled platelets has resulted in changes to working patterns. The current operating model manufactures components on the day after donation. This generates at least two days of work in progress (WIP) of red cells. Without adopting a 24/7 working this pattern is not sufficiently efficient.

# 6. FILTON – A MODEL FOR THE FUTURE

Filton is an excellent model for manufacturing across NHSBT, due to:

### 6.1 The Facility

The Filton manufacturing hall was built to create an environment in which a pharmaceutical/biotech culture could be established. There is a flexible workspace which is responsive to the needs of our customers, our regulators, the implementation of new processes and lean systems. The facility also provides a future-proofing capability for the introduction of automated processes.

### 6.2 Systems and workforce

There are inconsistencies in grading whereby the same activity is performed by different grades across sites. Filton staff grades are better aligned to activity. Three, full shifts working in Filton ensures that maximum use can be made of every donation and supports 24/7 customer demand. The shift system delivers better equipment utilisation and provides the flexibility to change the emphasis of production, as exemplified by the platelet supply chain project.

### 6.3 Economies of scale

Filton manufactures approximately 780,000 donations per year (43% total supply), enabling maximum efficiencies through economies of scale and the ability to flex distribution to stock holding units which require supply. The volume (and working practices) deliver a productivity of 10,386 units per person per year, compared to the national average of 9,483 excluding Filton.

### 7. FUTURE SITE CONFIGURATION

To re-create the Filton model across NHSBT in its current configuration would require the refurbishment of four other sites and the implementation of new working patterns at each. The activity at each site would not deliver economies of scale. Therefore, an operational assessment has been undertaken to evaluate the optimum number of sites for the future configuration of manufacturing. The criteria used (with the percentage weighting) were:

- ease of operating a 24/7 service (10%)
- reduce over capacity (10%)
- provide assurance of business continuity (25%)
- meets customer expectations (20%)
- financial payback (NPV) (25%)
- ease of modernisation and standardisation (10%).

The three site option scored highest: four sites 225, three sites 320, and two sites 240.

7.1 The strengths and weaknesses of each option are described in table 1.

Page 10 of 24

# **Options appraisal – Number of sites**

Description of Option	Strengths	Weaknesses
<b>Option 1</b> : No changes to current structure	<ul> <li>Established working environment.</li> <li>Proven track record at all sites.</li> <li>Skilled workforce with experience and knowledge.</li> <li>No impact on staff.</li> <li>No direct implementation costs.</li> </ul>	<ul> <li>Inflexible working practices.</li> <li>Harder to achieve high productivity due to huge excess capacity and lack of flexibility.</li> <li>No savings generated.</li> <li>Harder to standardise and modernise.</li> </ul>
<b>Option 2</b> : Consolidate onto 4 sites	<ul> <li>Delivers some productivity benefits with minimal change.</li> <li>Low impact on staff.</li> <li>Recurring revenue savings of c £600,000.</li> </ul>	<ul> <li>Would require the modernisation of two sites.</li> <li>Will be less economic as it will require night shifts on more sites to maximise the use of all donations.</li> </ul>
Option 3 : Consolidate onto 3 sites (Recommended option)	<ul> <li>Higher level of financial benefits.</li> <li>Will deliver the 2020 blood strategy.</li> <li>Will maximise use of every donation through the development of night shift working.</li> <li>Will reduce surplus capacity.</li> <li>Provides strong business continuity.</li> <li>Recurring revenue savings of £1.4m - £1.5m.</li> </ul>	<ul> <li>Will not maximise financial or productivity benefits.</li> <li>High staff impact.</li> <li>Requirement for significant one off costs ranging from approximately £6m - £11.5m depending on the extent of the development of the facility.</li> </ul>
<b>Option 4</b> : Consolidate onto 2 sites	<ul> <li>Large increase in productivity.</li> <li>Highest financial benefits.</li> <li>Will deliver modernisation strategy.</li> <li>Will maximise use of every donation.</li> <li>Will greatly reduce surplus capacity.</li> <li>Recurring revenue savings of £2.6m.</li> </ul>	<ul> <li>Could not support current SLAs to hospitals within our current logistical restraints and timelines.</li> <li>Risk of business continuity should one site become inoperable.</li> <li>Potential risk of adverse response from hospitals.</li> <li>Create significant logistical challenges.</li> <li>Requirement for significant one off costs of £13.1m.</li> </ul>

Table 1: Options appraisal – Number of sites

Based on this assessment it is recommended that NHSBT should consolidate manufacturing (including quality monitoring) activity onto three sites.

Page 11 of 24

# 8. LOCATION OF THE THREE SITES

Further review established which sites are of key strategic importance and how to maximise the benefits of the future operating model:

**8.1 Filton (SW Region)** – The Filton site is a modern purpose-built facility which is seen as a world leader in blood manufacture. It is not recommended that the site should be considered for closure.

**8.2 Colindale (SE Region)** - The Colindale centre is strategically located to serve the requirements of London's many specialist hospitals. The volume of activity undertaken currently (especially *ad hoc* requests, where approximately 25% are delivered from Colindale) would require complex arrangements to be put in place to maintain service levels. It is therefore not recommended that this site be considered for closure.

**8.3 Manchester, Newcastle, Sheffield (Northern Region)** - In order to provide a service which meets our service level agreements, the third centre is recommended to be placed in the Northern Region, at one of our three current manufacturing sites. An appraisal was undertaken to evaluate the best option in this region.

The Newcastle centre would be difficult to refurbish, given its size and construction. Because of its distance from other centres it would also create business continuity challenges if one of the remaining sites in the south became inoperable for a prolonged period. For these reasons Newcastle was rejected as an option.

Both the Manchester and Sheffield sites currently manufacture similar volumes of blood and it is expected that either site could reach the high operational performance levels required. In the appraisal each site was evaluated using the following criteria (with their percentage weighting):

- suitability of the estate and refurbishment investment (20%)
- operational effectiveness (15%)
- opportunity of estate redevelopment (15%)
- recurring savings (20%)
- redundancy impact (15%)
- ease of logistics (15%).

Manchester scored highest; 300 against 180 for Sheffield.

## 8.4 Refurbishment costs

Analysis of the refurbishment costs have been generated by the Estates construction office, in conjunction with external cost consultants. This has shown that the refurbishment costs in Manchester are less costly than those in Sheffield.

## 8.5 Operational effectiveness

In terms of performance a refurbished Sheffield centre would be able to perform as well as the proposed refurbished centre in Manchester. Testing and Donor Records are already consolidated onto the Manchester site (along with Filton) and the consolidation of manufacturing into Manchester will support close working relationships between these departments. Although it is not essential for operational departments to be co-located, where this is possible it is sensible to do so to ensure the best possible integrated working across the supply chain.

Page 12 of 24

**8.6 Opportunity for the future development of the East of Pennines estate** Consolidation into Manchester (and the release of space in Sheffield) provides NHSBT with a further opportunity to develop the estate in the Leeds and Sheffield area. This may include the possible consolidation of activities in this area. The development of these options is outside the scope of the modernisation of the manufacturing function, however, consolidation into Manchester is an important enabler to maximise these broader opportunities.

If the Board approve this proposal NHSBT will conduct a review of the estate in the Leeds/Sheffield area which will identify options by the end of 2015. A key part of that review will be the provision of the services which are currently supplied from Leeds and Sheffield, including stockholding and diagnostic services.

# 9. MANCHESTER REFURBISHMENT

**9.1** A number of options were considered for the refurbishment of the Manchester site as follows:

- Option 1: minimal refurbishment in Manchester with approx. 67% of collections in the region manufactured there. Approx. 33% of collections from the region would go to Colindale.
- Option 2: all collections from the region manufactured in Manchester. The estate is developed to create a smaller "Filton standard" facility.
- Option 3: all collections from the region are manufactured in Manchester. The facility is developed to create a Filton sized facility.

It is proposed to refurbish the Manchester centre to the same standard as Filton (and complete the planned refurbishment of Colindale). This will create additional capacity, allowing Manchester to receive all collections from the region (option 2). This will provide a modern, flexible facility that will be able to manage future demands from new technologies and changes in demand. It will provide a more consistent approach to our regulators and support our drive for continuous improvement in compliance.

It should be noted that there is a budget already allocated for the refurbishment of the Colindale centre. Should there be competition for these funds as a result of this proposal, then the refurbishment of Manchester will take precedence.

Option 2 aligns with the 2020 strategy for NHSBT to be a world leader and supports our stated aim of being the best in the world by any measure. The proposal delivers:

- a modern facility which will allow the flexibility for future process changes and automation
- facilitation of the adoption of lean working and methodologies
- an improved service to hospital customers due to
  - 24/7 working resulting in increased availability and reduced timescales for the provision of specialist products
  - hospitals receiving fresher blood due to the improved timelines and reduction of work in progress (WIP)
- a significant productivity increase of 17%

Page 13 of 24

- improved working practices plus a better utilisation of space and equipment
- a payback of 4.75 years at a cost of £6.1m
- avoided capital costs of £2.8m over 10 years
- support for our Quality systems and meeting future regulatory demands
- support for the introduction of future safety initiatives.
- **9.2** Option 3 would incur significant additional refurbishment investment (£9.2m) when compared to option 2 (£3.9m) with no additional recurring savings and has, therefore, been discounted.
- **9.3** Some of the additional drivers in the selection for option 2 are as follows:

# 9.3.1 Future-proofing

Option 2 will provide:

- a modern manufacturing hall, consistent with the Filton site. Option 1 provides facilities refurbishment to a minimum standard
- an additional c.260m<sup>2</sup> of space ensuring the flexibility to respond to new technologies and processes as they develop. It is likely that pathogen inactivation for platelets will become the international standard for the next stage in assurance of patient safety and will require additional space
- a fast and more agile approach to manufacturing, as is the case in Filton. A recent example is the expansion of platelet pool production to support the platelet strategy where implementation at Filton was on a larger scale, yet was implemented more quickly and efficiently.

A lack of investment now carries the risk that NHSBT would have to make significant changes urgently, at potentially extra cost.

# 9.3.2 Productivity

Option 2 will provide a change in national productivity levels of 17%. With option 1 this will be 11%.

# 9.3.3 Complexity and risk

Option 1 depends on Colindale moving to 24/7 working and undergoing immediate refurbishment, which would need to occur at the same time as this proposal. With option 2 we will retain the opportunity to separate these changes, if required.

## 9.3.4 Regulatory issues.

Not addressing the difference in our facilities presents two standards to our regulators. Developing Manchester to a lower level of facility will create inconsistencies in the standard of our estate and fall short of creating a pharmaceutical / biotech type environment for our manufacturing facilities and practices. We have also developed modern, compliant space in Birmingham and Tooting and are currently developing the Hospital Services department in Birmingham. Additionally, we are developing our blood donation clinics to a standard in line with our world class aims.

The adoption of option 2 supports a clear message to regulators and our staff that we are aiming for the best environment, supporting the best working practices.

Page 14 of 24

# 9.4 Cost

A comparison between options 1 and 2 is shown in table 2 below.

	Option 1 Facility	Option 2 Facility
One off Costs	£5.8m	£6.1m
Payback	4.46 years	4.75 years
Productivity increase	11.6%	17.0%
Capacity	Capable of processing 67% of the Newcastle and Sheffield activity.	Capable of processing 100% of the Newcastle and Sheffield activity.
24/7 working and new practices in Colindale	An immediate staff restructure required.	A more gradual change to avoid an immediate restructure.
Refurbishment	Full refurbishment of a limited number of areas to accommodate additional volume. Very limited changes in Manufacturing.	Full refurbishment of all areas to maximise space utilisation and create a Filton standard manufacturing environment.

#### Table 2: Refurbishment options

It must be emphasised that option 1 delivers none of the advantages described in section 9.3 above. It would be possible to refurbish Manchester to the standard required in option 1 and then to refurbish Manchester again to the standard of option 2 to accommodate new technologies. However, this will incur additional cost which has been estimated at £500,000 over five years. The total investment required would be £6.6m, compared to £6.1m, for option 2.

# **10. IMPACT ON STAFF & STAFF ENGAGEMENT**

The impact on staff will be:

- The manufacturing departments in Sheffield and Newcastle will be closed and staff will be placed at risk. Every effort will be made to redeploy staff or offer voluntary compulsory redundancy. The number of staff impacted will be 94 (86 wte)
- There will be 48 additional posts created in Manchester
- There will be some restructuring of staff in Manchester in order to move to 24/7 working and standardise grades. Wherever possible these changes will be made with minimal impact on staff.

**10.1** There will be an impact for Hospital Services including introducing an additional 24/7 shift rota at Manchester as the current system of lone workers out of hours will not support the additional activity that Manchester will be required to undertake. Changes to staffing have been calculated based on the established Filton model using standard work.

Page 15 of 24

**10.2** NHSBT and our Trades Unions have developed strong partnership arrangements. These were fundamental in the delivery of the former Patient Services consolidation programme. We need to maintain and build on these partnerships and have already begun early engagement with staff and their representatives. We plan to share information relating to the rationale behind the proposals, and the analysis which underpins them, at our functional partnership committees, specifically at the Patient Services Committee and the joint Blood Supply Partnership forum.

This change management programme will be delivered through formal consultation in accordance with legal requirements. We have a proven track record in the delivery of transformational change through consolidation. Assessments will be completed on a case by case basis to reduce the impact on staff and support, such as relocation or travel expenses, will be offered where it is deemed suitable.

# 11. FINANCIAL COSTS AND BENEFITS

**11.1** The consolidation of manufacturing into Manchester generates a requirement for recurring and non-recurring investment totalling £6.1m for year 2016/17.

(a) Non-recurring revenue costs for the project refer to:

- Staff redundancy costs £1.95m
- Refurbishment costs at Manchester £3.9m
- Double running staff costs £0.25m

## Total Non-recurring Revenue Cost Approx. £6.1m

(b) Recurring revenue savings identified refer to:

- Reduction in National Manufacturing staffing by circa 38 wte £1.32m
- Reduction in maintenance & other minor budgets £0.27m

## Recurring Revenue saving Approx. £1.60m

(c) Recurring revenue costs for the project refer to:

• Additional logistics costs £0.18m

Recurring Revenue Cost

Approx. £0.18m

# Total Recurring Revenue saving (b-c) Approx. £1.42m per annum

## Avoided capital cost

An additional benefit would be the avoided cost of replacing equipment at the Sheffield and Newcastle sites over the next ten years, based on current replacement costs this is estimated to be £2.8m.

The payback on revenue costs is approximately 4.75 years with a discounted cash flow saving of £4.5m over ten years. The summary of costs and benefits for the following five years can be found in table 3.

Page 16 of 24

Table 3 Full Financial summary table of Manchester option 2.Details are available on request.

Total Costs	Year 0 2016/17 £'000	Year 1 2017/18 £°000	Year 2 2018/19 £'000	Year 3 2019/20 €'000	Year 4 2020/21 £'000	Year 5 2021/22 €°000	Year 0-5 Total £'000
Total Capital Costs		0	0	0	0	0	0
Total Non-Recurring Revenue Costs	-3,375	-2,722	0	0	0	0	-6,097
Total Recurring Revenue Costs	0	-135	-180	-180	-180	-180	-855
Less Non-recurring Savings (from Benefits)							0
Less Recurring Savings (from Benefits)	0	930	1,595	1,595	1,595	1,595	7,308
Less Income Generation							
Total Cash Cost	-3,375	-1,927	1,415	1,415	1,415	1,415	356
10 yr NPV @ 3.5%							5,090

The refurbishment costs have been estimated using professional services, however detailed planning will be undertaken during the next phase of the project.

#### Financial analysis of developing the Sheffield site

An analysis was undertaken of the possible development of the Sheffield site to an equivalent standard and size to the preferred option in Manchester.

**11.2** The Sheffield site does not have sufficient space to develop this option within the current manufacturing estate (Manufacturing and the former Testing departments). A plan was developed for this option and the initial investment required to develop the Sheffield site would be £8.5m, compared to £6.1m for Manchester.

(d) Non-recurring revenue costs for the project refer to:

- Staff redundancy costs of £1.8m
- Refurbishment costs at Sheffield £6.5m
- Double running staff costs £0.25m

#### Total Non-recurring Revenue Cost Approx. £8.5m

(e) Recurring revenue savings identified refer to:

- Reduction in National Manufacturing staffing by circa 38 wte £1.32m
- Reduction in maintenance & other minor budgets 0.27m

## Recurring Revenue saving Approx. £1.60m

(f) Recurring revenue costs for the project refer to:

• Additional logistics costs £0.13m.

## Recurring Revenue Cost

Approx. £0.13m

## Total Recurring Revenue saving (b-c) Approx. £1.47m

## Avoided capital cost

The avoided cost of replacing equipment in Manchester and Newcastle over the next ten years, based on current replacement costs is estimated to be £2.8m.

Page 17 of 24

The payback on revenue costs is estimated to be 6.1 years with an estimated ten year Net Present Value for this option of £3.2m.

Total Costs	Year 0 2016/17 £*000	Year 1 2017/18 £*000	Year 2 2018/19 €*000	Year 3 2019/20 £*000	Year 4 2020/21 £'000	Year 5 2021/22 €*000	Year 0-5 Total £°000
Total Capital Costs		0	0	0	0	0	0
Total Non-Recurring Revenue Costs	-8,522	0	0	0	0	0	-8,522
Total Recurring Revenue Costs		-125	-125	-125	-125	-125	-625
Less Non-recurring Savings (from Benefits)							0
Less Recurring Savings (from Benefits)		1,194	1,595	1,595	1,595	1,595	7,573
Less Income Generation							
Total Cash Cost	-8,522	1,069	1,470	1,470	1,470	1,470	-1,574
10 ут NPV @ 3.5%						r	3,237

The total cost of this option is included in the table below.

Table 4 Summary table of Sheffield costs.

# **12. SERVICE TO HOSPITALS AND PATIENTS**

Analysis of the manufacture and delivery times to hospitals across this region has been undertaken. For customers the primary benefits will be the provision of a 24/7 service in all manufacturing sites and assurance that NHSBT will be able to respond effectively to future technologies and developments.

We will continue to hold stock in Sheffield, Newcastle and Leeds and we will primarily use the established logistics network for the transportation of testing samples in the Leeds, Sheffield and Newcastle areas to move blood components. NHSBT has an excellent track record in ensuring the safe and efficient transportation of blood across England and North Wales. We plan to move most components overnight when traffic is lighter and we will be able to deliver components off the shelf in the same way as we do now.

The 24/7 operation will ensure that requests for specialist components with a short shelf life can be manufactured at all times. Currently, this is not possible at all sites and is provided by an on call service, except in Filton. Specific arrangements will be put into place to ensure supply to the requirements of hospitals. This may include some routine storage of short shelf life components such as those for intra-uterine transfusion and washed red cells and platelets to provide emergency cover. This is documented in an initial clinical risk assessment which will be developed further as discussion with hospitals and other customer groups take place.

The move to 24/7 working will also allow for the best use to be made of every donation. This will ensure that, where there is competition for components from certain blood groups, there will be more flexibility to meet customer needs.

This option will also utilise the Planning and Control System's (PCS) new internal stock modules, leading to an improved service to hospitals, by optimising units held in each of the SHUs.

For routine components and most specialist components, the current service levels will remain unchanged as these components will be stored in local stock holding units as they are today. A reduction in work in progress (WIP) will result in hospitals receiving fresher red cells.

Page 18 of 24

# **13. BUSINESS CONTINUITY**

In conjunction with the Business Continuity function an analysis has been undertaken to assess contingency plans for the proposed structure. This has demonstrated that, should one site become inoperable, there is sufficient capacity at either of the other two sites to maintain business continuity.

**13.1** In a three site scenario, working at 80% of equipment utilisation, NHSBT will have the capability to manufacture 16,100 donations per day. Current collection volumes average 6,400 per day. This provides approximately 10,000 units of contingency capacity. In the worst case scenario with Filton becoming inoperable, Colindale and Manchester combined would have contingency capacity of 5,600 donations, approximately double the average daily workload in Filton. This is summarised in table 5 below. It should be noted that no single point failures will be introduced through these changes.

Centre	Current Daily Output Manufacturing (av.)	Enhanced Daily Out (av.) at	
	Total	Extra capacity	Total Capacity
Colindale	1,335	2,527	3,862
Filton	2,701	3,965	6,666
* Manchester	2,385	3,120	5,505
Total	6,421	9,612	16,033

Table 5: Summary of red ce	Il manufacturing capacity
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## **14. FUTURE STATE**

Implementation of the recommended option will result in manufacturing sites in Manchester (670,000 red cells per year), Filton (780,000) and Colindale (380,000).

Each site will operate in a "Filton-like" environment enabling lean working, flexible operations and future proofing. Each site will work to clear scheduled activity with shifts running 24/7. Staff gradings will be identical at each site, based on the Filton structure.

## 15. SCOPE

The scope of the project will include:

- Refurbishment of the Manchester site (note: the planned development and implementation of 24/7 working at Colindale will proceed as a separate initiative)
- Development of a workforce plan for 24/7 working in Manchester
- Development of standardised staff banding at Manchester
- Development of improved activity scheduling for Manchester
- Disestablishment of the Newcastle and Sheffield manufacturing functions

Page 19 of 24

- Consultation with staff side
- Communications with staff, hospitals and stakeholders
- Changes to Hospital Services operations in Manchester, Sheffield and Newcastle
- Changes to transport routes and vehicle type.

# **16. IMPLEMENTATION**

It is intended that pre-construction work will begin in Manchester as soon as possible with construction planned to begin in January 2016, following initial consultation. Construction will take circa 70 weeks and will be followed by consolidation of activity into Manchester during 2017.

The implementation timetable proposed in this paper is contingent on NHSBT ICT resource being available during Q4 2015/16.

Project Milestone				20	15				2016											2017										
Plan	Μ	J	J	Α	S	0	N	D	J	F	M	Α	M	J	J	Α	S	0	Ν	D	J	F	M	A	M	J	J	A		
Initiation																														
Estate planning /																									Ĩ					
Refurbishment																														
preparation		_	_																											
Delivery																						-								
Announcement to stakeholders / early																														
discussion with																														
staffside																														
Continue detailed																														
engagement with																														
hospitals																														
individually and																														
collectively.																														
Collective																														
Consultation																														
Consultation for																														
Manufacturing and HS staff in																														
Manchester																														
Refurbishment of			-				-																					-		
the Manchester site																														
Manchester																														
recruitment and																														
training																														
Consultation for																														
Manufacturing and																														
HS staff in																														
Newcastle and Sheffield																														
Movement of												-										-	-	-						
activity into																														
Manchester																														
Project Closure																							1							

The key implementation milestones are listed below:

Table 6: Key implementation milestones.

Page 20 of 24

The Manchester manufacturing site will continue to operate during the refurbishment work and the build will be phased, isolating small sections of the site to develop. To deliver the same operational capacity within a smaller footprint, the Manchester site will move to a limited night shift from April 2016.

# 17. GOVERNANCE AND COMMUNICATIONS PLANNING FOR MODERNISATION OF MANUFACTURING AND THE EAST OF PENNINES

The supply chain modernisation project is closely linked to other potential changes to our rolling estates programme as outlined in the January 2014 Board paper. As a result, it was agreed that:

- Individual projects will be established for supply chain modernisation (already in place) and estates changes East of the Pennines
- Both projects will be overseen by one Programme Manager to review the interdependencies between the projects
- A monthly Programme Board meeting will provide the governance for the projects.

**17.1** Briefings were held on 3 June 2015 with staff, managers and staff side representatives impacted by this proposed change in Manchester, Sheffield, Leeds, Newcastle and Colindale (primarily to inform staff how it is proposed to develop Colindale in the future).

The consolidation of manufacturing into Manchester raises concerns for the future of the Sheffield and Leeds centres for staff based there. We have briefed staff at these sites that as part of this work we will also be looking to establish the longerterm options for our sites in Leeds and Sheffield and will be seeking the views of staff and other stakeholders to inform decision making following the announcement of the Board decision in July. We will also be clear, that it is very much our intention to retain a presence in the Leeds/Sheffield area.

Communications were also issued to non-impacted employees about the development of these proposals.

17.2 We have written to local MPs, Councils and Hospitals during June/July.

In terms of media interest, so far there has been largely balanced and factual coverage of the proposal in the Newcastle and Sheffield areas only.

2015 2016 **Communications Plan** Α Μ J Α S 0 Ν D F J J M National SPC meeting Staff briefings in all centres Local stakeholder briefings - Hospitals, MPs and Councils (reactive media) Initial briefing/dialogue with key East of Pennines stakeholders re options **Director Roadshows Board Meeting** Briefings to impacted staff and stakeholders Ongoing internal consultation and external engagement Decision and plan for East of Pennines estate agreed and communicated

**17.3** The key communication milestones are listed below:

Table 7: Key communication milestones.

Page 21 of 24

**17.4** Based on previous consolidation initiatives, we will need to work closely with hospital customers to ensure the smooth transition of activity. We will need to emphasise the positive aspect of moving to true 24/7 operations and highlight how we will manage the supply of specialist components.

Following the announcement of the proposals to staff and communications to hospitals some feedback has been received raising questions regarding the sustainment of current service levels and the provision of short shelf life components. Our plan is to actively engage with hospitals in this discussion through our Customer Services function. A plan has been developed to do this and some engagement with Regional Transfusion Committees has already begun.

Some requests for information have been received from MPs and Health Boards.

**17.5** If this paper is approved by the Board it is intended to brief impacted manufacturing teams about the possible changes on 31 July. Employees were made aware of this date in the June briefings, and are expecting to be updated on the outcome of the Board decision on this date. This activity is part of an integrated communications plan and effective stakeholder engagement activity to ensure that the changes are successfully implemented and we manage interest and feedback from:

- Internal stakeholders staff and unions
- External stakeholders MPs, local councils and national/local media
- Hospital customers
- Donors (where applicable).

## 18. RISKS

The risks with a risk level of 10 or above are listed below.

		Q 3 and 4 2015/16, there may project during phase 1 on the
Impact: 5	Likelihood: 4	Risk Level: 20
Mitigation		
-	h the ICT function has taken a	200
	h the ICT function has taken pl	
<ul> <li>The dependency on of</li> </ul>	ther projects has been recogni	sed (IT upgrade / Network and
Telephony contract)		
<ul> <li>A national prioritisation</li> </ul>	n assessment has been compl	eted between the PMO and ITC
departments.		
and <b>T</b> is a set of the set of		
Risk 2 – Project timeline		
-		e e e e e e e e e e e e e e e e e e e
	de to the NHSBT estate, to acc	a car of some set as the inclusion of the set of the se
not be completed within proje	ct timeline. This risk will impac	t on NHSBT's ability to move
	e new site in tandem with plans	
sites, which may impede NHS	SBT's ability to produce sufficie	ent products to meet our
customer's demands.		
Impact: 5	Likelihood: 3	Risk Level: 15

Page 22 of 24

Miliantian		
Mitigation	with the Estates team has been	initiated
<ul> <li>Known contractors</li> </ul>	with the Estates team has been who have previously delivered s	
will be engaged	ill be menitered excinct the built	
	ill be monitored against the build be built into the timeline to repos	•
	ency plan to reprovision activity i	
Risk 3 – Stakeholder rea The closure of NHSBT Ma hospital and political stake	nufacturing sites may invoke ne	gative reactions from staffside,
Impact: 4	Likelihood: 3	Risk Level: 12
Mitigation		
	cations plan will be produced to embers will be briefed early on th	
Risk 4 – Staff retention		
Once the consolidation pla prior to the closure of their	ans have been announced, impa sites. This risk will impact on NI s to meet our customer's deman	HSBT's ability to operate and
Impact: 5 Mitigation	Likelihood: 2	Risk Level: 10
<ul> <li>A scoping exercise</li> </ul>	blan will be developed for impact will be completed to understand ages have helped to retain staff i	
<b>Risk 5 – Recruitment</b> The consolidated Manufac	turing sites may not be able to r	ecruit sufficient staff to cover the
The consolidated Manufac	will impact on NHSBT's ability to	ecruit sufficient staff to cover the produce sufficient products to
The consolidated Manufact new night shifts. This risk v	will impact on NHSBT's ability to	
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The consolidated Manufact new night shifts. This risk weet our customer's dema Impact: 5 Mitigation • Recruitment will be Risk 6 – Cost estimation Due to the confidential nat complete a detailed evaluat risk could result in the Deta the full project costs. Impact: 3 Mitigation • Estates have been • The production of a	will impact on NHSBT's ability to ands. Likelihood: 2 e started early during delivery. s ure of this project, the building c ation of the costs associated with ailed Business Case not contain <u>Likelihood: 3</u> fully engaged early in the plann an estate plan and specification s with the necessary skills have	Risk Level: 10         Risk Level: 10         ontractors have not been able to         n the estate refurbishment. This         ing an accurate representation of         Risk Level: 9         ing process         was made a priority
The consolidated Manufact new night shifts. This risk weet our customer's dema Impact: 5 Mitigation • Recruitment will be Risk 6 – Cost estimation Due to the confidential nat complete a detailed evaluat risk could result in the Deta the full project costs. Impact: 3 Mitigation • Estates have been • The production of a • External contractor	will impact on NHSBT's ability to ands. Likelihood: 2 e started early during delivery. s ure of this project, the building c ation of the costs associated with ailed Business Case not contain <u>Likelihood: 3</u> fully engaged early in the plann an estate plan and specification s with the necessary skills have	Risk Level: 10         Risk Level: 10         ontractors have not been able to         n the estate refurbishment. This         ing an accurate representation of         Risk Level: 9         ing process         was made a priority
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#### Mitigation

- Early engagement with all senior stakeholders
- The formation of a core project team immediately after the initial project communication announcement
- Highlighting the requirement for specialist resource early e.g. HR
- Fund adequate resource within the Business case.

#### Risk 8 – Increase in double running costs

These will increase one-off costs, reducing the payback.

	Impact: 4	Likelihood: 2	Risk Level: 8
Mitiga	ation		
٠	Project team review va	acancies as they arise to ensu	re tight control over redundancy

 Project team review vacancies as they arise to ensure tight control over redundancy costs and staffing in Newcastle and Sheffield.

After the project has gained Board approval, and is no longer confidential, then a risk workshop will be held to expand on this list.

#### **19. CONCLUSIONS**

Manufacturing faces key challenges including excess capacity, unsuitable estate and sub-optimal working arrangements. To improve current operational performance and future proof operations, it is recommended that the Board supports the following:

- close manufacturing departments in Sheffield and Newcastle and transfer of the activity to Manchester
- invest in the modernisation of manufacturing operations in Manchester
- move to 24/7 working in the Manchester manufacturing department
- changes within Hospital Services in Manchester, Sheffield and Newcastle to support the new operating model ensuring we continue to meet patient need.

Clive Ronaldson Director of Blood Supply

Stuart Penny Assistant Director of National Operations – Blood Supply July 2015

Page 24 of 24

## NHS BLOOD AND TRANSPLANT

# 30 JULY 2015

# CHIEF EXECUTIVE'S REPORT

## HIGHLIGHTS

- Blood stock levels generally good but universal platelet levels causing concern
- DTS sales income below plan but costs reduced to keep budget on track
- Organ donation levels lower than plan YTD but some strong in month performance.
- Two new Director appointments
- Successful annual stakeholder event with good engagement on the day from attendees and positive feedback
- Research and Development strategy 2015-20 received extensive media coverage
- A successful Blood Week generating significant media coverage and an influx of new donors registering and seeking appointments to donate
- Recognition for our communication activity with four wins at the Public Sector Communication Awards 2015.

# ACTIVITY SINCE LAST BOARD MEETING

## 1. Stakeholder engagement

We hosted the fourth annual NHSBT stakeholder event in London on 25 June with 62 external stakeholders joining us on the day. We launched our Research and Development Strategy 2015-20 at the event. We were delighted to have Rob Webster from NHS Confederation attend to give a keynote speech and highlight some of the challenges facing the NHS.

## 2. Parliamentary Engagement

To support National Blood Week, Jane Ellison MP, Public Health Minister, gave blood at West End Donor Centre on 10 June 2015. She also shared a photo on social media of her name with the As and 0s missing as part of our 'Missing Types' campaign.

# 3. Promoting donation

# Blood

We ran a hugely successful **National Blood Week** campaign in June, which led to more than 30,000 people registering as blood donors - a 3-fold increase on last year's campaign.

Headline results:

• 30,620 signed up during the 10-day campaign (Friday 5 – Sunday 14 June)



18,114 (or 59%)
 of those registering during the campaign were 17-34 years old, our target audience group

2,025 Black,
 Asian and
 Minority Ethnic
 people signed
 up, compared to
 832 last year.

The campaign centred around 'Missing Type' with the letters A, O and B – the letters that make up the blood groups – removed from public view to draw attention to the need for new blood donors.

During a campaign teaser phase, the Downing Street sign lost its O, Waterstones lost the A and O from its Trafalgar Square store, Odeon dimmed the Os at its flagship Leicester Square cinema and Green and Black's Organic momentarily altered the look of its Blood Orange bar.

NotOnTheHighStreet.com, NOW TV and GAME also supported the teaser phase.

On Friday 5 June, we revealed NHS Blood and Transplant was behind the confusing missing letters with a hard-hitting news story that 40% fewer new donors came forward last year compared to a decade ago. We explained that while blood stocks are currently good, if not enough new people donate blood and these 'types' were to go missing in years to come, there wouldn't be enough blood available when patients need it in future.

The story received extensive coverage across all channels, running across the whole week.

Regional events were held across the country.



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Thousands of people got behind #MissingType on social media. We secured over 700 pieces of media coverage for the campaign on TV, in print and online many of which relied on real life stories.

The campaign achieved global recognition and by the end of the week around 1000 businesses had dropped the A,B and O's from their logos.

The response to the campaign and the national media coverage led to an unprecedented online response which unfortunately led to the public website having to be taken down several times for short periods during peak media coverage. A review has been undertaken to build the resilience of the website in the short term while we work on the longer term improvements.

We attended **Glastonbury Festival** for the first time as one of only six 'worthy cause' partners, sharing their digital platforms with selected high profile charities including Greenpeace, Oxfam and Water Aid. Over 650 people registered to give blood during the festival weekend.

#### Organs

On Thursday 9 July, we launched the **new Organ Donor Register** for the UK. It offers more options for those who join while still ensuring the process is as quick and easy as possible. Each of the UK Governments issued their own announcements to ensure that they communicated relevant messages to people living in each country. Activity in Wales was co-ordinated with the ongoing public awareness campaign around the implementation of HumanTransplantation (Wales) Act 2013.

Since its launch we have seen a 52% increase in the number of users completing their registration. The new site is also mobile friendly and we have seen over a 100% increase in mobile registrations – with mobile users accounting for 21.5% of all registrants. There has also been an uplift in overall engagement with refreshed content, with users viewing more pages per visit and spending more time on the site.

Following Teddy's story of **neonatal donation**, Ami and Liam Duggleby told their story of donating their 23-day-old daughter Minnie's organs earlier this year in The Sun and Yorkshire Post. Both of Minnie's kidneys were successfully transplanted into a young adult. Her parents, who are from Yorkshire, are passionate about raising awareness of organ donation and are supporting a local awareness campaign, called Be A Hero, being run by Leeds Teaching Hospitals NHS Trust.

Our partnerships with **government and NHS transaction sites** continue to drive impressive registration figures. Since January 2015 over 650,000 people have clicked through to the organ donation website and over 258,000 people completed the online registration form. We are featured on over 20 end of transaction pages across a number of Government departments and are working to develop more links.

## 4. Media

We launched the new Research and Development Strategy 2015-20 to coincide with our annual stakeholder event. Our announcement about our progress towards labproduced red blood cells achieved widespread media coverage, including on the front page of the Daily Telegraph, on Radio 4's Today programme on Radio 5 Live. Around 30 outlets positively reported the story.

In May and June we achieved:

- > Over 1000 mentions of blood donation in the English and North Wales print media and national broadcast media:
  - Advertising value equivalent of £3,821,081 and a circulation of 451,839,045
  - 83.3% of these mentions were favourable, 15.3% neutral and 1.4% negative
  - 76% of the coverage was proactively generated by NHS Blood and Transplant
- > 634 mentions of organ donation across the UK print media and national broadcast media:
  - Advertising value equivalent of £3,122,366 and a circulation of 391,939,444
  - 75.9% of the pieces were positive, 24.1% neutral and 0% negative.
  - 4% of the articles carried the join the ODR message, 1% encouraged people to discuss their decision with loved ones, 3% gave details of how to sign up
  - The lower than usual message cut through was because we did not make any major national organ donation announcements in either month and we weren't in a campaign period.

# 5. Internal communication

We have run a programme of Director Roadshows over the last two months. These events were well attended and provided an opportunity for Directors to explain our plans for the year ahead face to face with teams and to answer their questions. The Roadshows complement our *Connect to a Region* initiative which launched earlier this year to improve senior leader visibility in the organisation.

## 6. Awards

NHSBT won four of the five awards we were shortlisted for at the recent UK Public Sector Communication Awards 2015 which celebrate excellent communication activity in local and national government, emergency services and not-for-profit bodies across the UK. This included awards for our recent blood campaigns, the enhanced blood website and our campaign to engage employees in responding to the Your Voice employee survey.

## 7. Performance and management

During this period blood stock levels have been generally good with stock levels exceeding 40,000 units for most of the period as part of the summer stock build. Stock balance has remained good with the exception of universal platelets which have been subject to weekly variation. Actions have been put in place to smooth production for this group.

DTS sales income is below plan but costs have been reduced to mitigate. This is an area of continued focus. We remain on plan to deliver two new TAS services in

Great Ormond Street and Birmingham Heartlands, taking our clinics up to 8 nationally. Despite early issues with the take-on of the Bristol eye bank this activity is now settling down and performance is improving.

Organ donation levels in the period have been variable with May being the best single month ever recorded but our YTD performance remains behind plan. Early assessment of changes in areas such as the introduction of the 'designated consenter' role are looking positive but it is too early to come to any firm conclusions.

The IT estate has been stabilised and the number of major incidents has been dramatically reduced. We remain on track to move the server room. The IT Advisory Board met for the first time and we agreed how we would make best use of the substantial experience now available to us in this area of work.

Sickness absence levels have been reduced as a result of widespread management action, with notable improvements in logistics.

Two new Directors have been appointed, Mike Stredder running Blood Donation, and Aaron Powell as our first Chief Digital Officer.

### ACTIVITY IN THE NEXT PERIOD

- Agree an approach to testing for Hep E.
- Continue with server room move activity
- Engage with Lord Carter's team to embed NHSBT in the new Model Hospital concept
- Launch NHSBT Way, management development activity
- Recruit new Director of Manufacturing

Ian Trenholm, 21<sup>st</sup> July 2015

# Board Performance Report For the period ended 30<sup>th</sup> June 2015

	Status	Trond	Comments
Blood Components			Red Cell issues in the year to date are 1.1% lower than plan and 4.5% lower than last year. The latest demand forecast has been amended to 1.600m (versus 1.610m agreed with the NCG). Platelet issues are also 1.1% lower than plan and 0.9% lower than in the previous year. Forecast platelet issues have been reduced to 277k (versus 280k agreed with NCG).
DTS			Cords issues and BBMR matches continue to be low and on a declining trajectory . This is the primary driver for a £1.3m contribution shortfall versus budget in the forecast for the year.
ODT			Deceased donors in June were marginally behind plan. Year to date deceased donors are now 7% behind target (316 vs 341), although 2% higher than the corresponding period in 2014/15. The number of transplants is 9% behind plan (841 vs 924). Living Donors (reported one month in arrears) are 28% behind plan year to date (ie to May).
Corporate			Sickness absence has maintained the recent improvement and is at 3.4% in the month, with a strong improvement seen in Logistics (3.9%). System uptime in Pulse, Hematos and the Donor Portal was behind target in the month.
Finance			The 2015/16 forecast remains equal to budget, although the actual outturn could be in the range £5m surplus to £2m deficit depending on the progress of transformation projects (with any deficit funded via our cash balance).
Change Programme			Four red flagged projects reported this month. EMDIS Cord continues to be reported at red status as a result of issues with supplier software delivery. The PCS, Stock Management Roll Out and TMS projects are also at red status with resource constraints being a common theme.

Contents	Pages
1. Performance Summary	1-17
2. Key Trends and Scorecard measures	18-38
3. Financial Report	39-42

DIVISION	PILLAR	STRATEGIC TARGET	R G 15/16	YTD TREND	PERFORMANCE
		69% percent of blood donors scoring =/> 9/10 for satisfaction with overall service (chart 17).	G	-	Better than plan in June 15 (70.1% vs 70%)
		No. of complaints per million donation	G	-	Worse than plan in June, although year to date continues to be better than plan.
		Number of Donors Donating over the last 12 months (000's)	G	-	Ahead of plan in June (899k vs 891k).
	Blood Donation and	Frequency of Donation (overall)	G	-	Slightly lower than plan in June, although within tolerance and reporting at 'Green' status (1.894).
	the Donor Experience	Number of O- neg Donors Donating over the last 12 months (000's)	G	-	Slightly higher in June (105.9k).
Blood		Frequency of Donation (O neg donors)	G	-	Marginally better than plan in June (1.98 vs 1.97)
		% of whole blood donations in donor centres	G	Better	Better than plan in June (14.5% vs 13.5%)
		% of 9 bed sessions	G	-	Better than plan in June (53.8% vs 49%).
		Blood Donation Productivity: units/FTE/year	G	-	Better than plan in June (1,380 vs 1375).
		Red Cell Blood Stocks – Alert Levels (chart 25).	G	-	Red cell stock > 3 day alert level for all groups during June 15.
		Platelet Demand vs. Stock levels (chart 26).	G	-	Platelet stock > than average daily demand on all occasions during the month.
	Supply-Chain Operations	Number of 'critical' and "major" regulatory non- compliances	G	-	None reported in June 2015
		96% of Products Issued on Time	G	-	Better than plan in June 96.5% (May 96.4%).

DIVISION	PILLAR	STRATEGIC TARGET	R G 15/16	YTD TREND	PERFORMANCE
	Supply-Chain	Manufacturing Productivity (units/FTE/year)	G	-	Slightly lower than plan in June (10.0k vs 10.3k), although year to date better than plan.
	Operations (cont.)	Testing Productivity (units/FTE/year)	G	-	Marginally lower than plan in June (24.93k vs 24.94k) although year to date better than plan.
	Customer Service and	Percent of hospitals scoring =/> 9/10 for satisfaction with overall service (chart 30).	А	Worse	June at 66% (March at 70%), worse than target. Next survey in September 2015.
Blood	the Hospital Interface	Red Cell Price £121.85 in 2015/16.	G	-	Post NCG 2015/16, which maintained flat prices, a price reduction ( $\pounds$ 120 p/unit) will be applied to Red Cells.
		Satisfaction with RCI at =/> 9/10		-	Reported under the DTS section (page 7).
	Hospital Integration	Hospital Served via Vendor Managed Inventory		-	To be reported from Q2.
		Hospital networks with extended / integrated services		-	As above.

#### Commentary – Blood Components

Red Cell issues in June were 137,200, 2.8% lower than plan. In the year to date red cell issues of 403,400 are 1.1% lower than plan and 4.5% lower than the previous year.

Following this month's DRG meeting the forecast for the year was reduced by 0.6%, to 1.600m issues (versus 1.610m agreed with the NCG). This represents a 3.5% reduction year on year (2014/15 – 1.659m). Pricing for 2015/16 includes a Demand Reduction Reserve (2%), which will provide pricing cover down to 1.578m units.

Whole Blood collections in June (147,100) were 1.1% higher than plan, with year to date collections of 431,200 now 2.6% higher than plan. At a regional level, collections (number of donors bled) in the month were higher in the West (2.3%) and North (1.5%) although slightly lower than plan in the East (0.3%), although year to date all regions continue to be higher than their respective plans with the West being the highest at 4.1% above plan.

With collections again higher than plan for the month, stocks increased during June to end the month at c47k units. During the first half of July, however, stocks have steadily reduced to 42k, albeit higher than the upper stock level target (40k). All blood groups remained above the 3 day alert level during the month, with

stock levels of vulnerable groups O- / B- neg, stable at c6-7 days for each group, reducing to be at c5-6 days in early July. A continued pressure on O neg supply remains, however, with the proportion on O neg demand steadily climbing each month. Year to date the proportion of O neg demand is now at 12.5% of total issues (versus population of 7%) and was at 12.7% in June. It was at an average of 12.1% in 2014/15.

The unprecedented success of the National Blood Week and the #Missingtype campaign during June resulted in a sharp increase in the recruitment of new whole blood donors (20.3k versus 17.5k planned). Year to date recruitment is now marginally ahead of target (50.5k versus 50.0k). The donor base overall (based on donors donating over the last 12 months) is now better than target, reporting at 900k donors versus 891k planned. There was also an increase in the number of new O neg donors and hence the donor base is now marginally higher than plan at 105.9k (versus 105.3k planned).

National Blood Week proved to be the most successful recruitment campaign that NHSBT has run. The campaign, was split into two main sections i) awareness campaign around the decline in new donors over the last decade and ii) introduction of the missing types theme where brands ,people and celebrities removed the letters "A" "B" and "O" from their names and mastheads. The downside was the impact of demand on the donor portal, which due to its integration with Pulse, required that it was taken off line for a number of short periods. The demand also had an impact on donor complaints (significantly higher in month) and donor satisfaction (which saw a sharp fall). The top three areas for donor complaints this month were i) turned away, ii) slot availability, and iii) not seen at appointment time. Although appointments were set aside for new donors and walk-ins, the scale of the response to National Blood Week was higher than anticipated. As such complaints are expected to return to past levels in the next months. Donor satisfaction in June was at 70.1% (versus 73.6% in May), although it remained marginally better plan of 70%. Again it would be expected that satisfaction will increase over the next few months.

Red cell wastage levels were at 3.65% in June, marginally worse than plan (3.60%) and also last year (3.64%), although the year to date position (3.59%), continues to be slightly better than plan. The number of red cell expiries was 0.31% in June, and continues to be substantially lower than both plan (0.52%) and the previous year (0.39%). At a group level, expiries of AB+ units continued to be high, accounting for 37% of the June total, and consistent with past experience.

Year to date platelet issues are now 1.1% lower than plan and 0.9% lower than in the previous year. The MAT, which climbed slowly through 2014/15 is now broadly flat at 274k units. The latest DRG review of the DRG has now revised this year's forecast to 277kk units (versus 280k agreed with the NCG).

Platelets wastage levels were better this month at 8.63% and, in the year to date, are at 9.21%. This is though worse than last year's outturn (8.1%) and also above this years plan (8.0%). The platelet expiry rate was lower in June at 5.31% but again the year to date position (6.66%) continues to be higher than the previous year (5.44%) and also plan (5.17%). There is an expectation that the expiry rate will continue to fall as we move into a period that is free of bank holidays. At a group level O+ units accounted for ca32% of all expiries in the month and c27% in the year to date (consistent with past experience).

Platelet stocks in aggregate and at a group level were above the alert level during June. There continues to be, however, periodic instances where group Aplatelet stock (the universal type) is lower than the alert level (3 out of 22 working days in June). These shortages tend to fall on a Wednesday and an action plan is being developed to address this ongoing supply planning issue.

OTIF delivery performance (before substitutions) was better this month, reporting at 96.5%, and better than plan (96%). This equates to 6.1k of 176.1k units issued. The key areas of under performance this month were i) ad-hoc delivery 95.3% and ii) supply of adult platelets 93.9%. A number of actions are being put in place to address these 'failing' units ie:

i) improvement to the timing of ad-hoc deliveries particularly at the Tooting, Colindale and Birmingham centres;

# NHSBT BOARD REPORT - 30th June 2015

- ii) adult red cells reducing the level of substitutions for Rh phenotyped blood, which accounted for 76% of the total missed units, by targeting the recruitment of this cohort and tracking their donations to ensure that optimal usage is made of them;
- iii) adult platelet substitutions, where 41% of the total (1,112), were due to irradiated units being issued for non-irradiated units;
- iv) collect timing fails, with Leeds the highest followed by Manchester and Tooting

The number of faints was worse this month at 188 and remains higher than target (160). The number of rebleeds was however, marginally lower this month at 30 (May 31) and equal to target.

There was an MHRA inspection at Manchester/Lancaster with no critical/ major non-compliances reported.

#### **Blood Supply – Transformation Project Status**

Total projects 12	Red	Amber	Green
Total projects 13	2	1	10

Project title	Status	This RAG	Last RAG	Approved Cost (£m's)	F/Cast Cost (£m's)	F/cast Benefit (£m's)	Planned to complete	F/Cast to complete
Transport Management System	Delivery	R	A	1.8	1.4	N/A	Apr 15	Jul 15
Standard Donor Carer Day	Delivery	G	G	0.4	0.4	0.4	Jan 16	Jan 16
All Wales	Initiation	А	A	0.5	0.4	N/A	Jan 17	Dec 16
Planning and Control System	Delivery	R	А	0.9	0.8	N/A	Apr 15	Jul 15
NAT Contract	Delivery	G	А	TBC	TBC	N/A	Dec 14	Sep 15
Platelets Supply Strategy	Delivery	G	G	3.6	3.3	3.0	Mar 16	Mar 16
Donor Portal Phase 2	Delivery	G	G	0.6	0.7	0.5	Jul 15	Oct 15
Session Consolidation Ph 2	Start-up	G	G	0.8	0.8	3.63	Dec 15	Mar 16
Modern Paperless Donor Journey (i)	Start-up	G	G	0.2	TBC	TBC	Apr 15	Jan 18
Supply Chain Modernisation	Start-up	G	G	TBC	6.1	1.42	Aug 17	Aug 17
Microbiology LIMS	Start-up	G	G	BAU	BAU	TBC	TBC	TBC
Bacterial Screening Contract	Start-up	G	G	0.1	TBC	TBC	TBC	TBC
Pulse Replacement Programme (i)	Define	G	G	0.1	TBC	TBC	TBC	TBC

Note: i) Project is described in detail in the table on the following page:

# Blood Supply – Transformation Project Status (cont.)

Project	RAG	Trend	Strategic Theme	Spend to date	Cost	Benefit	Complete
Modern Paperless Donor Journey (Online DHC)	G	-	Blood Donation and the Donor £0.1m		твс	твс	Jan 18
The project, which is in the start-up phase, will improve the donation experience. Key to these improvements will be the digitisation of the DHC form and donation audit trail. The focus at this stage is on the discovery phase to allow development of the business case to be completed. Research with donors has now been completed, prototypes produced and the MHRA engaged to review our proposition. Researchers have now produced the initial wireframe. Benefits are now being finalised, estimating completed and the high level plan produced. A meeting with key stakeholders will be used to deliver a presentation covering status, scope and next steps. The programme team focus will continue to be on our roll out approach and the technical support and maintenance required to deliver the project.							
Pulse Replacement Programme	G	-	Blood Donation and the Donor Experience	£0.1m*	ТВС	TBC	ТВС
Supply, Tissues and NCI b	ousiness I and wo	requirement orkflow to be	the existing Pulse core system, inclue ts. The programme will be delivered u utilised across NHSBT. Programme	using commercially in initiation and de	v available off-the-s	shelf software, allor s from the Platform	wing a single set

DIVISION	THEME	STRATEGIC TARGET	R G 15/16	YTD TREND	PERFORMANCE
		Sales Income (£m's)	А	Better	Better than plan in June (£5.5m vs £5.3m).
	Group	Number of Serious Untoward Incidents (SUI's)	G	-	None reported this month.
	Targets	Zero 'critical' regulatory non-compliances	G	-	None reported this month.
		Number of 'major' regulatory non-compliances	G	-	None reported this month.
		£8.6m sales income achieved (chart 37)	Α	Better	Better than plan in June (£1.1m vs £1.0m), year to date continues to be behind plan.
	Tissues	80% percent of customers scoring =/> 9/10 for satisfaction with Tissues	-	-	Next survey to be reported in June 15 (publish August).
		98.0% of Product issued on time	G	-	Better than plan, reporting at 98.6% in June.
DTS		£13.34 Sales Income achieved	G	Better	Better than target in June (£1.2m vs £1.1m).
		60% percent of hospitals scoring =/> 9/10 for satisfaction with H&I (chart 43).	G	-	68% in June 2015 Next survey scheduled for September 2015.
	H&I	% of patients receiving A or B1 platelets	R	Worse	Behind target in June (72% vs 78%), year to date also behind plan.
		Time to type DCD organ donors	R		Reporting monthly in arrears and behind target (63% vs 80%).
		Turnaround time vs SLA	А	-	Behind plan in June (95% vs 98%)
		£11.87m Sales income achieved	А		Better than plan in June (£1.0m vs £0.95m), although remains behind plan year to date
	RCI	60% percent of hospitals scoring =/> 9/10 for satisfaction with RCI (chart 43).	R	-	54% in June 2015. Next survey scheduled for September 2015
		Sample turnaround time vs SLA	G	Better	Better than target in June (97% vs 95%).

DIVISION	THEME	STRATEGIC TARGET		YTD TREND	PERFORMANCE
	СМТ	£9.71m sales income achieved	G	-	Better than plan in June (£0.9m vs £0.8m).
		Contribution to overheads (£1.3m)	G	-	Better than plan.
		£10.7m sales income achieved	R	-	Income below target in June (£0.8m vs £0.9m)
		Contribution to overheads (£2.03m)	R	-	Worse than plan in June.
		% Confirmatory typing within 14 days	А	Better	Better than plan in June (84% vs 80%), although year to date continues to be behind plan.
		2,300 increase to Banked Cords TNC > 140	Α	-	Behind plan in June (190 vs 192)
	SCDT	30% BAME Cord Blood units add to the bank	G	-	42% of total units banked in June 15 vs target (>30%).
DTS		Issue 60 Cord Blood units	R	-	No units issued in June.
		Adult Donor Provisions	R	-	Target for the year is 270 donors, June is behind plan (17 vs 22).
		Donors recruited to fit panel	G	-	2015/16 target is 8k, June is higher than planned (618 vs 400) .
		£6.93m sales income achieved	R	-	Worse than plan in June (£0.5m vs £0.6m)
	Therapeutic Apheresis Services	60% of hospitals scoring =/> 9/10 for satisfaction with TAS	-	-	Better than plan in Q4 2014/15 (68% vs 60%).
		98% of Patients rating patient experience =/>9/10 with the service	-	-	Latest survey, reported in January 2015 at 100%

#### **Commentary – Diagnostics and Therapeutic Services**

Sales income in June was higher than plan (£0.2m) and resulted in a small surplus I&E position of £0.3m. The year to date position is also reporting a surplus of £0.3m, albeit that income is lower than plan (£0.5m) and is more than offset by underspends against budget of (£0.7m) and also a small favourable cost of sales variance in Tissue and Eye Services (£0.1m). The year end position is, however, forecasting a deficit I&E position of £1.3m, reflecting lower income (in cord blood / BBMR matches especially) being only partially offset by reduced expenditure (£1.2m).

#### DTS Q1 sales by business unit:

DTS Business Unit	2015/16 YTD Budget	2015/16 YTD Income	2015/16 YTD Variance	2014/15 YTD Actual	YTD Year- on-year Growth
Tissue & Eye Services	2.9	2.9	-	2.2	29%
TAS	1.8	1.5	-0.3	1.6	-8%
H&I	3.2	3.2	-	3.1	4%
RCI	3.3	3.3	-	3.1	4%
DDRS	0.2	0.2	0.1	0.1	135%
CMT	2.1	2.4	0.3	2.3	6%
SCDT	2.7	2.2	-0.5	2.5	-13%
Customer Services	0.4	0.3	-	0.3	-5%
Total (£m's)	16.4	15.9	-0.5	15.2	5%

**Tissue and Eye Services.** Income growth in 2015/16 is mostly due to the transfer of the Bristol and Manchester eye banks into Tissue Services from the 1<sup>st</sup> April 2015. Sales income is on plan overall, driven especially by strong demand for cardiovascular, skin, autologous serum eyedrops and demineralised bone matrix. Sales of decellularised skin continue to struggle and are running at 70% of plan.

In Diagnostics **RCI** income is 1.1% behind plan but 4.1% higher than last year with antenatal referrals continuing to be the primary shortfall versus plan. **H&I** income is 1% ahead of plan and 4% ahead of last year with strong demand for red cell investigations. The overall forecast outturn for Diagnostics is a reduced contribution of c£0.5m with lower income not being matched by a reduction in forecast costs.

**Stem Cell Donation & Transplantation** income continues to be significantly worse than plan and is now 33% behind plan and 23% lower than last year (with a similar decline seen in both cord blood and BBMR matches). There were no cord units issued this month and only 7 in the year to date (vs a reduced target of 15). The target for the year was reduced to 60 units (75 units in 2014/15) and achievement of this lower target is now likely to prove challenging. Searches on the NHS-CBB tend to focus on cords above a TNC of 140 and in particular >190 TNC, with c80% of units issued during 2014/15 (34/43) coming from these groups. Those cords with the highest TNC represent only 5% of the overall bank, however. Increasing the number of cords banked of this quality continues to be challenging with only c20% of new units within the bank coming from these categories during last year. The downward trend in the use of the bank appears to mirror a wider decline in demand worldwide and is evidenced by other providers taking the decision to exit or re-consider their participation in cord banking.

The target for the number of cords banked this year has been retained at 2,300 and continues to reflect the decision to bank only those cords with a high total nucleated count (TNC) >  $140 \times 10^{8}$ . The number of collections this month, was close to target at 190 (vs 192). The bank is now also reporting a WIP of c2,500 units which is significantly higher than would be expected (c600). Work is ongoing to reduce this to more normal levels and increase the number of searchable units in the bank. The proportion of units banked from BAME communities was at 42% in June – remaining much better than plan of 30%).

Overall the forecast for the year is forecasting a £1.6m contribution shortfall versus budget.

**Cellular and Molecular Therapies** - income year to date is 15% higher than target and 6% better than in the previous year with all segments performing well. This is driving a year to date income and expenditure surplus of £0.3m and this is expected to be maintained to the year end.

Therapeutic Apheresis Services income year to date is 16% lower than plan and also 8% lower than last year with low demand for both plasma exchange and photopheresis. Some recovery is expected with income for the year anticipated to be 5% ahead of last year although 5% behind plan. The income shortfall will be matched by cost reduction and hence contribution is expected to be in line with plan..

#### DTS – Transformation project Status

Total projects 5	Red	Amber	Green
Total projects 5	2	1	2

Project title	Status	This RAG	Last RAG	Approved Cost (£m's)	F/Cast Cost (£m's)	F/cast Benefit (£m's)	Planned to complete	F/Cast to complete
EDI Phase 2	Delivery	G	G	0.2	0.1	N/A	Aug 15	Aug 15
EMDIS Cord	Delivery	R	R	0.015	0.015	N/A	Aug 15	Oct 15
Next Generation Sequencing	Delivery	A	G	0.7	0.7	N/A	Nov 15	Nov 15
Eye banking	Delivery	G	А	0.9	0.9	N/A	Dec 15	Dec 15
Stock Management Rollout	Delivery	R	A	0.3	0.3	N/A	Apr 16	May 16

DIVISION	THEME	STRATEGIC TARGET	YTD R G	YTD TREND	PERFORMANCE
[					
		Increase % Consent/Authorisation rate (Overall)	R	-	June returned 62.9% versus plan of 64%, although year to date continues to be behind plan and reporting at 60.3%
		Deceased donors 1365, (chart 49)	R	-	109 Donors in June vs 114, year to date is behind target by 25 donors (316 vs 341).
		Deceased Organ Donors per million population	А	-	Reported quarterly, June at 20m vs 21m planned. Next return is September 2015.
		Number of Living donors (1,223) – reported one month in arrears (chart 52).	R	-	Behind plan in May , reporting 70 vs 102 donors.
ODT	Key Outcome	OD register at 21.1m – internal NHSBT target based on 2m new registrations in 2015/16.	R	-	Worse than plan (0.23m vs 0.25m).
	Measures	% Consent/Authorisation rate (patient expressed a wish to donate on ODR)	R	-	Worse than target in June 87.7% vs 95%.
		% Consent / Authorisation rate (patient not expressed a wish to donate or ODR status not known)	А	Better	Better than target in June at 52.8 (vs 51%).
		Organ Transplants – Deceased (3,694)	R	-	280 transplants in June (versus plan of 308).
		Deceased Organ Transplants per million population	R	-	Reported quarterly. June at 52.3m vs 57.0m planned. Next return is September 2015.
		NHSBT Cost per Transplant (chart 51).	G	-	Forecast for 2015/16 - £18.1k, reported quarterly, next report in September 2015.

#### Commentary - ODT

Following the record number of deceased donors in May (123) June reported 109 donors, lower than plan for the month of 114. Year to date the number of deceased donors continues to be 25 (7%) behind plan. However, the MAT has improved again this month to 1,287 donors and slightly higher than the outturn for last year of 1,282 donors.

DBDs were worse than plan in June (61 vs 71) and remain behind 23 (11%) plan in the year to date. In contrast, the number of DCD donors reported this month has continued to be better than plan (48 vs 43) and in the year to date is now only 3 donors (2%) behind plan.

June was another better month for the consent rate, although it remains behind plan, year to date, due to the low consent rate achieved in April and hence remains at 'Red' status.

In June, there were nine families who overruled a family member's decision compared versus 6 in May. In the year to date there has now been 27 such interventions. This has resulted in a lower ODR consent rate of 87.78% (lower than plan of 95%).

Of the 109 deceased donors this month, 106 resulted in at least one transplant. Deceased donor transplants were 28 (9%) below plan in the month (280 versus 308). Year to date also continues to be worse than plan and is now 83 (9%) below target (841 versus 924). The MAT has, however, continued to improve and is now slightly ahead of the outturn for 2014/15 (3,363 vs 3,341).

Living donors are reported a month in arrears. Following the low number in April (76), May saw the lowest number of living donors in more than four years with 70 donors against a monthly target of 102. Year to date, living donors are now 58 (28%) below target (146 vs 204), with the MAT having been falling steadily since December 2014 (to 1,069 this month).

The targeted number of new registrants on the ODR for 2015/16 has been increased to 2m (2014/15 – 1m). Overall there is now a total of 21.3m on the register. Year to date the ODR is reporting 231k new registrants (versus 250k planned).

NHSBT, in collaboration with the four UK Governments, launched the new <u>NHS Organ Donor Register</u> (ODR) on the 9<sup>th</sup> July. The new register will support the implementation of the Human Transplantation (Wales) Act 2013 which comes into effect in Wales on 1 December 2015. It means that unless a person living in Wales has expressed a decision not to be a donor then they will be regarded as having no objection to organ donation or to have 'deemed consent'.

The forecast financial outturn for 2015/16 is an underspend of £1m (effectively representing £1m of unallocated funds for transformation projects). It is intended that any surplus in ODT will be carried forward in our year end cash balance for use against future transformation projects.

# ODT – Transformation project status

Total projecto 5	Red	Amber	Green
	0	1	2

Project title	Status	This RAG	Last RAG	Approved Cost (£m's)	F/Cast Cost (£m's)	F/cast Benefit (£m's)	Planned to complete	F/Cast to complete
Donor Registration Transformation	Delivery	A	A	4.4	4.4	N/A	May 16	Jun 16
Opt Out System & Register	Delivery	G	A	4.0	4.2	N/A	Dec 15	Dec 15
Bristol Consolidation	Start Up	-	G	TBC	0.8	0.4	TBC	TBC
ODT Workforce Profiles - Phase 2	Delivery	G	G	0.3	0.3	1.0	Feb 16	Feb 16
ODT National Hub (i)	Identify	-	-	TBC	TBC	TBC	TBC	TBC

Project	RAG	Trend	Strategic Theme	Spend to date	Cost	Benefit	Complete
ODT National Hub	А	-	Outcome 4 – Better support systems and processes will be place		£1.5m	N/A	Apr 16
Phase 1 of the National Hub programme is to prove the concept for migration away from the NTxD software application. Phase 1 will be focussed on developing the Urgent Heart Pathway via the new CRM and BPMS platforms in three distinct Transition phases. As such there is a large dependency on the Platform Selection project, as the assumption is that detailed work on the transition phases can start in September after the platforms and implementation partners have been selected.							
Donor Registration Transformation	А	-	Outcome 2 – Each donor can give as many organs as possible	£2.1m	£4.4m	N/A	Jun 16
supporting the DRT projec deployment of code (and is The PM/AE are working to	t ie the p s estima provide	project will ne ted to create the required	rrent processes for registering organ of meet planned EOSUAT dates and a delay of 2-3 weeks). The NTxD u resource to support DRT testing. Th erall project also remains unchanged	is dependent on new ser acceptance testi ne delay, however, is	v EOS infrastructu ng is also delayed, not expected to in	re being in place to due to lack of bus mpact delivery plar	o enable the siness resource. ns for Apadmi's

GROUP	NOTES/UPDATE REPORT
NHSBT Corporate	Sickness levels were marginally higher this month at 3.4%. This remains lower than target (4.5%) and also better than 2014/15 (4.37%). The transport function has maintained the improvement seen last month with sickness in June reducing further to 3.95%. System uptime in Pulse, Hematos and the Donor Portal was behind target in the month. System availability in June was especially impacted by the impact of National Blood Week and the need to take the Donor Portal off line for a number of periods as a result of high donor demand.
	An income and expenditure surplus of £2.8m was reported in June - £1.1m better than plan. Year to date we are now reporting a surplus of £6.0m, £4.5m better than plan, mainly due to higher red cell stocks (£2.2m), combined with substantial favourable expenditure variances in Blood Donation (£0.6m) and also ODT (£0.7m).
	The formal year end forecast continues to remain equal to budget. Underlying this there is a potential deficit of £1.5m, driven mainly by the income shortfall in SCDT. However, as the transformation plan is subject to major uncertainly, a break even forecast has been retained.
FINANCIAL RESULTS	<u>Balance Sheet</u> - Current Assets were £59.2m at the end of June. This includes a cash balance of £43.1m, including a liability of c£4.1m for capital charges, with programme funding drawn down from DH, equal to plan. BPPC was 99.2% by value and 97.0% by number (target 95%); Debtor Days – were 29 in June, which is an improvement (May 36), although it continues to be higher than target (22). Creditor days were 11, significantly better than the target (30). Debtors are lower this month at £30m (May £33m) although £4.5m higher than the corresponding month last year. At a customer level the key overdue accounts are i) Bart's Health NHS Trust (£1.7m), Kings College Hospitals NHS Foundation Trust (£1.3m), St George's University Hospitals NHS Trust (c£0.8m). The AR team are actively chasing these debts.
	<u>Capital</u> – DH have now confirmed the requested allocation for 2015/16 (£8.5m). Bids against this years requested allocation have been re-prioritised and there is now a broadly balanced plan corporately for the year. Capital leads are now being asked to prepare proposals for approval. At the end of June 2015, capital spend is £1.6m and is mainly from those projects where there is a carry forward liability/commitment from 2014/15.

# Corporate - Transformation project status

Total projects 10		Red			Amber					
Total projects 10	0				1			9		
Project title	Status	This RAG	Last RAG	Approved Cost (£m's)	F/Cast Cost (£m's)	F/cast Benefit (£m's)	Planned to complete	F/Cast to complete		
Brentwood Estates Optimisation	Delivery	G	A	7.1	6.9	1.4	Sep 15	Sep 16		
ISMS (Integrated Service Management Systems)	Delivery	G	G	0.6	0.7	N/A	Jan 15	Jun 15		
Key Machines Upgrade	Delivery	G	G	0.2	0.2	N/A	Jun 14	Aug 15		
ODT Infrastructure Refresh	Delivery	A	G	0.3	0.2	N/A	Nov 14	Jul 15		
Infrastructure Hosting Project (i)	Initiation	G	G	8.5	8.5	N/A	Jun 16	Jun 16		
OBOS Phase 2	Delivery	G	A	0.1	0.1	N/A	Dec 14	Jul 15		
Networks & Telephony Contract	Initiation	G	G	TBC	10.15	N/A	Dec 16	Dec 16		
Hematos Platform Upgrade	Start-Up	G	G	TBC	0.04	N/A	Jan 16	Jan 16		
Platform Selection (i)	Start-Up	G	-	0.08	TBC	N/A	Oct 15	Oct 15		
Automated Solution testing Service	Start-Up	G	-	0.06	0.1	N/A	TBC	TBC		

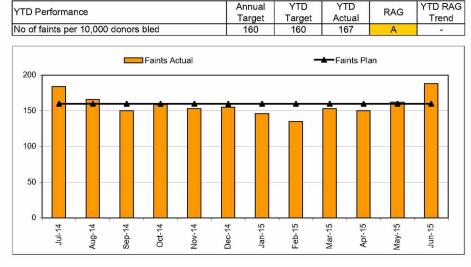
Note: i) Project is described in detail in the following table:

Project	RAG	Trend	Strategic Theme	Spend to date	Cost	Benefit	Complete
Infrastructure Hosting Project	G	-72	Group System & Processes	£0.6m	£8.5m	N/A	Jun 16
within plan and budget. Gl provide migration partners	DS have and the by NHS	been advis challenge th BT. A pape	igence with SCC and a stage-gate re ed of our plan to proceed with SCC ra his creates to procure this in our times r will be presented to the July NHSB on strategy.	ather than Crown Ho scales; CH cannot m	sting (CH). The re eet our latency red	easons for this incluquirements; CH do	ude: CH do not not offer the

# Corporate - Transformation project status (cont.)

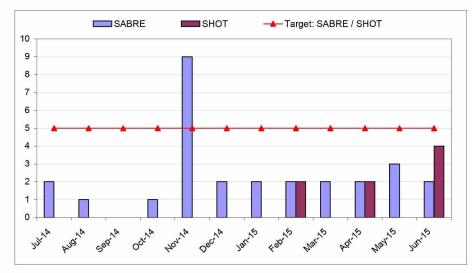
Project	RAG	Trend	Strategic Theme	Spend to date	Cost	Benefit	Complete
Platform Selection	G	-	Group System & Processes	-	£0.1m	N/A	Oct 15
platforms and implementat financial benefits from this national Hub etc.) to delive and procurement approach Resource Planning and Ma	tion partr project v er financi n for sele anageme	ners required will be seen al benefits. ection of sup ent). Working	d for potentially seven strategic IT pla d to deliver the first phases of the Pu as it will select the technology that w The project is now underway comme pliers for 5 IT Platforms (Customer, I g with external supplier (Transform) v ories and review of process maps.	lse Replacement Pro ill be used by project ncing with the 8 wee Donor, Manufacturing	gramme and the C s and programmes k agile/sprint activi g & Diagnostics, Bl	DDT National Hub. s (Pulse Replacem ities to deliver user PMS/Workflow Inte	No direct ent, ODT specifications egration and

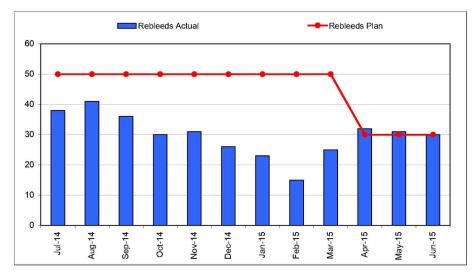
	Summary of key (net ) risks reflected in the r	isk register:		
	Corporate Risk Register Summary	Red	Amber	Green
	146	19	110	17
Risk Management	The dependency and reliance on the SMEs the particular their ability to retain the necessary of The ability to supply sufficient volumes/service (Pulse, Hematos, networks etc). The risk of data centre hosting, new desktop, PULSE report the scale of the transformation programme a NHSBT to safely execute the change (both IC). The ability to maintain a red cell blood price of to generate significant productivity improvements services (e.g. fewer / larger mobile sessions a not managed and communicated well.	capability to deliver to agree es in case of the loss of a k critical system loss is increa placement etc.) and the sign cross NHSBT/Blood will cre CT and business resources) of c£120 per unit (or better) ents in Blood Donation. In t	ed service levels. ey facility (e.g. Filton, Speke) or the asing on the back of the significant nificant complexity and inter-depen- eate a significant challenge on the and a potential distraction to delive after 2015/16 continues to remain l curn this will imply significant chang	e loss of critical IT systems changes that are planned (e.g. dency between them. capacity and capability of ering business as usual. highly dependant on being able es to the configuration of
	The downturn in demand from hospitals for re- offset the trend. This is having a significant ir term. If it were to continue for another 2-3 ye 2016/17 and beyond, as well as maintain the infrastructure and applications).	npact on our immediate fina ears we may be unable to re	ancial position, but this is being ma emove (fixed) costs at a sufficient p	naged / mitigated in the short pace to avoid price increases in
	There is a high prevalence of manual, paper testing and in the duty office within organ don there is a residual risk that these are ineffecti	ation and transplant. Altho	ugh these are mitigated by approp	riate manual control checks
	The availability of funding from 2016/17 onwa the ageing and inflexible NTxD platform.	ards would impact the delive	ery of the ODT 2020 strategy and e	specially the need to replace
	Changing clinical/commissioning intentions in outcomes and therefore the future viability of		I / BBMR, as a recommended trea	tment, are impacting on the
	There were no new high/extreme risks raised	this month.		



#### 1. On-Session Adverse Events - Faints per 10,000 Donors Bled

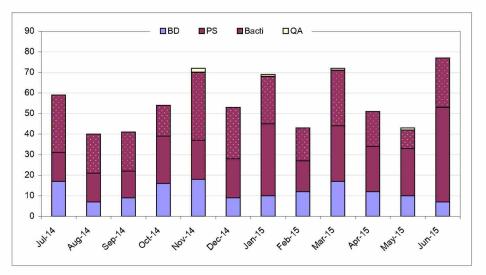
#### 3. SABRE and SHOT Events Reported per Month





#### 2. On-Session Adverse Events - Rebleeds per 10,000 Donors Bled

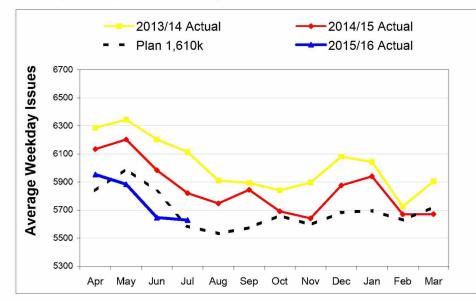
4. Major QI's raised per month - Blood Supply Directorate



Monthly Performance Report: As at the end of June 2015

Page 18 of 42

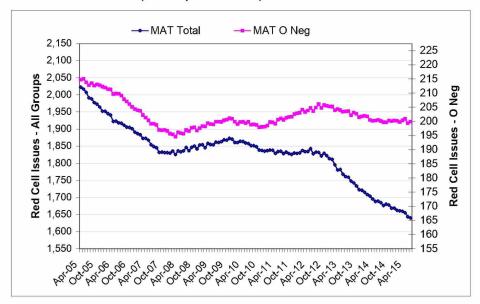
#### **Blood Supply Chain - Red Cell Demand**



#### 5. Average Weekday Red Cell Issues By Month -> April 2013

#### 7. Red Cell Supply - Year to Date by Blood Group

Blood Group	2015/16 - YTD June 15	2014/15 - YTD June 14	Change
A Neg	31,975	33,478	-4.5%
A Pos	122,644	129,634	-5.4%
AB Neg	3,109	3,213	-3.2%
AB Pos	8,993	9,386	-4.2%
B Neg	9,582	9,840	-2.6%
B Pos	32,147	33,312	-3.5%
O Neg	50,270	50,730	-0.9%
O Pos	144,729	153,086	-5.5%
Total	403,449	422,679	-4.5%

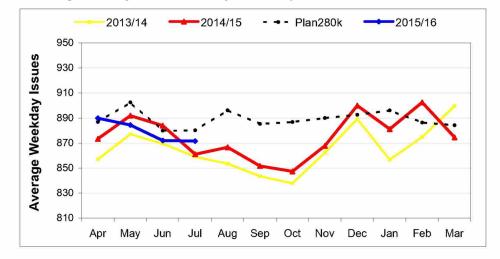


#### 6. MAT Red Cells Issues (Adult Equivalant Units) - 000's

#### 8. Red Cell Supply - Year to Date by Regional Transfusion Committee

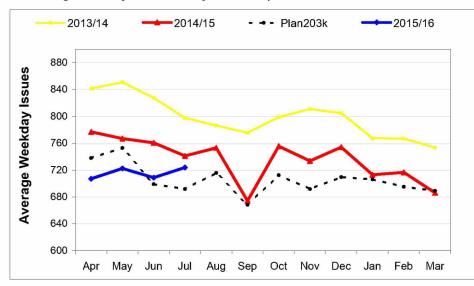
Regional Transfusion Committee	2015/16 - YTD June 15	2014/15 - YTD June 14	Change
EM - East Midlands	24,881	25,319	-1.7%
EE - East of England	37,668	40,162	-6.2%
LON - London	92,636	95,585	-3.1%
NE - North East	20,756	21,973	-5.5%
NW - North West	57,841	60,388	-4.2%
SC - South Central	26,906	27,231	-1.2%
SEC - South East Coast	28,074	29,215	-3.9%
SW - South West	33,131	36,920	-10.3%
WM - West Midlands	42,519	44,921	-5.3%
YH - Yorkshire and Humber	35,601	36,792	-3.2%
Other	3,436	4,173	-17.7%
Total	403,449	422,679	-4.5%

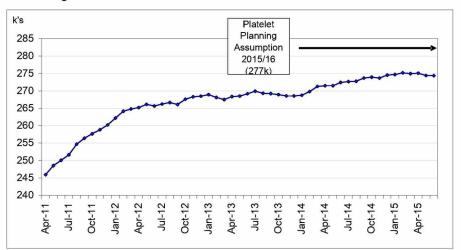
## **Blood Supply Chain - Platelet and Frozen Products Supply**



#### 9. Average Weekday Platelet Issues By Month ->April 2013

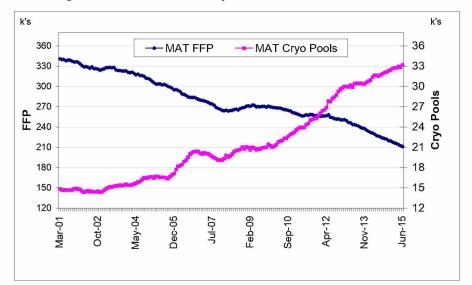
# 11. Average Weekday FFP Issues By Month ->April 2013



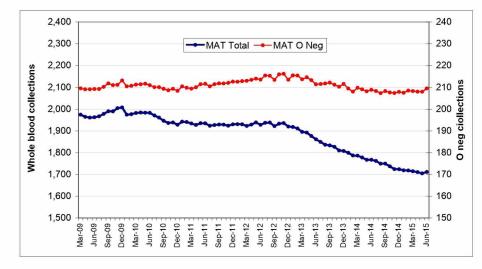


#### 10. Moving Annual Total Platelet Product Issues

#### 12. Moving Annual Total of FFP and Cryo Issues

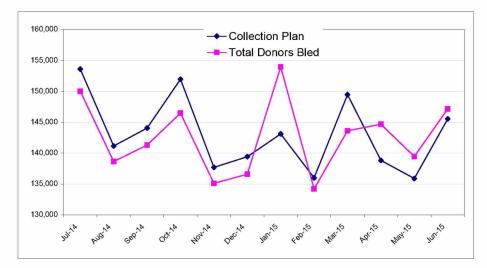


#### **Blood Supply Chain - Blood Donation**

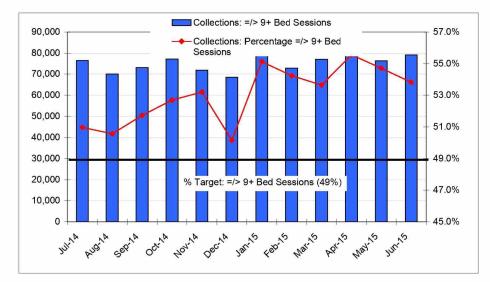


#### 13. MAT Whole Blood Donors Bled (Adult Equivalant Units) - 000's

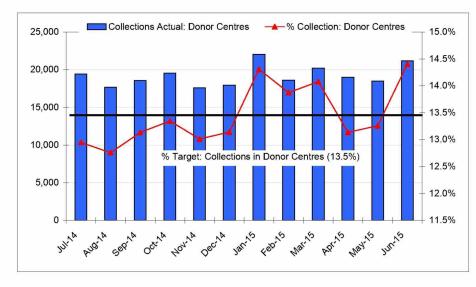
#### 14. Collections versus Plan



#### 16. Collections from 9+ Bed Sessions



#### 15. Collections in Donor Centres



Monthly Performance Report: As at the end of June 2015

Page 21 of 42

#### **Blood Supply Chain - Blood Donor Base**

#### 17. Donor Satisfaction

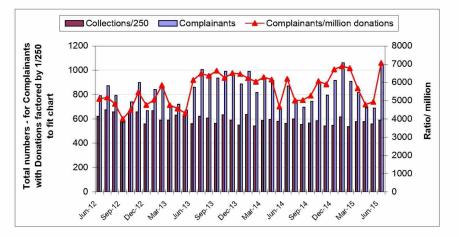


#### 19. Donor Base and Frequency of Donation

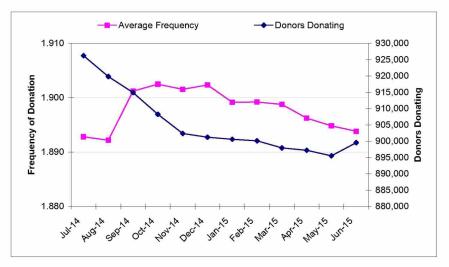
Current Month Position	Annual Target	Period Target	Period Actual	RAG	RAG Trend
Number of donors donating over the last 12 months	882	891.0	899.6	G	×
Frequency of donation overall	1.90	1.90	1.89	G	-
Number of O neg donors donating over the last 12 months	105	105.3	105.9	G	-
Frequency of O neg donation	1.98	1.98	1.98	G	-

#### 18. Donor Complaints

YTD Performance	Plan	YTD Plan	YTD Act	RAG	YTD RAG
Donor Complaints per million donations	4,900	5,733	5,612	G	-



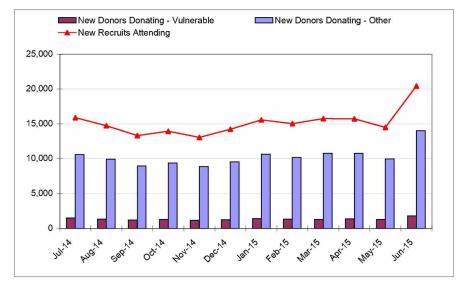
#### 20. Donor Base and Frequency of Donation



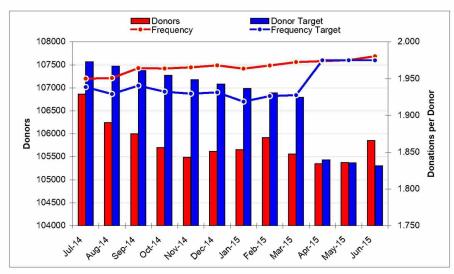
Page 22 of 42

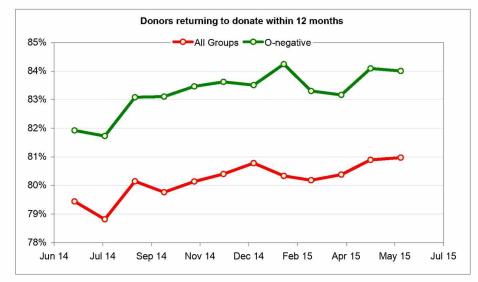
#### **Blood Supply Chain - Donor Recruitment and Retention**

#### 21. Donor Recruitment (Whole Blood)



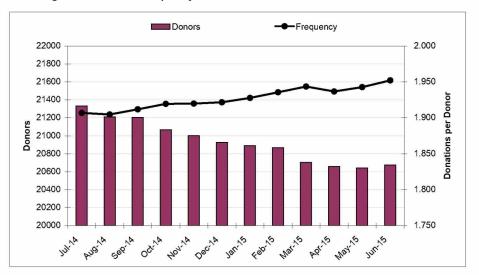
#### 23. O-Neg Donorbase and Frequency





#### 22. Donor Retention Rate (Whole Blood)

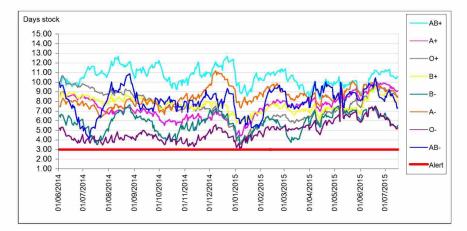
#### 24. B Neg Donorbase and Frequency



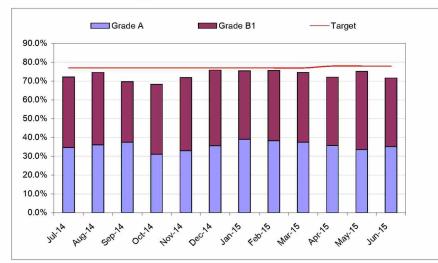
#### **Blood Supply Chain - Red Cell and Platelet Supply**

#### 25. Red Cell Weekday Stock Levels by Blood Group

YTD Performance	Annual Target	Period Target	Period Actual	RAG	YTD RAG Trend
Number of occasions where red cell stocks (for any blood group) are below the three day alert level for three or more consecutive days	0	0	0	G	e.



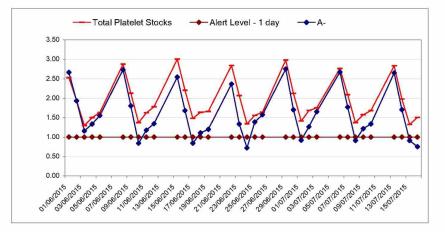
#### 27. % of Patients Receiving Grade A or B1 HLA Matched Platelets



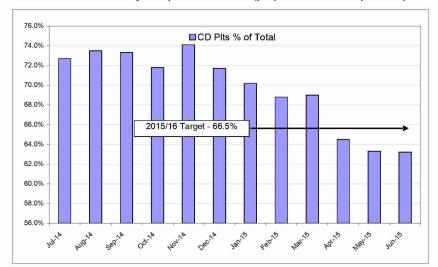
Monthly Performance Report: As at the end of June 2015

#### 26. Platelet Stock Levels

YTD Performance	Annual Target	Period Target	Period Actual	RAG	YTD RAG Trend
Number of occasions where opening stock of platelets (for any blood group) is below average daily demand for two or more consecutive days	0	0	0	G	÷



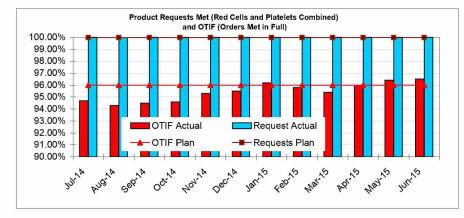
#### 28. Platelet Production by Component Donation (proportion of issues platelets)



#### **Blood Supply Chain - Customer Service**

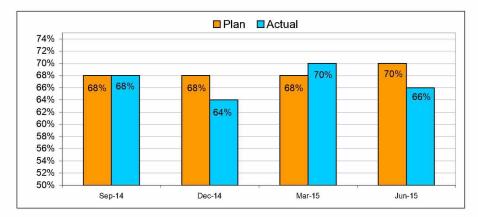
#### 29. Percentage of Product Requests Met and OTIF

YTD Performance	Annual Target	YTD Target	YTD Actual	YTD RAG	YTD RAG Trend
Percentage of Products Issued On-Time-In-Full (OTIF)	96.00%	96.00%	96.30%	G	-



#### 30. Hospital Satisfaction - next survey results due in September 2015

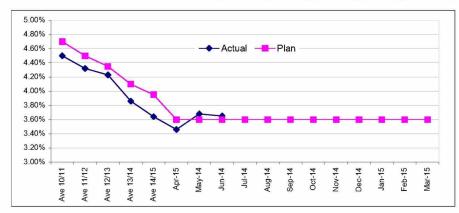
YTD Performance	Annual Target	YTD Target	YTD Actual	RAG	YTD RAG Trend
Percentage of hospitals scoring =/> 9/10 for satisfaction with overall service	70.0%	70.0%	66.00%	А	-



# **Blood Supply Chain - Wastage**

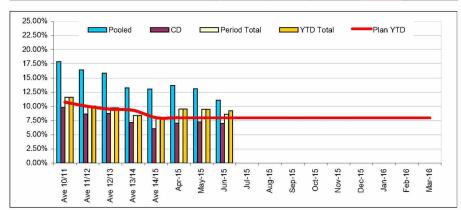
#### 31. Percentage of Donations NOT Converted to Validated Red Cells

YTD Performance	Annual Target	YTD Target	YTD Actual	RAG	YTD RAG Trend
Percentage of donations NOT converted to validated red cells (in conjunction with BD)	3.60%	3.60%	3.59%	G	-



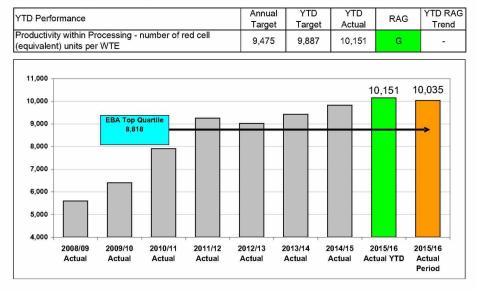
#### 32. Percentage of Platelets Produced NOT Issued

YTD Performance	Annual Target	YTD Target	YTD Actual	RAG	YTD RAG Trend
Percentage of platelets produced not issued	8.00%	8.00%	9.21%	R	-

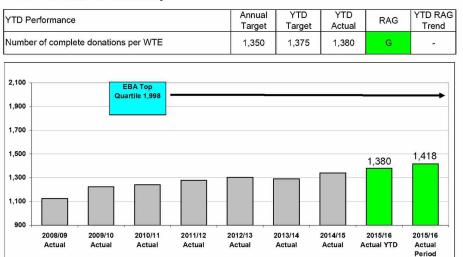


#### Blood Supply Chain - Productivity

#### **33. Processing Productivity**

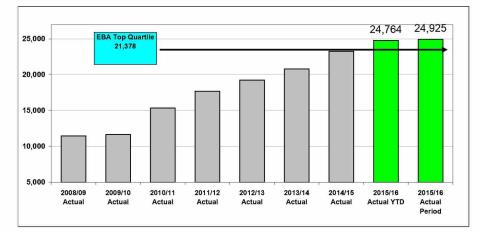


#### 35. Blood Donation Productivity

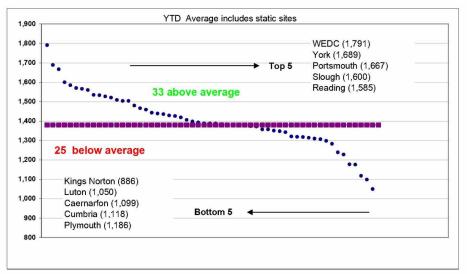


#### 34. Testing Productivity

YTD Performance	Annual Target	YTD Target	YTD Actual	RAG	YTD RAG Trend
Productivity within Testing - number of samples (excluding NAT) per WTE	22,250	24,081	24,764	G	-



#### 36. Blood Donation Productivity - Distribution Mobile Teams

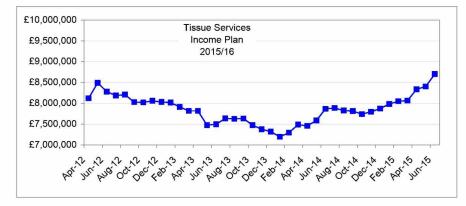


Monthly Performance Report: As at the end of June 2015

#### **Diagnostic and Therapeutic Services - Income**

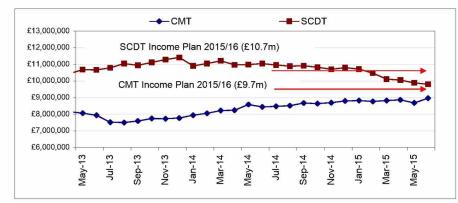
#### 37. Tissue Services Income (MAT)

YTD Performance	Annual Target	YTD Target	YTD Actual	RAG	YTD RAG Trend
Sales Income (£m)	£12.54	£2.89	£2.86	A	-



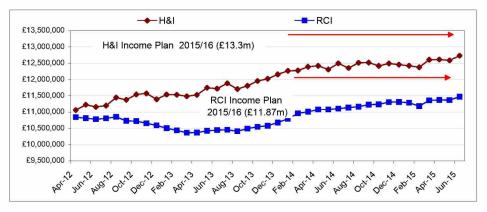
#### 39. Stem Cells - SCDT/CMT -incl. CBC from 1st April 2013 (MAT)

YTD Performance	Annual	YTD	YTD	RAG	YTD RAG
	Target	Target	Actual		Trend
Sales Income (£m) - CMT	£9.71	£2.12	£2.44	G	-
Sales Income (£m) - SCDT	£10.73	£2.67	£2.15	R	-



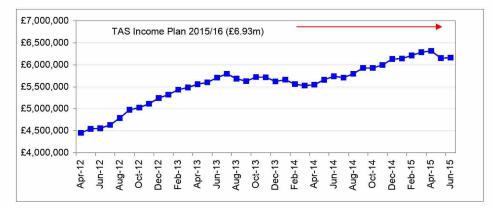
#### 38. Diagnostic Service Income (MAT)

YTD Performance	Annual Target	YTD Target	YTD Actual	RAG	YTD RAG Trend
Sales Income (£m) RCI	£11.87	£2.89	£2.87	A	
Sales Income (£m) - H&I	£13.34	£3.15	£3.18	G	



#### 40. Therapeutic Apheresis Services (MAT)

YTD Performance	Annual Target	YTD Target	YTD Actual	RAG	YTD RAG Trend
Sales Income (£m)	£6.93	£1.78	£1.50	R	-



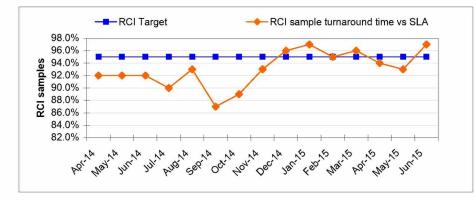
Monthly Performance Report: As at the end of June 2015

Page 27 of 42

# **Diagnostic and Therapeutic Services**

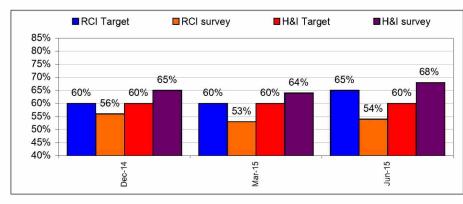
#### 41. Turnaround Time vs SLA (RCI)

YTD Performance	Annual Target	YTD Target	YTD Actual	RAG	YTD RAG Trend
RCI sample turnaround time vs SLA	95%	95%	94.7%	A	-



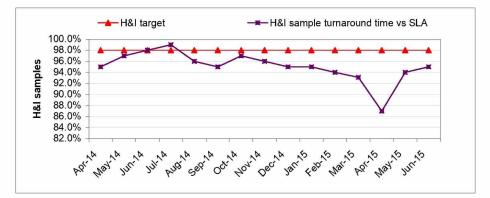
#### 43. Hospital Satisfaction - next survey results due in September 15

YTD Performance	Annual	YTD	YTD	DAC	YTD RAG
TTD Fenomance	Target	Target	Actual	RAG	Trend
Hospitals =/> 9/10 for satisfaction with - H&I	60.0%	60.0%	68.0%	G	-
Hospitals =/> 9/10 for satisfaction with - RCI	65.0%	65.0%	54.0%	R	-

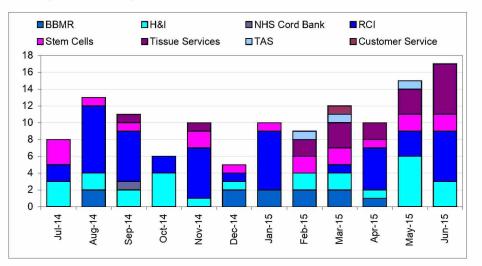


#### 42. Turnaround Time vs SLA (H&I)

YTD Performance	Annual Target	YTD Target	YTD Actual	RAG	YTD RAG Trend
H&I sample turnaround time vs SLA	98%	98%	90.8%	R	-



#### 44. Major QI's raised per month - DTS

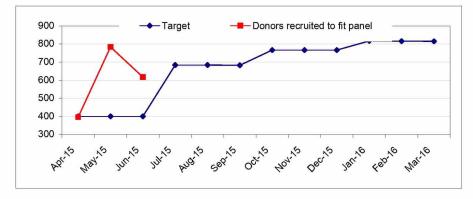


Monthly Performance Report: As at the end of June 2015

# **Stem Cell Donation and Transplantation**

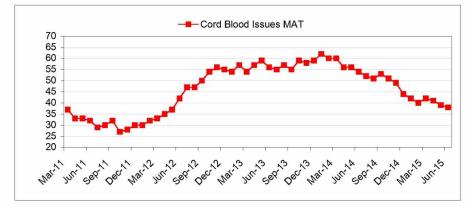
#### 45. Donors recruited to fit panel

YTD Performance	Annual Target	YTD Target	YTD Actual	RAG	YTD RAG Trend
Donors recruited to fit panel	8,000	1,467	1,798	G	- 1



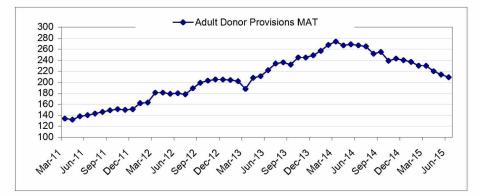
#### 47. Issue of cord blood units - MAT

YTD Performance	Annual Target	YTD Target	YTD Actual	RAG	YTD RAG Trend
Cord Blood Issues	60	15	7	R	-



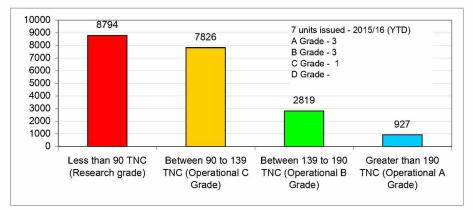
#### 46. Adult donor provisions - MAT

YTD Performance	Annual Target	YTD Target	YTD Actual	RAG	YTD RAG Trend
Adult donor provisions	270	65	41	R	



#### 48. NHSBT CBB stock (active units - cell dose post process TNC)

YTD Performance	Annual Target	YTD Target	YTD Actual	RAG	YTD RAG Trend
Banked Donations (Cumulative) TNC > 140	2,300	576	560	А	-

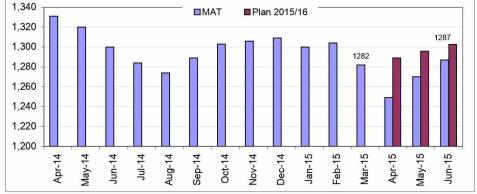


Monthly Performance Report: As at the end of June 2015

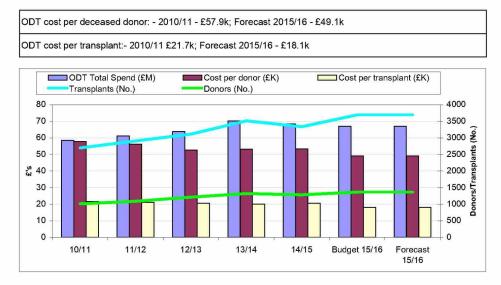
#### **Organ Donation and Transplant - Outcomes**

#### 49. MAT number of Deceased Organ Donors

YTD Performance	Annual Target	YTD Target	YTD Actual	YTD RAG	YTD RAG Trend
Number of Deceased Organ Donors	1365	341	316	R	-
	0.000		of the restriction of		

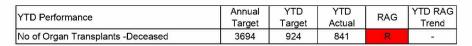


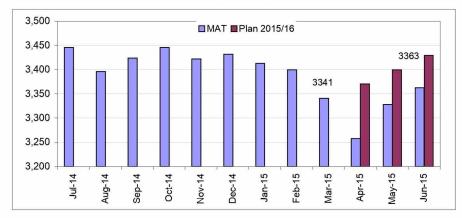
#### 51. ODT Cost per Donor/Transplant



Monthly Performance Report: As at the end of June 2015

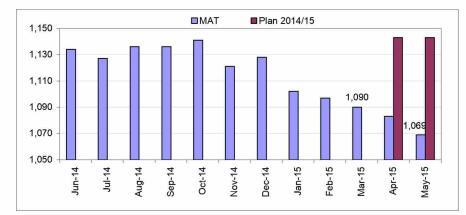
50. MAT number of Deceased Organ Transplants





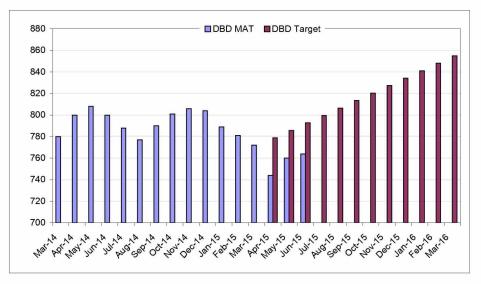
#### 52. MAT number of Live Organ Donors (reported one month in arrears)

YTD Performance	Annual	YTD	YTD	YTD	YTD RAG
	Target	Target	Actual	RAG	Trend
Number of Live Organ Donors	1223	204	146	R	-

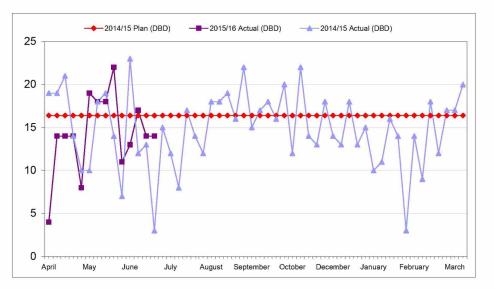


Page 30 of 42

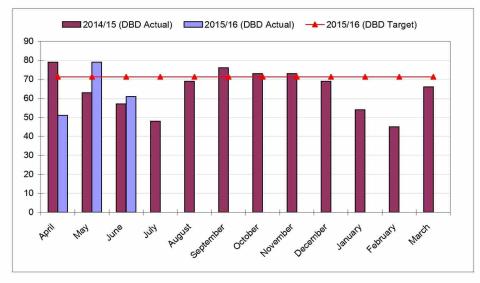
#### 53. MAT number of Deceased Organ Donors (DBD)



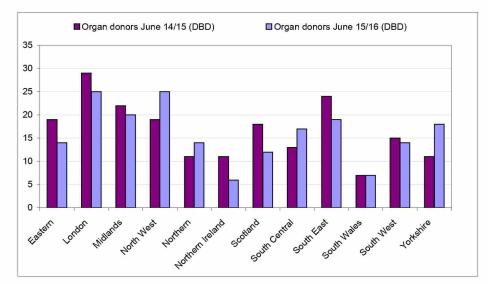
#### 55. Deceased Organ Donors - Weekly (DBD)



54. Deceased Organ Donors - Monthly (DBD)



56. Deceased Organ Donors - Team (DBD)

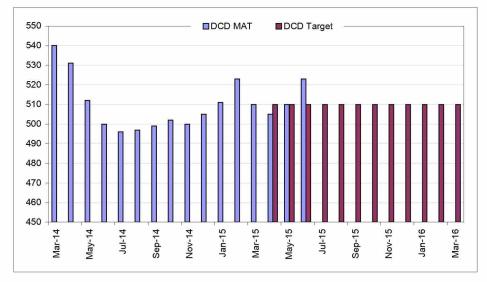


Monthly Performance Report: As at the end of June 2015

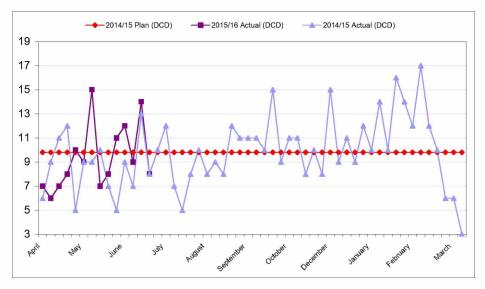
Page 31 of 42

#### Organ Donation and Transplant - Pathway 2 of 6

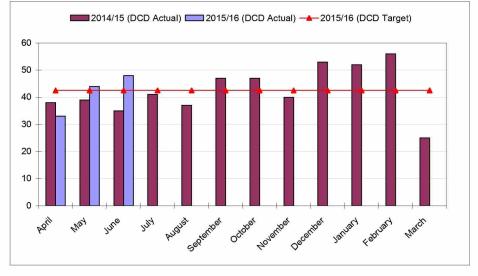
#### 57. MAT number of Deceased Organ Donors (DCD)



#### 59. Deceased Organ Donors - Weekly (DCD)

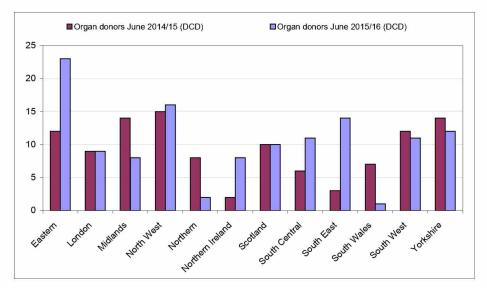


Monthly Performance Report: As at the end of June 2015



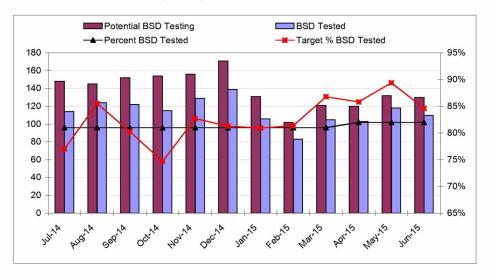
#### 58. Deceased Organ Donors - Monthly (DCD)

60. Deceased Organ Donors - Team (DCD)



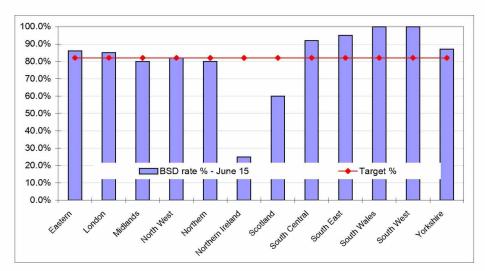
Page 32 of 42

#### Organ Donation and Transplant - Pathway 3 of 6

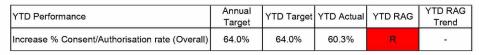


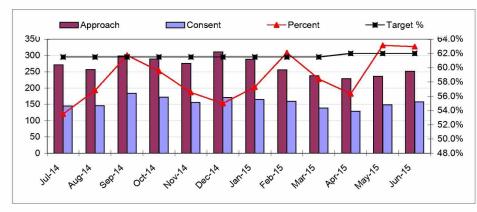
#### 61. Brain Stem Death Testing Rate (DBD &DCD) - Trend

# 62. Brain Stem Death Testing - by Region

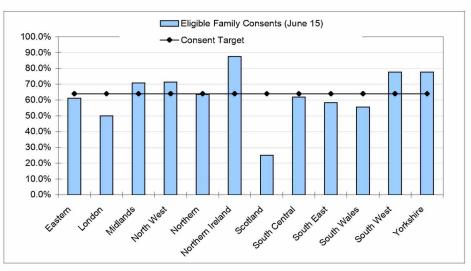


#### 63. Consent/Authorisation rate (DBD/DCD)





#### 64. Consent/Authorisation rate % by Region

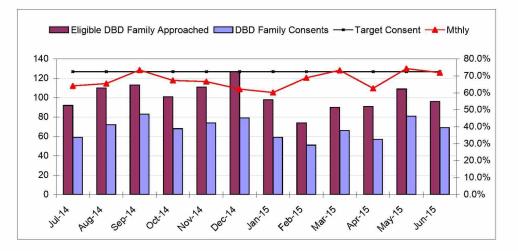


Monthly Performance Report: As at the end of June 2015

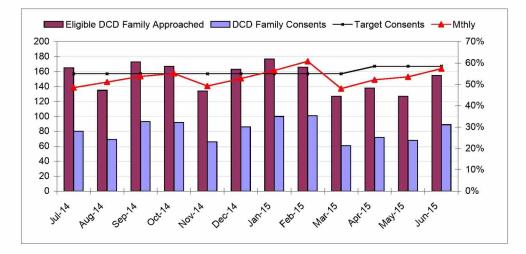
Page 33 of 42

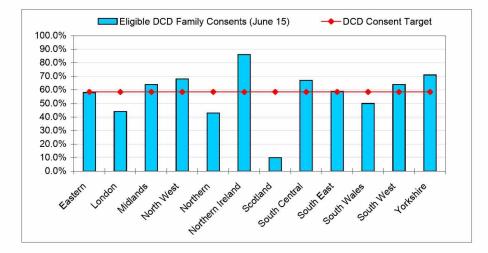
#### **Organ Donation and Transplant - Pathway 4 of 6**

#### 65. Consent/Authorisation rate (DCD) per Month and MAT%



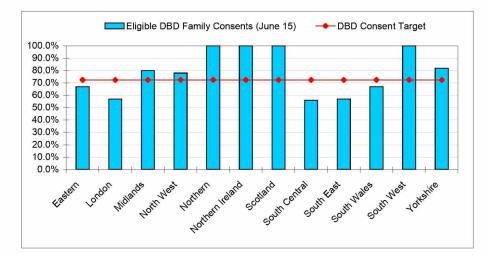
#### 67. Consent/Authorisation rate (DBD) per Month and MAT%





#### 66. Consent/Authorisation rate (DCD) % by Region

#### 68. Consent/Authorisation rate (DBD) % by Region



Monthly Performance Report: As at the end of June 2015

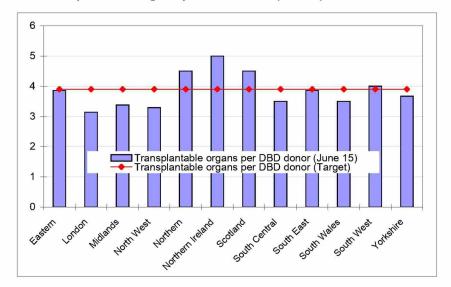
Page 34 of 42

# Organ Donation and Transplant - Pathway 5 of 6

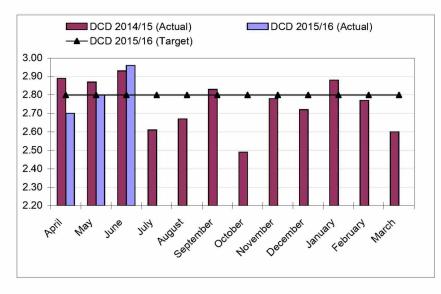
#### DBD 2014/15 (Actual) DBD 2015/16 (Actual) → DBD 2015/16 (Target) 4.20 4.10 4.00 3.90 3.80 3.70 3.60 3.50 3.40 3.30 September December October November JUNY May June August Poril er January February March

#### 69. Transplantable Organs per DBD Donor

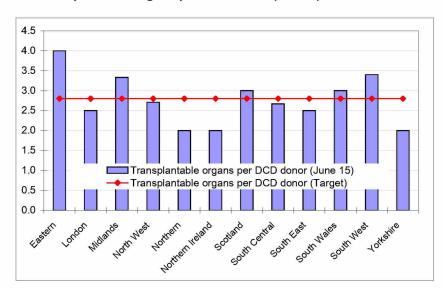
70. Transplantable Organs per DBD Donor (Teams)



#### 71. Transplantable Organs per DCD Donor



72. Transplantable Organs per DCD Donor (Teams)



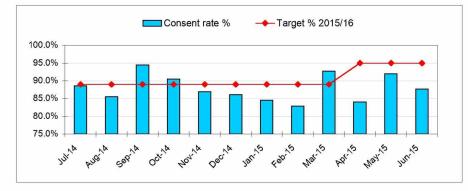
Monthly Performance Report: As at the end of June 2015

Page 35 of 42

#### Organ Donation and Transplant - Pathway 6 of 6

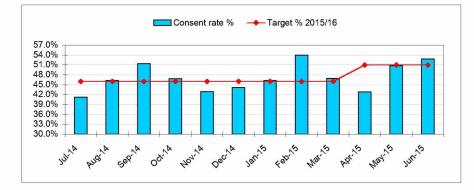
#### 73. % Consent/Authorisation rate (patient expressed wish to donate on the ODR)

YTD Performance	Annual Target	YTD Target	YTD Actual	YTD RAG	YTD RAG Trend
% Consent/Authorisation rate (patient expressed a wish to donate on ODR)	95.0%	95.0%	87.9%	R	1



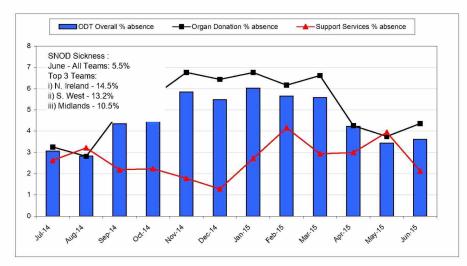
# 74. % Consent/Authorisation rate (patient not expressed a wish to donate or ODR status not known)

YTD Performance	Annual Target	YTD Target	YTD Actual	YTD RAG	YTD RAG Trend
% Consent/Authorisation rate (patient not expressed a wish to donate or ODR status not known)	51%	51.0%	48.9%	А	

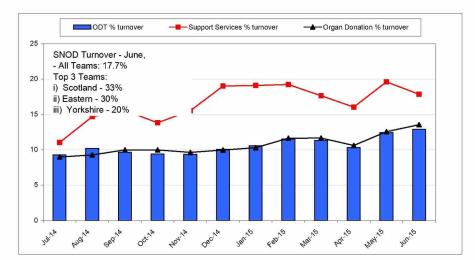


## **Organ Donation and Transplant - Absence/Turnover**

#### 75. ODT Absence rate



#### 76. Annual Turnover rate

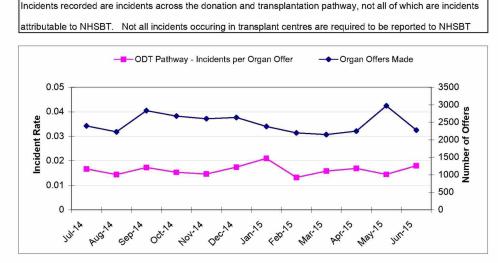


Monthly Performance Report: As at the end of June 2015

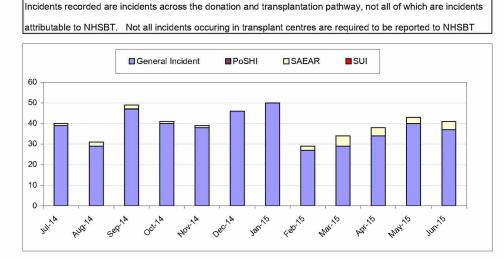
Page 36 of 42

#### Organ Donation and Transplant - ODT Pathway - Incidents / ODR

#### 77. ODT Pathway - Incidents per Organ Offer

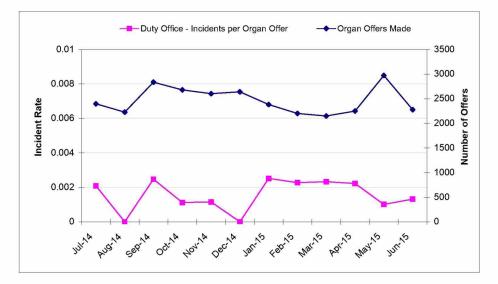


#### 79. ODT Pathway - Incidents



Monthly Performance Report: As at the end of June 2015

#### 78. Duty Office - Incidents per Organ Offer



#### 80. Number of people registered on the ODR

YTD Performance	Annual Target	YTD Target	YTD Actual	YTD RAG	YTD RAG Trend
New Registrations on the ODR (m)	2.00	0.25	0.31	G	Better



Page 37 of 42

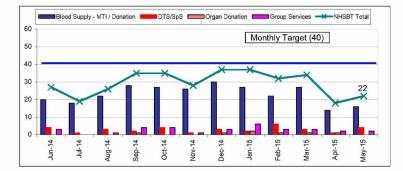
## NHSBT Corporate - ICT / Workforce

#### 81. IT system performance

System availability	Period Target	Period Actual	Period RAG	RAG Trend
Donor Portal	99.99%	98.97%	R	Worse
-				
Pulse	99.99%	99.38%	R	Worse
OBOS	99.99%	100.0%	G	Better
Hematos	99.99%	98.71%	R	Worse
EOS	99.99%	100%	G	-
NtXD	99.99%	100%	G	-
	1	l		
тмѕ	99.99%	100%	G	-

#### 82. Health and Safety - Accident Reporting

H&S Incident Levels (x 1 mth	Level 1&2	Level 1&2 MAT	Level 1-3	Level 1-3
in arrears)	MAT Target	Total	Mthly Target	Period Actual
Blood Supply - MTI / Donation	=/<28	31	=/<35	16
DTS/SpS	=/<2	1	=/<2	4
Organ Donation	0	1	1	0
Group Services	=<10	9	=/<3	2
NHSBT	=<40	42	=/<40	22



## 83. Headcount / WTE (as at payroll date)

Function	Plan WTE (Ave YTD)		Variance WTE	Variance %
Blood Supply: Manufacturing, Testing & Issue	841	812	29	3.4%
Blood Supply: Blood Donation	1,585	5 1,588	-2	-0.29
Diagnostic and Therapeutic Services	793	3 757	37	4.6%
Organ Donation (including Group Services)	387	381	7	1.79
Sub-total Operational	3,607	3,538	70	1.9%
CEO and Board		3 4	-1	-20.39
Quality	86	82	5	5.6%
Communications	65	5 52	13	20.79
Estates & Facilities	82	2 76	5	6.69
Blood Supply: Logistics	362	332	29	8.19
Finance	101	101	1	0.69
HR and BTS Project Management	147	/ 141	6	4.0%
BTS - Information Communication Technology	154	134	20	13.29
Clinical	189	178	10	5.5%
Research and Development	47	64	-17	-35.9%
Change Programme & Development	4	9	-5	-113.39
Sub-total Group Service	1,240	1,172	68	-105
Total	4,847	4,710	137	2.89
% Operational WTE to Total WTE	74%	75%	51%	

YTD Variance %	YTD Variance £k	YTD Total Actual Pay Spend £k	YTD Temporary Staff Spend £k	YTD Employee Pay Spend £k	YTD Pay Budget £k
0 -0.4%	-£30	£7,687	£247	£7,440	£7,657
9 1.4%	£189	£13,053	£243	£12,810	£13,242
5 5.5%	£495	£8,478	£50	£8,428	£8,972
6 5.0%	£306	£5,823	£187	£5,636	£6,129
0 2.7%	£960	£35,041	£728	£34,313	£36,001
	£4	£108	£0	£108	£111
7 8.8%	£97	£1,008	£0	£1,008	£1,106
7 4.1%	£27	£635	£65	£571	£663
2 0.2%	£2	£842	£31	£811	£843
6.8%	£210	£2,858	£48	£2,810	£3,068
2 1.9%	£22	£1,144	£13	£1,131	£1,165
2 0.1%	£2	£1,758	£29	£1,729	£1,760
6 2.5%	£46	£1,769	£95	£1,674	£1,815
2 3.3%	£102	£3,017	£12	£3,005	£3,119
2 -29.2%	-£182	£804	£32	£772	£623
2 -0.5%	-£2	£510	£407	£103	£508
7 2.2%	£327	£14,454	£732	£13,723	£14,782
7 2.5%	£1,287	£49,495	£1,459	£48,036	£50,782

Monthly Performance Report: As at the end of June 2015

Page 38 of 42

# NHSBT REVENUE STATEMENT - FOR THE PERIOD ENDED 30 JUNE 2015

	Period				Year to date	1	[	Full y	ear	
Budget	Actual	Variance	Income	Budget	Actual	Variance	2014-15 Actual	Initial Budget	Latest Budget	Forecast
£k	£k	£k		£k	£k	£k	£k	£k	£k	£k
5,152	5,152	0	Revenue Cash Limit - Organ Donation & Transplantation	15,457	15,457	0	56,601	61,827	61,827	61,827
356	356	0	Revenue Cash Limit - Diagnostic and Therapeutic Services	1,068	1.068	0	4,373	4,273	4,273	4,273
0	0	0	Revenue Cash Limit - Other	0	0	0	2,074	0	0	0
23,394	23,400	5	Blood & Components Income	67,972	68,318	346	284,507	270,516	270,516	270,353
5,320	5,501	181	Diagnostic and Therapeutic Services Income	15,356	14,890	(466)	56,689	64,443	64,443	61,867
364	490	126	Research & Development	1,092	1,271	178	5,475	2,873	2,873	2,705
975	1,063	88	Organ Donation & Transplantation Other Income	2,925	3,029	103	13,922	11,702	11,702	11,702
387	377	(10)	All Other Income	1,128	1,155	27	5,574	4,591	4,597	4,508
35,949	36,340	390	Total Income	104,999	105,188	189	429,215	420,224	420,230	417,234
			Expenditure							
(194)	583	776	Cost of Sales - Blood Component Stock Movement	(576)	1,592	2,168	(1,828)	0	0	226
(134)	(13)	(13)	Cost of Sales - Tissues Stock Movement	(370)	63	63	(1,020)	0	0	0
(5,098)	(4,854)	244	Organ Donation & Transplantation Operational Expenditure	(15,524)	(14,851)	673	(63,288)	(65,463)	(65,463)	(64,473)
(6,078)	(6,148)	(70)	Blood Supply: Manufacturing, Testing & Issue	(18,044)	(18,114)	(70)	(71,271)	(70,183)	(70,295)	(70,188)
(6,968)	(7,036)	(67)	Blood Supply: Blood Donation	(21,646)	(21,022)	625	(88,395)	(83,296)	(83,363)	(82,184)
(1,915)	(2,076)	(161)	Blood Supply: Logistics	(5,699)	(5,859)	(160)	(22,996)	(22,943)	(22,943)	(23,480)
(4,784)	(4,656)	128	Diagnostic and Therapeutic Services	(14,321)	(13,614)	708	(51,121)	(56,745)	(56,745)	(55,522)
(437)	(395)	42	Quality	(1,287)	(1,164)	124	(4,520)	(5,136)	(5,136)	(4,936)
(90)	(97)	(7)	Chief Executive and Board	(218)	(215)	3	(551)	(623)	(623)	(623)
(390)	(375)	15	Communications	(1,054)	(1,032)	23	(5,052)	(5,054)	(5,054)	(5,054)
(3,339)	(3,315)	24	Estates & Facilities	(9,773)	(9,545)	228	(39,891)	(38,138)	(38,229)	(38,179)
(566)	(542)	24	Finance	(1,692)	(1,647)	45	(6,675)	(6,707)	(6,707)	(6,597)
(722)	(760)	(38)	HR and BTS Project Management	(2,282)	(2,234)	48	(8,936)	(9,418)	(9,207)	(9,083)
(1,549)	(1,542)	8	BTS - Information Communication Technology	(4,528)	(4,746)	(218)	(18,019)	(18,409)	(18,609)	(19,095)
(1,156)	(1,171)	(15)	Clinical Directorate	(3,433)	(3,372)	61	(13,391)	(13,671)	(13,671)	(13,961)
(438)	(519)	(80)	Research & Development	(2,081)	(2,343)	(262)	(8,861)	(6,295)	(6,295)	(6,545)
(330)	(300)	30	Change Programme & Development	(1,074)	(1,074)	(0)	(8,343)	(17,228)	(16,945)	(16,945)
(138)	(288)	(150)	Miscellaneous and Capital Charges	(325)	(48)	277	(426)	(914)	(946)	(596)
(34,191)	(33,502)	689	Total Expenditure	(103,559)	(99,225)	4,334	(413,558)	(420,224)	(420,230)	(417,234)
1,758	2,838	1,079	Surplus/(Deficit)	1,440	5,963	4,523	15,658	0	0	0
1,700	2,000	1,010	earpreaterenty	1,40	0,000	4,020	10,000	0	0	0
			Statutory Accounts Presentation							
			NHSBT Surplus/(Deficit) as above	1,440	5,963	4,523	15,658	0	0	0
			Add back Notional Cost of Capital	1,630	1,630		6,703	6,520	6,520	6,520
			Remove Revenue Cash Limit	(16,525)	(16,525)		(63,048)	(66,100)	(66,100)	(66,100)
			Deduct Capital Charges Cash Payment	(4,112)	(4,112)		(16,267)	(16,447)	(16,447)	(16,447)
			Net Expenditure	(17,567)	(13,044)	4,523	(56,954)	(76,027)	(76,027)	(76,027)

# NHSBT BALANCE SHEET AT 30 JUN 2015

	Jun 2014 £k	Mar 2015 £k	Jun 2015 £k	Forecast YE £k
Fixed Assets	168,396	178,101	176,505	176,67
<u>Current Assets</u> Stocks Trade Debtors (incl accrued income) Prepayments Other Debtors Bank and Cash Less:-	17,566 25,536 9,989 1,029 <u>39,063</u> 93,183	16,824 23,998 7,915 2,997 <u>22,112</u> 73,846	18,212 30,144 12,486 1,807 <u>43,070</u> 105,719	17,0 24,0 8,0 2,8 <u>21,0</u> 72,8
Current Liabilities Trade Creditors Accruals and Deferred Income DH Cash Limit Drawn in Advance DH Capital Charges payable Others	6,648 24,179 146 4,067 <u>9,044</u> 44,084	2,435 15,195 <u>1,839</u> 19,469	9,430 22,918 4,112 <u>10,078</u> 46,538	2,5 14,7 
Net Current Assets	49,099	54,377	59,181	53,4
Finance Lease Creditor	4,594	4,512	4,392	4,3
Provisions Total Net Assets	<u>5,472</u> 207,429	2,681 225,285	2,528 228,766	2,00
Represented by:-				
Department of Health Funding General Reserve Revaluation & Donated Asset Reserve Total Dept of Health Funding	160,415 47,014 207,429	172,252 53,033 225,285	175,733 53,033 228,766	170,82 53,03 223,84

# NHSBT CASH FLOW AND STATISTICS FORECAST 2015/16

	Actual Apr-15 £k	Actual May-15 £k	Actual Jun-15 £k	Forecast Jul-15 £k	Forecast Aug-15 £k	Forecast Sep-15 £k	Forecast Oct-15 £k	Forecast Nov-15 £k	Forecast Dec-15 £k	Forecast Jan-16 £k	Forecast Feb-16 £k		Total £k
Opening bank balance	22,112	18,001	37,784	43,070	45,078	50,536	57,445	56,653	51,437	53,296	54,654	50,762	22,112
Receipts													
Debtors & Other Receipts	18,149	34,333	36,157	30,100	30,100	30,100	30,100	30,100	30,100	30,100	30,100	30,100	359,539
Revenue Cash Limit	0	16,525	0	5,508	5,508	5,509	5,508	5,508	5,509	5,508	5,508	5,509	66,100
Capital Cash Limit	0	0	0	2,500	0	2,000	0	0	0	2,500	0	1,500	8,500
Total income	18,149	50,858	36,157	38,108	35,608	37,609	35,608	35,608	35,609	38,108	35,608	37,109	434,139
Payments													
Staff Expenses	10,651	16,327	16,286	16,500	16,500	16,500	16,500	16,500	16,500	16,500	16,500	23,000	198,264
Other Revenue Payments	10,477	14,662	14,235	19,500	13,500	14,000	19,500	15,500	16,500	19,400	21,800	32,966	212,040
Capital Charges	0	0	0	0	0	0	0	8,224	0	0	0	8,223	16,447
Capital Payments	1,132	86	350	100	150	200	400	600	750	850	1,200	2,682	8,500
Total costs	22,260	31,075	30,871	36,100	30,150	30,700	36,400	40,824	33,750	36,750	39,500	66,871	435,251
Closing bank balance	18,001	37,784	43,070	45,078	50,536	57,445	56,653	51,437	53,296	54,654	50,762	21,000	21,000
Debtor Days (Target is 22 days)	37	36	29										
YTD BPPC By Value % (Target is 95%)	98.7%	99.1%	99.1%										
YTD BPPC By Number % (Target is 95%)	96.4%	97.1%	97.1%										

			Diagnostics				Stem Cells				
Year to date Actual £m	Blood & Components inc. R&D	RCI	H&I	Reagents	Tissue & Eye Services	СМТ	BBMR	СВВ	TAS	ODT	TOTAL
Income											
Prices	69.4	2.8	3.2	0.4	2.9	2.1	0.5	0.1	1.5	=	82.9
Central Funding from DHAs	-	-	-	-	-	-	-		-	3.0	3.0
Grant in Aid	-	-	-	-	-	0.0	0.5	0.6	-	15.5	16.5
Other	1.7	0.2	0.0	-	-	0.3	0.1	0.3	0.1	0.0	2.8
Total Income	71.1	3.0	3.2	0.4	2.9	2.4	1.2	1.0	1.5	18.5	105.2
Expenditure											
Variable Costs											
Consumables	(11.4)	(0.3)	(0.9)	(0.1)	(0.4)	(0.4)	(0.2)	(0.1)	(0.4)	(1.1)	(15.3)
Other	(0.4)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.4)
Total Variable Costs	(11.8)	(0.3)	(0.9)	(0.1)	(0.4)	(0.4)	(0.2)	(0.1)	(0.4)	(1.1)	(15.8)
Variable Contribution	59.4	2.7	2.3	0.3	2.5	2.1	0.9	0.9	1.1	17.3	89.4
Direct Costs											
Pay	(22.8)	(1.5)	(1.4)	(0.2)	(1.3)	(1.0)	(0.5)	(0.5)	(0.4)	(5.9)	(35.6)
Non Pay	(7.7)	(0.2)	(0.2)	(0.0)	(0.4)	(0.2)	(0.3)	(0.1)	(0.2)	(8.1)	(17.5)
Total Direct Costs	(30.5)	(1.7)	(1.6)	(0.2)	(1.7)	(1.2)	(0.8)	(0.7)	(0.6)	(14.0)	(53.0)
Direct Contribution	28.9	1.0	0.7	0.1	0.8	0.8	0.1	0.2	0.4	3.3	36.4
Direct Support											
Operational Directorate costs	(1.5)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.4)	(1.9)
Logistics	(5.3)	(0.0)	(0.0)	(0.0)	(0.2)	(0.0)	(0.0)	(0.0)	(0.0)	(0.3)	(5.8)
Clinical	(2.1)	(0.1)	(0.0)	-	(0.0)	(0.0)	(0.0)	(0.0)	(0.1)	(0.2)	(2.6)
Attributable Estates costs	(5.6)	(0.3)	(0.2)	(0.0)	(0.3)	(0.3)	(0.0)	(0.1)	(0.0)	(0.3)	(7.2)
Attributable IT costs	(0.8)	(0.1)	(0.1)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.0)	(0.7)	(1.8)
Depreciation / Cost of Capital Total Direct Support	(0.6) (16.0)	(0.1) (0.6)	(0.1) (0.4)	(0.0) (0.1)	(0.1) (0.6)	(0.1) (0.5)	(0.0) (0.1)	(0.0) (0.2)	(0.0) (0.2)	(0.0) (1.9)	(1.1) (20.5)
Cost of Sales	1.7	(0.0)	(0.4)	(0.1)	0.0	(0.5)	(0.1)	(0.2)	(0.2)	(1.9)	(20.3)
Contribution to Unallocated Costs	14.6	0.4	0.3	(0.0)	0.0	0.4	0.0	0.0	0.3	1.4	17.6
Total Allocated Costs	(56.6)	(2.6)	(2.9)	(0.4)	(2.6)	(2.1)	(1.2)	(1.0)	(1.3)	(17.1)	(87.6)
Unallocated Costs Apportioned	(00.0)	(2.0)	(2.3)	(0.4)	(2.0)	(2.1)	(1.2)	(1.0)	(1.5)	(17.1)	(07.0)
Directorate costs	(7.1)	(0.3)	(0.4)	(0.1)	(0.3)	(0.3)	(0.2)	(0.1)	(0.2)		(8.9)
Estates costs	(1.8)	(0.3)	(0.4)	(0.1)	(0.3)	(0.3)	(0.2)	(0.1)	(0.2)		(2.2)
Depreciation / Cost of Capital	(0.4)	(0.1)	(0.1)	(0.0)	(0.1)	(0.1)	(0.0)	(0.0)	(0.0)	-	(2.2)
Total Unallocated Costs	(9.2)	(0.0)	(0.0)	(0.0)	(0.0)	(0.3)	(0.0)	(0.0)	(0.0)	-	(0.4)
Net Surplus / (Deficit)	5.3	(0.0)	(0.1)	(0.1)	(0.2)	0.0	(0.2)	(0.1)	0.0	1.4	6.0
RAG STATUS (Actuals V Plan)	G	G	G	R	G	G	R	R	G	G	G
R&D PROGRAMME COSTS	(2.2)	(0.4)	(0.1)	-	(0.3)	(0.5)	-	-	-	-	(3.5)

# NHSBT HIGH LEVEL ABC CONTRIBUTION ANALYSIS FOR THE PERIOD ENDED 30 JUNE 2015

# NHS BLOOD AND TRANSPLANT

# JULY 2015

# CLINICAL GOVERNANCE REPORT

# 1. INCIDENTS AND ADVERSE EVENTS

# 1.1 Serious Incident Requiring Investigation (SIRI)

There has been one new SIRI since the last report; which occurred in Tissue Services (TS).

### Heart valve SIRI:

A call was received by staff in TS from a senior nurse at a Trust stating that an aortic valve had been received instead of a pulmonary valve. The paperwork accompanying the tissue and its packaging stated the graft was a pulmonary valve, but theatre staff identified that it was in fact an aortic valve. The surgeon decided to proceed with the operation using an alternative tissue, a bovine pericardial patch, and it has been confirmed that this achieved a satisfactory result. The surgeon has also informed our investigating team that using the alternative tissue posed no incremental risk to the patient, and therefore the surgical team had not informed the patient's family of our error, considering it a near miss incident rather than one having caused harm. On that basis, the Trust has raised a quality incident but has not escalated it further.

The corresponding valve obtained from the same donation, labelled as an aortic valve, was quarantined by TS. On return of the valve to TS from the hospital, it was confirmed the two valves had been switched at some point during the processing, labelling, and transfer to storage procedures.

The operator who had been responsible for these steps in the process has been suspended from duties, having informed the investigation team that procedures had not been followed. A management investigation of this operator's practice has commenced. All heart valve tissues processed by this operator, 45 in total, were identified and put on hold pending the Root Cause Analysis (RCA) and risk assessment. It is planned to return 22 valves to issue stock on the basis that the other valve of the pair has been issued and used; it is being invsetigated whether the remaining 23 could be imaged whilst frozen, and returned to stock if correct.

Apologies have been given to the team at the Trust, both verbally and in a formal letter, including an offer to meet and discuss the incident. We have also offered to provide a copy of our final report. Apologies were offered to the patient's family via the Trust; however, this has not been passed on. In order to be as open as possible about this incident, we will send the final report to the Trust Medical Director as well as the surgical team, explaining that we have made an error, and the situation regarding communication with the family.

The incident has been reported to the Human Tissue Authority (HTA) but it does not fulfil the criteria for NHSBT to report to the Care Quality Commission (CQC).

# Update on SIRIs previously reported:

**The needlestick injury** SIRI which occurred in Blood Supply was presented at the Clinical Audit Risk and Effectiveness Committee (CARE) with a recommendation this be closed by the GAC. This will be done offline. Opportunities for shared learning from the incident are currently being reviewed by DTS CARE and ODT CARE.

The Bristol Eye Bank SIRI currently remains open as one action is yet to be closed; 'Confirm the additional investigations performed by the Mycology lab on samples from the media from time expired corneas are negative. If results are positive re-evaluation must be performed regarding the suitability for release'. It is currently thought the results are negative; however, they are being followed up for completeness. This action is therefore due to be closed imminently.

A letter of commendation has been sent to lan Trenholm by the Chair of the Ocular Tissue Advisory Group, a consultant ophthalmologist in Bristol who acts as the Medical Director of the Eye Bank. The letter praises the Head of Tissue Services and her team for an excellent job in taking over the eye bank. Corneal stock is now over 300, the highest for some time. TS and quality staff are working closely with the Bristol Eye bank to promote a quality culture; this has resulted in reoprting of 7 quality incidents, a number which will fall as standards improve. The business case for transfer of the Eye Bank to Filton has been approved.

# 1.2 Donor and patient adverse events/reactions

A total of four Serious Adverse Events of Donation (SAED) occurred since the last report; including the first with respect to autologous serum eye drop collection. A 60 year old female fainted on session; fortunately she sustained no injuries. She had a significant medical history but had previously donated uneventfully five times for autologous serum eye drop production. She was taken to hospital and given antibiotics and subsequently was given a blood transfusion due to her haemoglobin being low; she stayed in hospital for five days. She will be offered the donor serum eye drop product and hence will not donate again. There were no NHSBT process errors in this event.

# 2. CLINICAL AUDIT

# 2.1 Clinical Audit Programme

The clinical audit annual report for 2014/15 was approved by CARE. We now ensure that audits are appropriately linked to incidents, risk, and complaints, with prioritisation and approval at senior level. CARE also approved the clinical audit programme for 2015/16 which now includes a priority rating for each audit, and development of an improved schedule for reporting. A total of 42 clinical audits have been included in the 2015/16 programme; nine priority one (highest), eighteen priority two, and fifteen priority three audits. No clinical audit actions are currently overdue. It was also agreed that a greater emphasis will be placed on publications from clinical audits, which will include conference posters.

# 2.2 Audit of Bristol TAS

An audit of medicines prescribed to Bristol Therapeutic Apheresis Service (TAS) patients and donors has been approved by DTS CARE. This audit has established that current practice around the completion of the prescription chart requires improvement, the main areas being the use of appropriate abbreviations, good documentation practice, and record keeping. The recommendations will be applied across all TAS Units.

# 3. CLINICAL RISKS

The number of risks on the corporate risk register, for which the dominant risk is clinical, is 44; this is an increase from 40 reported in the previous report. Five new risks have been added and one removed. A total of ten clinical risks have a residual risk of 15 or above, this is an increase from nine. Of the five new risks three are scored fifteen or above;

Ref	Risk description	Residual risk score
X-ICT-044	Business Continuity- Infrastructure The move of the data centres from Elstree and Colindale to a third party provider may not happen in accordance with the planned migration causing disruption to service. This is linked to risk ICT-035	15
X-ICT-045	Scale of Change The replacement of Pulse by a number of different platforms causes disruption to current services	15
X-ICT-046	Scale of Change The introduction of a new desktop causes a disruption to current services	15

CARE supported the proposed work to be undertaken with directorates to review, update, and embed the risk registers and risk management across the organisation.

A risk relating to the supply of Human Albumin Solution had been placed on the DTS Risk Register and was raised at May CARE, and reported in the previous report. The issues surrounding UK supply have now been temporarily resolved. The Commercial Medicines Unit, Department of Health (DH) are planning to develop a national framework for the procurement of albumin, and aim to have this in place by June 2016. NHSBT are engaged with the development of this.

# 4. ALERTS, GUIDANCE AND REGULATIONS

Since the last report, the National Institute for Health and Clinical Excellence (NICE) has issued a total of eight documents; no specific action is required from NHSBT in relation to the guidance published. However, consideration is being given by BS to; *Violence and aggression: short term management in mental health and community health settings,* in order to be clear what the BS policy is on managing aggression in a community setting.

A total of eleven alerts were issued via the Central Alerting System (CAS). One Patient Safety Alert potentially relevant to NHSBT was considered by BS and DTS CARE groups: Risk of death or severe harm due to inadvertent injection of skin preparation solution. This has been confirmed as not relevant.

A review of NHSBT's current CQC registration is nearing completion and will establish which regulated activity is undertaken from each NHSBT location. The review has also confirmed the need for a number of changes to the current registration which is consistent with the initial objective and approach, agreed in 2014. This includes the removal of some NHSBT locations from registration and the addition of some others. These changes will ensure that locations undertaking a regulated activity are correctly registered only for the activity they provide. To date one site has been identified (Horsham team base) which requires new registration with the CQC.

# Being Open Policy (including Duty of Candour)

The draft Being Open Policy was discussed at CARE, and support given to the policy being applied across the organisation; regardless of whether or not the activity is regulated by the CQC. The policy is to be finalised through continued engagement with the directorates and discussion with the CQC.

# 5. INQUESTS

# Human Leucocyte Antigen (HLA) Error (Ref: ODT INC 218)

The inquest touching upon the death of this recipient was held in May 2015. H. M. Coroner has delayed conclusion, which had been due mid June and was delivered on 22 July 2015. The written conclusions are awaited.

# 6. COMPLAINTS AND COMPLIMENTS

# 6.1 Complaints

a) Blood Supply

One new serious complaint has been received during this period: A donor was unhappy with the current selection guidelines relating to MSM. The donor's original letter was sent to numerous recipients including SaBTO and the DH. NHSBT has responded on behalf of all organisations.

b) Diagnostic and Therapeutic Services

The total number of monthly Hospital Complaints is continuing to trend down.

c) Organ Donation and Transplantation

ODT undertook a piece of work to review the previously reported increase in complaints. There were 113 ODT clinical and non-clinical complaints in 2014/15, and 75 in the previous year. This increase has been seen following a series of workshops held during 2014, facilitated by ODT's Clinical Governance and Quality Assurance team. This actively requested and encouraged Organ Donation Services Teams to report complaints centrally. Hitherto, many teams received and managed complaints locally. A full report was submitted to and accepted by the GAC.

# 7. KEY ITEMS FROM DIRECTORATES SINCE LAST REPORT

# 7.1 Blood Supply

- a) In the previously confirmed Transfusion Transmitted Infection (TTI) through a pooled platelet product, a male donor has been identified as the source of *Staphylococcus. aureus.* This donor has been withdrawn. A final closure report will be sent to the hospital.
- b) Probable bacterial transfusion transmitted infection from day 7 pooled platelets (INC60058). A patient having an outpatient platelet transfusion for a chronic bone marrow disorder suffered, fever, rigors and angiooedema. The patient was admitted, shown to have bacterial infection in their blood, and treated with Tazocin and steroids. The patient fully recovered and was discharged home within a few days of being admitted. The pack was returned to NHSBT and grew *Streptococcus agalactiae* (oral streptococcus), the same organism as in the patient. There was no growth from red cell units. This is a probable transfusion transmitted infection, the second since testing began in 2011, and the first from platelets stored beyond 5 days. We are liaising with

4

the hospital regarding an explanation to the patient, even though there is no suggestion of error.

c) There is an ongoing Hepatitis E Virus (HEV) investigation. The patient was discovered to be HEV positive February 2015, having been negative in March 2013. This requires investigation of 26 donors.

# 7.2 Organ Donation and Transplantation

- a) There have been a number (twelve in the last three months) of Serious Adverse Events/Serious Adverse Reaction incidents reported to the HTA under NHSBT's assisted function role, many of which related to donor related malignancy and infections. Robust investigation, overseen by representatives from HTA, confirmed that no errors had been made by NHSBT or other staff.
- b) There has been a significant decline in reported incidents in February and March (26 and 29 respectively), which could be related to a fall in transplant activity. Reports have increased in April and May, in line with increased donor activity.
- c) The Terms of Reference for ODT CARE and the Governance Improvement Group have been revised. It was agreed learning from this review should be shared across all directorates.

# 7.3 Diagnostic and Therapeutic Services

- a) The first case of Transfusion Related Acute Lung Injury (TRALI) has been reported for 2015-16. There was no error on the part of NHSBT. A female donor who had contributed platelets, not resuspending plasma, to a pooled platelet pack was found to have antibodies against a class I Human Leucocyte Antigen (HLA) that was present on the white cells and tissues of the recipient. The recipient had existing multiple organ failure and was treated palliatively prior to death.
- b) The number of major quality incidents has remained stable in operational areas other than Tissues Services and Histocompatibility and Immunogenetics (H&I). For the former, taking responsibility for the Bristol heart valve stock, and taking on the investigation of an incident prior to formally being responsible for ocular tissue, has contributed to the increased number of incidents. For the latter, H&I have raised three major incidents in relation to supplier notices; these have not led to patient harm.
- c) On four separate occasions eye tissue was retrieved while there was no Third Party Agreement (TPA) in place between the Trust and NHSBT. The agreements had been sent to the individual trusts and training provided; however, they had not been signed and returned to NHSBT. A new standard operating procedure, SOP 4866, "confirming TPA status before Consent" has been approved and all staff have been trained to this procedure.
- A report has been published by the UK Cell Salvage Action Group detailing the results of a UK intraoperative cell salvage survey. There are 2 recommendations for Blood Services, these are:

- Each blood service should ensure they have a named contact for cell salvage for every relevant hospital in their country and ensure they are provided with regular updates etc. This is in progress.
- Blood services should consider bulk buying cell salvage equipment and providing it 'at cost' or free to hospitals – this is to be reviewed as part of NHSBT's Patient Blood Management Strategy.

# 7.4 General

a) Information Governance (IG)

CARE supported the IG priorities which will form the basis of the IG 2014/15 workplan and the establishment of an IG sub-group to oversee the workplan. The overarching priorities agreed were:

- Information Governance Infrastructure
- Information Risk Management
- Records Management
- Registration Authority
- Information Technology (IT) Security Infrastructure.

# 8. SAFETY

# 8.1 SaBTO matters

# A. Hepatitis E

Options for HEV testing of blood donations were considered at an extraordinary SaBTO meeting on 7 July 2015, using costed Blood Service plans for universal versus selective donation screening. This work was led by Steve Thomas, Interim Assistant Director Manufacturing Development, and contributed to by all NHSBT stakeholders and other Blood Services.

A business case for approval to undertake HEV testing as recommended by SaBTO, along with other actions regarding clinican awareness and dietary advice for patients, is included in the Board agenda for this meeting.

# B. Donor Compliance Study

Detailed analysis of results will be presented to SaBTO at the September 2015 meeting. Data gathered relating to Blood Service policy, for example on travel and piercings, will be fed back to the Joint Professional Advisory Committee (JPAC) for consideration.

# C. Human T-Lymphotropic Virus (HTLV) Testing

JPAC will make a recommendation regarding the HTLV screening of all, versus only first-time blood donors, to then be considered at the SaBTO meeting of 1 September 2015.

# 8.2 Bacterial Risk Reduction

Following assessment of bacterial testing and pathogen inactivation using the safety Framework, a paper will be presented to the Board in November 2015.

# 8.3 West Nile Virus (WNV) Testing

The European Union (EU) regulation which permits WNV NAT testing as an alternative to deferral mandates testing of individual donations rather than our current practice of testing in pools. There was no consultation phase of this policy, and the European Blood Alliance has expressed concern at this and the lack of expert input. An option appraisal of WNV individual testing versus deferral will be presented to the 30 September meeting of the Therapeutic Product Safety Group (TSPG).

Authors: Louise Cheung Assistant Director – Governance and Clinical Effectiveness Jo Tossell Safety Co-ordinator

Approved by: Lorna Williamson Medical and Research Director.

1	Date / title of meeting	BOARD 30 JULY 2015
2	Title of paper	FRANCIS REPORT ACTION PLAN UPDATE
3	Status	Official
4	Tweet (max 140 characters)	This paper provides an update to the Board on the action plan that was agreed in March 2013 following recommendations from the Francis Report.
5	Executive Summary	Since the last update report to the Board in January 2015, key actions/changes include:
		<ul> <li>Approval of new process for handling Serious Incidents</li> <li>Development of a 'Being Open' Policy</li> <li>Comms team winning a Public Sector Award for effectiveness of its employee engagement survey</li> <li>Recommendations from the Query and Complaints Handling Review have been accepted by ET</li> <li>Chief Nurses have commenced discussion with NHS England Chief Nurse, and Public Health England's (PHE) Director of Nursing regarding the development of our Nursing Strategy</li> <li>Blood Donation 'Care Quality Walkarounds' toolkit has been developed</li> </ul>
6	Action requested	<ul> <li>The Board is asked to note the progress against the Francis Report action plan, with the expectation of a final update report in January 2016.</li> </ul>
7	Background and customer promise	Following publication of the Francis Report in February 2013, a cross-directorate project group considered all 290 recommendations in the context of the business of NHSBT, and aligned these to five main themes. An action plan was approved by the Board in March 2013, to address the recommendations that could be implemented immediately; reflecting the government's initial response 'Patients First and Foremost'. Progress reports have been provided to the Board in July 2013, January 2014, July 2014, and January 2015. Since January 2015, 2 of the 7 open actions have been closed, and 2 others have approved plans for completion. Options are being considered for progression 2 actions realting to nursing strategy and leadership, while Phase 2 of the IT project will be re-considered in spring 2016 against

Page 1 of 5

8       Why is this important?       o       Demonstrates NHSBT's learning and actions from the Francis Inquiry into Mid Staffordshire NHS Foundation Trust.         9       Who else has been involved so far?       o       Work on the NHSBT Francis Action Plan multidisciplinary. Key teams are the Communication Directorate, Workforce Development, Humm Resources, Nursing Leadership Team, and Clinic Directorate.         10       Costs and benefits       Not applicable         11       Significant next Actions       • Being Open Policy will be formally approved         • Programme of 'Care Quality Walkarounds' will commence in Blood Supply       • Establishment of central complaints team responsib for handling complaints made into the organisation from various points.         12       How does this impact on sustainability?       No direct impact. No assessment required         13       What is the impact?       Not applicable         14       Employee impact?       The Francis Action Plan has delivered significant benefits to staff through the embedding of the new core competency framework and the work on core values in appraisals, recruitment and day-to-day operations.         15       Donor impact?       Not applicable         16       Taxpayer impact?       Not applicable         16       Taxpayer impact?       Not applicable         17       Author       Louise Cheung Assistant Director Governance and Clinical Effectiveness         18       Resp			other IT priorities.
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19 NED input None		Director	Medical and Research Director
	19	•	None
20 Appendices None	20	Appendices	None

Page 2 of 5

# NHS BLOOD AND TRANSPLANT

# JULY 2015

# FRANCIS REPORT ACTION PLAN UPDATE: PROGRESS SINCE JANUARY 2015

In January 2015 the update report to the Board outlined seven actions which remained on-going, although with some elements of those actions already complete. Outlined below is an update against each of those actions and an indication as to whether or not these can now be closed or remain open. Please note the action numbering reflects the action numbers in the original action plan.

# Action 5: Continue to promote a safety culture, one where reporting of errors and incidents is encouraged, and concealment is considered unacceptable.

Since the January report to the Board the Serious Incident Requiring Investigation (SIRI) MPD has been approved and implemented with effect from April 2015.

A Duty of Candour audit was undertaken across all appropriate SIRIs, with improvements identified regarding recording, which are now being implemented. An organisational Being Open Policy, inclusive of Duty of Candour, has been developed with the operational directorates and an advanced draft reviewed by CARE earlier this month. This will be signed off shortly and discussed with the Care Quality Commission (CQC), for support and agreement where NHSBT has to deviate from the regulation due to not having direct contact with patients involved in incidents.

A Board Risk Development Session was held in May 2015. Work is planned with the directorates to review and update all risk registers, and ensure they are live and meaningful at all levels. Development and training sessions will be held with directorate Senior Management Teams, and as a result of those sessions, training plans agreed for front line staff.

It is recommended this action remain open until the Being Open Policy and training on risk management are rolled out.

# Action 6: Consider whether there is a 'cultural barometer' which could add value in embedding the improvements in behaviours.

There remains as yet no one accepted NHS wide 'cultural barometer' tool. However, the majority of organisations appear to be refreshing their staff surveys and running follow up snapshot surveys, with ongoing feedback to ensure that any issues hidden in the surveys are flushed out. The NHSBT staff surveys in 2012 and 2014 have included staff engagement questions and an index/score. Focus groups have been planned in specific operational areas to ensure action plans are effective and root out underlying issues. We have also used central communication channels to encourage a culture of feeding back and raising issues. The culture of NHSBT will continue to be monitored through the annual staff survey and smaller, targeted surveys to check the progress of

Page 3 of 5

particular action plans. Most recently NHSBT won a Public Sector Communications award for the effectiveness of its employee engagement survey communication.

It is proposed this action is closed and NHSBT continue to use the staff survey and engagement questions to meet this requirement.

# Action 7: Review the complaints procedure, ensuring an easy process with timely feedback, adequate use of narrative, and an organisation-wide view of trends and common themes

In February the Executive Team accepted the recommendations made in the Query and Complaints Handling Review. The Review made a number of short and long-term recommendations to improve the process of making and handling complaints across NHSBT. Key to this work, and linked to the Francis recommendations, is the decision to establish a central complaints team responsible for tracking and logging complaints made into the organisation from various points. It has already been agreed that the Board will be sighted on NHSBT-wide complaints trends as well as progress in improving services in response to these.

It is recommended this action remain open until the new complaints function is established and new procedures embedded.

# Action 8: A new nursing strategy is being developed, incorporating the Chief Nurse's '6 Cs of care' (courage, commitment, communication, care, compassion and competence).

A nursing seminar for the Board was held in July 2014. It was agreed that a Nursing Strategy would be developed for the Board to consider in 2015/16. NHSBT Chief Nurses have now met with Jane Cummings, Chief Nurse: NHS England, and Viv Bennett, Director of Nursing: PHE; to discuss nursing services and strategy in NHSBT. The Nursing Strategy Development remains ongoing and is expected to be presented at a Board meeting during 15-16. Options are being considered regarding resource for nurse development.

It is recommended this action remain open, pending approval of the new Nursing Strategy.

# Action 10: Consider how professional support and leadership in nursing could best be developed.

The Nursing Leadership Team (NLT) scoped the requirements for a nurse tutor and a preliminary proposal discussed at Clinical Directorate SMT (CDSMT). It was agreed that further work would be undertaken on the proposal, including possible funding mechanisms. Further work within the operational directorates is underway to look at how this role can be undertaken. This action remains on-.going and is expected to be completed at the end of October 2015.

It is recommended this action remain open until the Nursing Strategy and support needed for delivery are approved.

Page 4 of 5

# Action 15: For the Board to be increasingly curious in establishing how care is being delivered at the front line e.g. the 15 steps challenge.

Following three pilot 'Care Quality Walkarounds' a toolkit has been created and will be rolled out to all blood donation teams during August 2015; following approval by Blood Supply CARE. The walkarounds will be undertaken every six months by the Senior Sister/Charge Nurse; the walkaround team will always include a donor, and someone from outside the team. The toolkit includes a checklist and feedback sheet and proforma for an interview with a donor who has completed their donor journey the day of the walkaround. Any actions or areas for improvement will be added to the team improvement action plan and overseen by the Area Matron/Manager.

It is recommended this action is now closed.

# Action 16: Use phase 2 of the IT system for clinical governance to ensure that data from different sources are connected to give a coherent picture, and consider whether greater use of statistics would add value.

In April 2015 the Transformation Project Board (TPB) made a considered decision to defer approval and commencement of this project until April 2016. The project has been approved for consideration on the prioritisation list for 16-17.

It is recommended this action remain open until either the project is approved or an alternative approach agreed.

# Author:Louise CheungAssistant Director Governance and Clinical Effectiveness

Approved: Lorna Williamson Medical and Research Director.

Page 5 of 5

#### NHS BLOOD AND TRANSPLANT

#### **JULY 2015**

#### PENROSE INQUIRY: POINTS FOR REFLECTION.

#### **EXECUTIVE SUMMARY**

The Penrose Inquiry, which reported on 25th March 2015, had a remit to explore the circumstances of HIV and HCV transmissions from blood components and fractionated plasma products in Scotland between 1<sup>st</sup> January 1974 and 1<sup>st</sup> September 1991. The report made a single recommendation, which is that individuals in Scotland transfused before September 1991 (when HCV screening of blood donors was introduced) should seek a test for HCV, if not already performed. No such recommendation has been made in England, although we undertook patient lookback from HCV-positive donors in the mid-1990s.

In addition, however, Penrose drew attention to a number of aspects of donor policy and patient care, which were considered not inappropriate at the time, but which would not meet today's standards. This paper is intended to:

- (i) summarise these additional points
- (ii) describe current policies within Blood and Transplant Services that relate to them
- (iii) consider how similar issues arising today would be handled.

This review has concluded that there is strong assurance that many practices of the past would no longer apply, and that today's processes relating to safety policy and implementation, are much more consistent and transparent. There remains, however, sub-optimal clarity over funding and commission of laboratory testing of organ donors in England; discussions are ongoing with NHS England.

There is also the possibility of different actions on safety matters being taken by the 4 nations of the UK, either on policy or timing of actions.

## Recommendation: The Board is asked to note the analysis and conclusions.

Authors: James Neuberger and Lorna Williamson.

#### APPENDIX: PENROSE OBSERVATIONS AND CURRENT PRACTICE.

#### A. BLOOD SUPPLY

PENROSE OBSERVATION	CURRENT POLICY ON SPECIFIC ISSUE/ HANDLING OF SIMILAR ISSUES
A. DONOR SELECTION	
1. International Society of Blood Transfusion (ISBT) guidance on intra- venous drug users (IVDU) was not followed.	<ol> <li>UK blood donor policy on IVDU specifies lifelong deferral.</li> <li>There are UK-wide Donor Selection Guidelines developed by Standing Advisory Committee for Care and Selection of Donors, and approved by JPAC.</li> <li>Remit of JPAC's SACs includes horizon scanning for international guidance</li> <li>CARE has a standing item for national guidance eg from SHOT, BCSH, Royal Colleges. We try to have NHSBT clinicians as members of external guideline groups.</li> </ol>
2. ISBT guidance on collection of blood in prisons was not followed	UK Blood Services no longer collect blood in prisons. See (2), (3) and (4) above. Change to MSM deferral were made only after recommendations by SaBTO were accepted by UK Health Ministers (not N Ireland).
3. Blood donation considered a social function, specifically a means of reparation for prisoners	Blood donation is recognised in the Equality Act 2010 as a service to patients, but NOT to the donor. The European Blood Alliance, of which UK Blood Services are members, has adopted a position that blood donation should continue to be altruistic ie of no benefit to the donor.
4. Different centres within Scotland had freedom to set own donor selection policies	This is no longer the case. There are UK-wide Donor Selection Guidelines developed by SACCSD, and approved by JPAC.
5 Local donor leaflets produced by every centre	This is no longer the case. Donor leaflets are produced nationally by each UK Blood Service and signed off at senior level.
6. Low awareness of risks by public	Calculated residual risks of HIV, HCV and HBV appear on JPAC website. The comms team refer to this location when relevant. These are also included in patient information leaflets.
B. POLICY MAKING	Recommendation for significant changes to blood safety policy are made either by: (1) SaBTO, requiring sign-off by 4 Health Ministers, or (2) JPAC, requiring sign-off by the 4 UK Blood Service Medical Directors. However, health is a now a devolved responsibility, and

	each Blood Service is legally liable for the products they manufacture (blood was conceded to be a product under Product Liability legislation during HCV litigation in England in the mid-1990's, the 'Burton judgement'). Therefore, there is now the possibility that individual health administrations/ blood services may make different decisions regarding safety steps eg MSM deferral, or implement them at different time points eg Hepatitis E testing.
1. Blood service policy makers	Appointment to SaBTO and JPAC is by competitive process including interview. Members are subject to
lacked knowledge	annual appraisal.
	There is annual appraisal and a personal development plan for all doctors, senior scientists and nurses in NHSBT.
	Attendees at conferences are required to provide a
2. Policy makers	report on return for the relevant teams. Decision makers use decision making frameworks that
had to choose	recognise the precautionary principle.
between the known benefit and	SaBTO is reviewing its framework in the light of Penrose.
suspected risk of	NHSBT has a safety framework, and will adopt the new
treatments.	Alliance of Blood Operators framework once a usable
	version is released (due in next 3 months).
3. National communication	NHSBT and SNBTS now have national management structures. The UK Forum of Chief
between centres was not optimal.	Executives/Managing Directors and Medical Directors meets x4/year and JPAC x3/year.
	There is international information exchange through European Blood Alliance and Alliance of Blood Operators.
	Emerging infections are monitored through the EBA-
	Emerging Infectious Disease group tcons which feed
	into SACTTI. The process for handling emerging infections has been audited by internal audit, and is
	being streamlined and documented.
4. Tension between	UK Blood Services continue to have different funding
different models of health	models eg with cross-charging to hospitals in England, but not in Scotland .
reimbursement	In England, the blood price is set annually through the
reimpursement	National Commissioning Group for Blood, with a 6-9
reimpursement	National Commissioning Group for Blood, with a 6-9 month lead time. Safety initiatives which impact on the blood price are flagged up at an early stage through this
reimpursement	National Commissioning Group for Blood, with a 6-9 month lead time. Safety initiatives which impact on the blood price are flagged up at an early stage through this group. For safety steps instructed by DH/Ministers (eg
reimbursement	National Commissioning Group for Blood, with a 6-9 month lead time. Safety initiatives which impact on the blood price are flagged up at an early stage through this
reimpursement	National Commissioning Group for Blood, with a 6-9 month lead time. Safety initiatives which impact on the blood price are flagged up at an early stage through this group. For safety steps instructed by DH/Ministers (eg after a SaBTO recommendation), there would be negotiation regarding a price increase. Increasingly, and certainly for measures proposed by NHSBT without a
reimpursement	National Commissioning Group for Blood, with a 6-9 month lead time. Safety initiatives which impact on the blood price are flagged up at an early stage through this group. For safety steps instructed by DH/Ministers (eg after a SaBTO recommendation), there would be negotiation regarding a price increase. Increasingly, and

5. There needs to be speed in approving funding through government structures	SaBTO working groups work to an agreed timetable for production of recommendations to main SaBTO meeting. Thereafter, each health department makes its own decision; these may come at different times.
6. Recall of non- heat-treated product was not optimal.	UK Blood Services no longer manufacture fractionated plasma products. Each Blood Service has a protocol for recall of components on the basis of post-issue information.
7. There was lack of clarity regarding compensation for patients harmed by a trial product	Burton judgement opinion was that blood can be regarded as a product under Product Liability legislation. Therefore Blood Services, as manufacturers, are liable to compensate patients for damage sustained without the need for patients to prove negligence. NHSBT has contingent liability for patients harmed in trials who do not receive a product.
C. DONOR SCREENING	
1. No mechanism for licencing test kits.	Test kits are now CE marked.
2. Separate validations needed England and Scotland	There is a UK approval mechanism for Blood Services through SACTTI/JPAC.
3. Uniform date agreed across UK for introducing a new test even though some parts were ready before others	For major safety initiatives, there is generally an implementation group which includes representatives from all 4 Blood Services. A common timetable is generally agreed. However, each Blood Service may implement a new safety initiative at slightly different times. Within NHSBT, roll-out across England may occur gradually, but with a pre-defined end-date.
4. Having everything on the shelf tested before the start date	A plan for swap-out of untested stock is agreed as part of each specific project.
5. Structures for UK decision making	SaBTO covers the whole UK but the 4 Health Ministers/Health departments accept the recommendations individually. JPAC is also UK wide, but each Medical Director signs off change notifications individually, so an individual service could be more stringent that the JPAC recommendation.
6. Use of surrogate testing.	There are no current issues relating to surrogate tests; there are specific tests for bacteria and viruses of interest and no specific or surrogate test for vCJD. Viral test specificity and sensitivity are now defined at European level through a Common Technical Specification.

7. The dependence on MRC funding for studies on post- transfusion hepatitis	Budgets for policy-making studies on safety matters are available within NHSBT and through the UK Forum, thus reducing dependency on competitive funding sources which have long lead times to decisions, and uncertain outcomes.
8. Long delay in decision making re HCV screening due to wanting additional information	Inclusion of the precautionary principle in safety frameworks is designed to prevent this. Decision makers need to be clearly inducted and trained in the use of the relevant framework.
D. IMPACT ON PATIENTS	
1. Lack of hospital protocols for junior doctors treating haemophilia away from haemophilia centres	Blood Services do not produce clinical guidelines. We have strong representation on the British Society for Haematology Transfusion Task Force and other guideline writing groups. We ensure that guidelines are included in our teaching programmes for trainee haematologists, and in communications to hospitals. National patient information leaflets are produced by
2. Keeping patient information up to date	each Blood Service.
3. Patient testing without consent	Donor testing is clearly laid out in information leaflets and covered by the consenting procedure. Patient testing for infections should always include informed consent and documentation of the reason for testing.
4. Steps taken to trace patients	Blood Services agree a lookback strategy when a new screening test is introduced. Other tracing exercises are led by Public Health Services with Blood Service collaboration.
5. Information provided to infected patients	Not a Blood Service responsibility. We provide information for clinicians as part of undertaking lookback exercises. Donors with positive viral markers are contacted for a post-test discussion with a trained nurse or doctor.
6. Care for infected patients and their families	We always inform a recipient's clinician where a post- transfusion infection has been identified (now enshrined in Duty of Candour requirements). The post-test discussion with blood donors includes guidance as to where further care can be obtained (via GP).

#### **B. ORGAN TRANSPLANTATION.**

It is important to remember some of the differences between blood and organs with respect to safety and to governance:

- (i) NHSBT, in England, is responsible for the process of recruiting, and screening blood donors and preparing and distributing blood products. The role of NHSBT in organ donation and allocation is more limited: NHSBT is responsible, amongst other areas, for maintaining the National Transplant Waiting list, developing and implementing the selection and allocation policies. employing the SN-ODs and commissioning the National Organ Retrieval Service
- (ii) There is a very different risk profile: while no one in the UK dies from lack of available blood or blood products, up to 20% of those listed for a deceased donor liver, kidney or heart die or become too ill for a transplant.
- (iii) Organ donation, retrieval and transplantation is UK-wide service with policies applying across all four nations; however, the commissioning and accountability varies between nations

PENROSE	CURRENT POLICY ON SPECIFIC ISSUE/	
OBSERVATION	HANDLING OF SIMILAR ISSUES	
A. DONOR SELECTION	TANDEING OF SIMILAR 1830E3	
1. International Society of Blood Transfusion (ISBT) guidance on intra- venous drug users (IVDU) was not followed.	<ol> <li>The guidance for the characterisation of deceased donors is provided by the EU Directive on Organ Donation and SaBTO.</li> <li>Additional guidance is provided by NHSBT and professional bodies</li> <li>In the last few years, NHSBT has developed much closer working relationships with SaBTO and with national Public Health bodies (notably PHE)</li> <li>NHSBT works hard to disseminate national guidance on the screening of donors and use of organs from higher risk donors through emails, website, governance documentation, and peer review visits. However, awareness of such guidance by clinicians is variable.</li> <li>NHSBT takes a medical and social full history from the families and medical advisers, of all donors, and will continue to offer organs from those who have or are active IVDU. The final decision to accept an organ is that of the translanting surgeon.</li> </ol>	
2. ISBT guidance in collection of blood in prisons not followed	NHSBT will request organs from those who were at the time of their death or previously prisoners. (see above)	

<ul> <li>3. Blood donation considered a social function, specifically a means of retribution for prisoners</li> <li>4. Different centres within Scotland had freedom to set own</li> </ul>	Organ donation is also considered a social function and the Behaviour Strategy is designed to encourage this behaviour.
donor selection policies	
5 Local donor leaflets produced by every centre	NHSBT does produce some information and leaflets and SNODs work to common processes. However, hospitals often have their own policies, procedures and processes which may not align to NHSBT policies
6. Low awareness of risks by public	This remains true today. Ensuring the potential transplant recipient gives informed consent is the responsibility of the recipient team. However, NHSBT is working to provide information to enable clinicians and patients to have a better understanding of risk
B. POLICY MAKING	Recommendation for significant changes to organ safety policy are made by SaBTO, requiring sign-off by 4 Health Ministers. However there is now the possibility that individual health administrations may make different decisions regarding safety steps, or implement them at different time points.
1. Blood service policy makers lacked knowledge	Appointment to SaBTO is by competitive process including interview. Members are subject to annual appraisal. There is annual appraisal and a personal development plan for all doctors, senior scientists and nurses.
2. Policy makers had to choose between the known benefit and suspected risk of treatments.	Decision makers use decision making frameworks that recognise the precautionary principle and SaBTO is reviewing its framework in the light of Penrose. The position taken by NHSBT is that its role is to characterise the potential donor and ensure the recipient team receive the information in a timely and effective manner. There is a lack of clarity about the commissioning of donor tests (microbiology and HLA) – see section C.
3. National communication between centres was not optimal.	NHSBT has a UK-wide management structures with 12 regions for the management of SNODs. Nonetheless, communications between all partners (commissioners, regulators, hospitals, health departments and NHSBT) could be improved.

4. Tension between	NHSBT receives funding from all four departments
different models of	
health	
reimbursement	
5. There needs to	NHSBT has regular reviews with the Departments of
be speed in	Health
approving funding	
through	
government	
structures	
6. Recall of non-	There are processes for communicating to transplant
heat-treated	centres any information about an organ donor which
product was not	becomes available after their organs have been
optimal.	transplanted.
7. There was lack	Organs are considered not to be products.
of clarity regarding	We have contingent liability which covers clinical trials.
compensation for	
patients harmed by	
a trial product	
C. DONOR	
SCREENING	
1. No mechanism	Test kits are now CE marked.
for licencing test	
kits.	
2. Separate	There is no clarity around donor testing for microbiology
validations needed	and HLA. There is no clear commissioning process
in England and	across the UK (outside Scotland), no agreed standards
Scotland	for doing tests or reporting results
3. Uniform date	As there is no transparent process for commissioning
agreed across UK	donor tests, there is no process for introducing new
for introducing a	tests.
new test even	
though some parts	
were ready before	
others	There is no process for ansuring that all laboratories
4. Having	There is no process for ensuring that all laboratories work to the same standards
everything on the shelf tested before	
the start date	
	SoBTO source the whole LIK but the Alleeth
5. Structures for UK	SaBTO covers the whole UK but the 4 Health
decision making	Ministers/Health departments accept the
	recommendations individually.
	There is no process for implementing advice from
	SaBTO through the commissioning process.
6. Use of surrogate	There are no current issues relating to surrogate tests
testing.	other than no agreed standards that operate across the
	UK. There are specific tests for bacteria and viruses of
	interest and no specific or surrogate test for vCJD.
	Tests for tissue typing (as HLA) are variable

	1
7. The dependence on MRC funding for studies on post- transfusion hepatitis	NHSBT runs the transplant registry and Transplant Centres should, under their licence, report all significant and unexpected donor transmitted disease to NHSBT (under its assisted functions). This is not always done. There is a budget within NHSBT R&D for studies on organ recipients.
8. Long delay in decision making re HCV screening due to wanting additional information	There is no commissioning process (outside Scotland) for ensuring changes in recommendations are put in place
C. IMPACT ON PATIENTS	
1. Lack of hospital protocols for junior doctors treating haemophilia away from haemophilia centres	Hospitals are responsible for the care of transplant recipients. NHSBT has worked with BTS to produce joint guidelines where appropriate.
2. Keeping patient information up to date	National patient information leaflets are the responsibility of the transplant hospital There is no central coordination although NHSBT does provide information and advice, and a guidance document on content in conjunction with BTS.
3. Patient testing without consent	Donor testing follows agreed protocols by the SN-ODs
4. Steps taken to trace patients	NHSBT maintains the national transplant registry. There are some links with national mortality data but not with other registries.
5. Information provided to infected patients	We provide information for clinicians as part of undertaking lookback exercises. Donors with positive viral markers are contacted for a post-test discussion with a trained nurse or doctor.
6. Care for infected patients and their families	We would always make a clincian aware of an infection acquired through transfusion or transplantation.



#### AGREED

#### The 47<sup>th</sup> NHSBT Governance and Audit Committee Meeting Held on Friday 24th April 2015 In the, Intavent Suite at the Association of Anaesthetists, 21 Portland Place, London, W1B 1PY

Present:	Andrew Blakeman ( <b>AB</b> ) – Chairman Roy Griffins ( <b>RG</b> ) Keith Rigg ( <b>KR</b> ) Shaun Williams ( <b>SW</b> )	
Apologies:	Kay Ellis	DH
	Karen Finlayson	PwC
In Attendance:	Ian Bateman (IB) Rob Bradburn (RBr) Louise Cheung (LC) Denise Dourado (DD) David Evans (DE) Louise Fullwood (LF) Linda Haigh (LH) Paul Hewitson (PH) Ben Hume (BH) Sally Johnson (SJ), Aaron Powell (AP)	NHSBT NHSBT NHSBT NHSBT NHSBT Non Executive Director NHSBT Deloitte NHSBT NHSBT NHSBT
	Clive Ronaldson ( <b>CR</b> ) Ann Smith ( <b>AS</b> ) Peter Stephenson ( <b>PS</b> ) Paul Thomson ( <b>PT</b> ) Nick Todd ( <b>NT</b> ) Huw Williams ( <b>HW</b> ) Lorna Williamson ( <b>LW</b> )	NHSBT NHSBT (Minutes) PwC Deloitte NAO NHSBT NHSBT

Action

#### **Declarations of Conflict of Interest**

Members confirmed that they had no conflicts of interest.

#### **Chairman's Introduction**

AB welcomed all to the meeting, including Paul Thomson, Paul Hewitson and Nick Todd. AB noted there would be no Therapeutic Apheresis Services (TAS) risk presentation but a TAS Assurance Map paper would be presented to the GAC in item 7.

#### 15-26 Minutes of the 46<sup>th</sup> Meeting Held 27 February 2015

The minutes were accepted as a true and accurate record of the meeting.

#### 15-27 Matters Arising

The matters arising table was reviewed. The Committee discussed the clarity of the matters arising table and agreed that a new document should be developed which clearly defines each action, with timescales, and person responsible. LC and AS to produce an updated matters arising table for the July 2015 meeting.

LC/AS

LW

Action

LW

#### 1 Clinical Governance Report

15-28 Clinical Governance Report

The report was presented to the Board in March 2015. LW noted that the Safety of Blood, Tissues and Organs (SaBTO) meeting has considered Hepatitis E and a number of streams of work have commenced; including cost of universal testing. SaBTO to meet again in July to consider outcome of the work undertaken. KR commented that complaints have recently increased, with many relating to the organ donation side of the pathway. These are currently being reviewed to identify any underlying causes and remedial actions. LW to provide the GAC with a report at the June 2015 GAC meeting, outlining complaints relating to the organ donation pathway. AB requested the findings should be sent to all attendees ahead of the June meeting, for early sight.

#### Serious Incident report - verbal

As of 1 April 2015 managerial and legal responsibility for the Bristol Eye Bank (BEB) transferred from the University of Bristol to Tissue Services, at NHS Blood and Transplant (NHSBT). There were three instances of contamination detected by microbiological testing. All three identified the same fungal species, Scopulariopsis gracilis, and the BEB was closed for deep cleaning. HW informed the GAC that a Root Cause Analysis (RCA) has taken place, although the cause of the contamination to date has not been identified. Patients were informed of cancellations up to a week in advance and normal supply was hoped to be resumed by mid May 2015. An apology letter explaining the current situation has been provided to the chair of the Ocular Tissue Advisory Group (OTAG), for distribution to all surgeons who transplant corneas. And, as a result of this incident, NHSBT will produce a customised letter to families of donation explaining the reason for the donated tissue being discarded. SJ noted that NHSBT always supply the families of donors with all feedback that they request. The Committee discussed the future possibility of providing further eye bank services in the future and how NHSBT are best strategically placed for this development. HW to raise at the Executive Team (ET) for discussion and agreement regarding current and future strategy/appetite and report to May Board. IB to explore potential of longer term option of a precautionary step to import eye corneas if requires. ET to consider and notify GAC of decision. Assistant Director of Governance and Business Continuity is reviewing business continuity plans to prepare for this issue in the future,

HW

IB

# The second serious incident reported to the GAC was that of an event, which involved a ten year old child acquiring a needle stick injury after finding a needle in a school hall during a PE lesson. A Blood collection session was held at the school on 10 April 2015 and therefore it was thought to be a needle used by NHSBT left behind after the session. This incident has been classified as a Serious Incidents Requiring Investigation (SIRI), (as defined in the new SIRI policy), based on potential reputational damage, plus potential for unnecessary treatment to child and potential psychological harm. A written apology will be sent to the school post full investigation. A full RCA will be carried out at the end of April 2015.

15-29 Care Quality Commission (CQC) Annual report It was noted that TAS and Blood Collection were not inspected by the CQC during 2014/15. The GAC considered the scope of inspections, going forward due to the

#### Action

CQC introducing two new styles of inspections, which replaces any previous approach taken by the CQC. The first change in approach is named a Comprehensive inspection. These inspections are formal, planned inspections, with organisations receiving six to eight weeks notice. During this notice period a significant volume of information regarding the organisation must be provided to the CQC within the timeframe given. The second change in approach is named a Focused Inspection. The CQC undertake focused inspections in order to respond to a concern or to changes to the provider.

NHSBT's CQC link person is communicating within the CQC internally in order to ascertain the position regarding the management of blood, and blood derived products and if this should continue in the CQC's scope of registration.

LW reported that NHSBT are clear, in regard to awareness, of the requirements for the Duty of Candour, which has been shared with each directorate. Details of the requirements continue to be reinforced, forming part of the presentations on the Fundamental standards and also the new SIRI.

#### 2 Quality Assurance

15-30 <u>Serious Adverse Blood Reactions and Events (SaBRE) report</u> A recent review of Medicines and Health Products Regulatory Agency (MHRA)

A recent review of Medicines and Health Products Regulatory Agency (MHRA) SABRE reports, highlighted a number of reportable events related to recall errors. IB noted that immediate action has been taken, following a review of the data. The paper has been reviewed by the ET. An Operational Improvement Programme (OIP) event to re-engineer the process, to reduce the level of complexity and therefore the potential for error will take place 5<sup>th</sup> May 2015.

#### 3 Whistleblowing Annual Report

15-31 DE informed the GAC that a total of four concerns have been raised through A,B&C letters, or to the 'Press Office' email account. The four concerns were anonymous and therefore, NHSBT were unable to provide direct feed back, to the whistleblowers.

The Francis Report placed a significant emphasis on the importance of encouraging staff to raise concerns. In order to support this, NHSBT published a series of communications in Connect Magazine and Connect briefing to raise awareness of how an employee could raise a concern. DE confirmed to the GAC, that the majority of NHSBT employees have an above average knowledge of how to report a concern regarding fraud, malpractice, or wrongdoing. This figure is higher than reported in the wider NHS. It was noted there were several avenues in which staff can raise an issue, although this causes concern; as this could in turn cause confusion. This issue will be reviewed.

The Freedom to Speak Up report is currently out to public consultation and the Secretary of State has already agreed the recommendations in principle. It is felt unlikely there will be significant changes in respect of the principles and actions. The GAC were advised that NHSBT are currently in a good position regarding the principles, actions & NHSBT response, with regard to the Freedom to Speak Up report.

#### 4 **IT Governance**

#### 15-32 Incident and action plan

AP reported two major IT incidents to the GAC, which occurred in February and March 2015. The total outage on this occasion was 11 hours. At least one hospital patient had a procedure deferred on 23 February as a consequence of NHSBT's inability to supply a matched product in a timely manner. A formal investigation took place in March 2015, into the incidents, including a RCA investigation. A formal action plan has now been developed, both to address the immediate root cause, and to ensure the systems are more stable in the medium long term. A third party, with knowledge of NHSBT's systems, has been commissioned to carry out an assessment of IT infrastructure. This assessment will take place over the next ten to twelve weeks. Weekly Serious Incident Review meetings are taking place onsite in the data centres to review all incidents that have occurred. In turn, this will be reported weekly to ET. The GAC accepted the report and actions and HW will take the report to the ET as part of reporting on HW business continuity. This will also be included on the Board Development Day session on Risk in May.

RBr

PS

15-33 Information Technology (IT) Business Continuity - internal audit report PS reported on the review of IT resilience and disaster recovery planning and noted there is evidence of an awareness for the need of a more robust disaster recovery procedures and documentation, in respect of NHSBT's core systems. AB noted that a clear action plan needed to be crafted, within resources. PS to compose a response action plan and finalise the internal audit report. Day to day operational challenges was discussed, noting that good housekeeping activities are formally incorporated to reduce the risks of system failures. AB concluded that a response should be considered carefully, with regard to where NHSBT is currently at this stage.

#### Information Security

15-34 Following the appointment of a Head of Information Security, within the Information and Communication Technologies (ICT) team, a full review of NHSBT's information security provisions has been carried out. Following the audit, the ICT team have taken a number of actions to begin the remediation process and to add greater level of clarity of certain areas of concern. The accompanying Action Plan details thirty high level actions, the owners and completion due dates. The actions have been divided up into sections which correspond to ISO 27001. When NHSBT have an established Information Security Management System (ISMS) with agreed policies and controls, a continual improvement plan will be put into place. Policies, Procedures and Guidance will be reviewed at least annually to ensure they are relevant and continue to provide protection for the organisation. External audit from a third party will also be encouraged and recommendations reviewed. PS to make PS available at the July 2015 GAC meeting, two final reports, which include the management responses - for Business Continuity and Information Security.

#### Infrastructure hosting update - verbal

Contract discussions have taken place and are now closed. A detailed report will be prepared for mid May 2015, followed by a report to the Board in July 2015.

#### 5 Transformation Programme

#### 15-35 Transformation Project Board (TPB) report

DD focused on key issues for April 2015, also noting that the report would now be presented to the ET.

The number of Red/Amber projects across the portfolio has fallen marginally. The decrease is largely due to key contractual issues being resolved; procurement scope being amended or wider planning reviews being undertaken resulting in a different approach being adopted. The current focus of activity is on delivering existing projects ahead of, or to agreed plans; so that resource and activity is clear of the planned IT change freeze for Infrastructure Hosting. This is due to begin in October 2015. Discussions are ongoing to engage an external resource. DD will feedback findings from the TPB workshops to the GAC.

DD

#### 15-36 Transformation Programme summary report

It was noted the GAC wish to gain assurance that the change project is achievable and that forecasting is accurate. DD summarised the report noting that current Red and Amber statuses were acceptable but the TPB were constantly seeking to improve. It was questioned whether the TPB was too large. The GAC were assured that the project as a whole was possible and was endorsed by the ET. The GAC noted that it accepted the report, however, it would continue to monitor and will evaluate specific risks for this committee.

#### 6 Risk Management

#### 15-37 Risk management update

RBr reported the main focus of the action plan is to continue to develop the case for an IT based solution designed to improve the level of engagement by the front line to capture incidents/risks and to strengthen risk awareness across NHSBT and also by reviewing and updating the supporting processes. AB noted that the structure of scoring risks was not consistent and re-visiting the matrix would be good practice.

#### 7 Other Governance Issues / Assurance Map

#### 15-38 Board performance report - governance issues arising

RBr reviewed the March 2015 report, noting that overall the objectives were in good order.

In Blood Supply (BS) there is some evidence that the rate of demand decline, is slowing. And, in Organ Donation Transplantation (ODT) activity in February was lower than recent months, with fewer deceased donors. SJ noted NHSBT need to make an impression on families with regard to consent.

RBr confirmed to the GAC that the Board report is considered comprehensive.

#### Assurance Framework checklist - verbal

Flagging issues had been reaffirmed and reviewed carefully. The internal audit was noted as a high quality report.

#### 15-39 Therapeutic Apheresis Services (TAS) Assurance Map

HW clarified the structure of the Assurance Map to the GAC, advising how the map was logically formatted. The GAC questioned whether this was the best format to

use in terms of Risks. RBr commented that Board Assurance maps should be used as a checklist to reinforce that there are no gaps in assurance.

The Committee discussed the importance of capturing the risks in the correct way, and ensuring assurance maps reflect the key strategic risks for the directorates.

#### 8 Internal Audit

#### 15-40 Internal PwC Progress report

PS provided the progress report, which summarises the progress against the approved internal audit plan for 2014/15. A total of five of the areas audited were given an overall moderate rating, the PAYE audit was given an advisory rating, and four audits were given a limited rating or unsatisfactory. These audits were given an account of at the meeting.

PwC have agreed to defer the Data Mapping review until 2016, after discussing this with NHSBT management. Business Continuity Planning work has taken place in early 2015 and has provided useful insights.

#### 15-41 Information Services Audit (follow up)

The audit provided further insight into the approach to IT core systems software maintenance and improvement within ODT. BH reported that as small scale changes are needed a 'hot fix' approach has been adopted. AB thanked PwC for their work in 2014/15 and noted that this form of approach is working well.

The report provided assurance to the GAC that all change requests are assessed and that lower priority and smaller IT changes have a route to completion. LF commented it was reassuring a hot fix approach can work. Going forward, ICT and ODT are now taking a more rounded service management approach, and in future, ICT will identify a core resource to deliver ongoing service improvements, which will provide an opportunity to address some of these smaller change requests.

#### 15-42 Donor Registration Transformation

PS reported on the Donor Registration Transformation Project. Specialist Nurses for Organ Donation (SN-ODs) currently use a number of paper forms for donor registration and transfer a sub-set of the data into the Electronic Offering System (EOS).

Four high risk findings were identified, with five medium findings identified and reported on. A general concern was noted regarding Risks associated with using an overseas software supplier. It was considered that overseas suppliers add complexities to the project in terms of ensuring that the supplier is effectively able to understand the project requirements and is able to engage in an effective working relationship with NHSBT.

#### 15-43 Cryogenic Storage

An RCA of the project to build a cryogenic storage room at the Southampton Blood Centre was undertaken internally and reported to the GAC November 2014.

There were found to be fundamental weaknesses in the framework of governance, risk management and control such that it is inadequate and ineffective or is likely to fail. With management commitment the project will move forward and is scheduled to be completed at the beginning of May 2015.

Action

Information Security

As discussed in section 4 paper 15-34

#### 15-44

#### Outstanding and Overdue Audit Actions

The report contains all the medium and high internal audit points which are outstanding. Three medium points are outstanding as at mid April 2015. Owners are requesting an extension from the GAC, for two of the points, which was granted.

- The Project Resource (Business Transformation) has asked for a small extension and the revised deadline has been set for the end of April 2015.
- Review of programme and project resource capacity and capability initially due for completion by January 2015. The audit continues to stay on hold until June 2015.

#### Draft Internal Audit Report & Opinion – 2014-15

15-54 PS noted that the opinion is based solely on the assessment of whether the controls in place support the achievement of management's objectives as set out in the 2014/15 Internal Audit Plan and Individual Assignment Reports. The opinion is based on the outcomes of the work Internal Audit has conducted throughout the course of the reporting year and on the follow up action from audits conducted in the previous reporting year. There have been no undue limitations on the scope of Internal Audit work and the appropriate level of resource has been in place to enable the function to satisfactorily complete the work planned. Three areas were reported on

#### 9 <u>Annual Reports and Accounts</u>

#### 15-47 <u>Timetable for draft/final accounts</u>

LH informed the GAC that all comments for the draft Annual Report and Accounts will be documented and the document will return to the June 2015 GAC meeting for approval/sign off.

External Audit Progress/update verbal

PH noted that although the audit was in its early stages, no issues had arisen. PH assured the GAC that the external audit is on track and will meet all of the deadlines that are set out. PH also noted that the Risk assessment had not changed and no reconciled issues had arisen.

15-48 Internal and external co-operation report The report was taken as read, with nothing to note.

#### 15-49 Draft governance statement for review

The governance structure and process within NHSBT is documented by an NHSBT Integrated Governance Framework that was approved by the Board in 2011/12, and is reviewed annually by the GAC. The Integrated Governance Framework formally describes the assurances provided to the Board regarding the delivery of NHSBT's statutory and strategic objectives, its internal controls and risk management processes. The Integrated Governance Framework is supported by an Assurance Map which outlines the areas on which assurance is required and how assurance is then provided.

PT covered two observations the GAC in the statement:

• That the risks outlined in the Quality Management System (QMS) section,

were clearly set out however, what happens next in the risk process needed to be clearer.	Action
<ul> <li>The final statement showed no evidence regarding issues.</li> <li>All comments on the statement should be emailed to RBr.</li> </ul>	All

#### 10 Committee Business

15-50 <u>Self-assess GAC's Effectiveness</u> In line with best practice, the GAC assess the Committee's effectiveness annually. A questionnaire was distributed to the thirteen GAC members/regular attendees, and was based on a shortened self-assessment checklist. LC summarised the captured comments and noted from the responses that the GAC are accomplishing its function according to good governance, accounting, audit and risk management arrangements, however, there were a number of concerns/areas for improvement identified which require further discussion. It was agreed LC to produce a further report focusing on key areas for discussion/action to be discussed at the June GAC.

LC

#### 11 Chair's Actions (for discussion only as required)

15-51 <u>Fraud Annual Report and Workplan – for Review</u> The report was taken as read, with nothing to note.

#### 12 Any Other Business

There were no further items to note.

#### 13 Review the effectiveness of the meeting

No comments were made, concerning the effectiveness of the meeting.

#### **Date of next Meeting**

Friday 26 June 2015

Please note: The next meeting will be held in the **President Room at the King's Fund No. 11 Cavendish Square, London from 09.30 – 13.00 hrs** 

#### Minutes of the 15<sup>th</sup> Expenditure Controls Committee held at 09.45am on Monday 27<sup>th</sup> April 2015 Venue – meeting held by Telecon

Present:

Mr A Blakeman Mr I Trenholm Mr R Bradburn Mr M Taylor

#### 1.0 **APOLOGIES**

No apologies were received.

#### 2.0 MINUTES OF THE LAST MEETING

The minutes of the meeting held on the 14<sup>th</sup> March 2015 were reviewed and approved.

#### 3.0 **PROFESSIONAL SERVICES – ANALYSIS OF EXPENDITURE** JANUARY – MARCH 2015.

MT noted, that at the time of the meeting, the audit report for Q3 was yet not available and would therefore be included as part of the Q1 2015/16 papers.

MT presented the Quarter 4 paper summarising the expenditure through to the end of March 15. There was then a general discussion on the types of spend being reported under Professional Services / Appendix A, and specifically, whether there was a more appropriate category that could be adopted for some suppliers eg Hitachi Capital (Fleet Maintenance) and European Blood Alliance (Membership fees). MT actioned to review for Q1 reporting.

MT was also requested to review the description applied to spend for supplier SCC - due diligence for migration of NHSBT data centres at Elstree and Colindale/£35k (Contract ref. NHSBT0602/IT/AC – NHSBT & Specialist Computer Centres PLC, contract for co-location services – contract period is two years from the commencement date, with options for a further 2 one year extensions).

The high level of expenditure under Legal Services / Appendix C was noted, in relation to the NAT challenge/re-procurement.

It was also noted, that although there had been approval from DH/CO for management consultancy spend on ITS, there was now likely be a re-scoping of requirements undertaken, followed by a re-tender. The ECC would need to re-approve a revised business case.

MT confirmed that there had not been any non-frontline expenditure from programme funding (formerly referred to as GIA) sources. DH

approval was not therefore required for expenditure incurred by the Authority at quarter 4.

MT stated that in line with routine practice, and following the review meeting, the ECC papers would be forwarded to the DH.

#### 4.0 APPROVAL OF EXPENDITURE

MT requested approval from the ECC, that expenditure incurred in Quarter 4, had been compliant with the ambit and spirit of the guidance and advice received by the Authority. The ECC gave their approval that the expenditure from both programme funding and income from prices had been consistent with DH guidance.

#### 5.0 ANY OTHER BUSINESS

There was no further business noted and the meeting was closed.

#### 6.0 DATE OF NEXT MEETING

The date of the next meeting is 20<sup>th</sup> July 2015.



#### **Research and Development Committee Meeting**

#### 9 a.m. Thursday 14<sup>th</sup> May 2015 The King's Fund, London

#### **Committee Members**

Christine Costello (Chair of RDC, Non-Executive NHSBT Board Member) Jeremy Monroe (Non-Executive NHSBT Board Member) Harvey Klein (NIH, USA: External expert) Ellen van der Schoot (Sanquin, The Netherlands: External Expert) Gail Miflin (Associate Medical Director – Blood Supply) Huw Williams (Director of Diagnostic and Therapeutic Services) Lorna Williamson (Medical & Research Director) Rob Bradburn (Finance Director) Sally Johnson (Director of Organ Donation and Transplantation)

#### Observers

Chris Sims (Planning and Management Accountant, Group Services) Dave Collett (Associate Director, Statistics & Clinical Studies) Rutger Ploeg (Pl observer) Cedric Ghevaert (Pl observer) Ashley Toye (Pl observer) Nick Watkins (Assistant Director, Research & Development)

Lewis Matthews (National Research Manager, Scientific Secretary) Jan Wright (HR Clinical Lead)

#### Apologies

Clive Ronaldson (Director of Blood Supply, Gail Miflin Deputising) Louise Fullwood (Non-Executive NHSBT Board Member) Jonas Wadstrom (University of Stockholm, Sweden: External Expert)

#### 1. Introductions, Apologies and Conflicts of Interest

Welcome to Jan Wright (Human Resources - Clinical Lead)

Apologies were noted as above.

Two Principal Investigators who were applying for funding were in attendance and would be asked to leave when their applications were considered.

#### 2. Minutes of meeting held 24th November 2014

The minutes of the last meeting were approved as a correct record.

#### 3. Update on Actions from November 2014

NW informed the Committee that all actions were complete, except for the action regarding funding to replace that available from the Trust Fund. A similar funding stream is proposed as part of the 2015 – 2020 R&D Strategy, with Funds still available from the Trust Fund for two further awards. Applications for these would be considered in the autumn. These will be the final awards made by the Trust Fund.

It was noted that no response had been received from Mr Jassam following the letter expressing concerns over his completed project.

#### 4. Outcome of NIHR BTRU competition

NW gave a summary of the second round NIHR BTRU competition regarding the manufacture and clinical assessment of cultured red blood cells. An offer has been made to the University of Bristol subject to a number of conditions being met:

- NHSBT Board approval of the GMP cost (£1.8m, already approved at March Board)
- Revised Governance structure
- Satisfactory peer review of revised Public & Patient Involvement (PPI) section
- Confirmation of continued baseline funding (in the 2015-20 strategy).

Subject to Board approval of the 2015 – 2020 R&D Strategy, all conditions that depended upon NHSBT would be met. The revised proposals for qualitative research in PPI/PPE would be subject to peer review. Andy Gibson, University of the West of England, has been appointed as PPI/PPE lead.

It was noted that Ellen van der Schoot has agreed to join the supervisory board of the BTRU. The selection of membership was at the discretion of the NIHR BTRU Director. Committee confirmed the importance of ensuring that governance roles are well defined and that it is made clear where responsibilities lie. The Operations Manager would be responsible for ensuring that the governance mechanisms are effective and also preparing reports for NHSBT's Change Programme Board.

The organisational change process to manage changes to NIHR funding is proceeding as planned with no issues of concern.

#### 5. 2015-2020 R&D Strategy

LW opened the discussion by stating that the 2015-2020 Strategy builds upon the structures and good practice of the previous Strategy. The Research Strategy Groups will continue to provide fora at which research priorities are identified and proposals developed. In light of changes to research funding, further prioritisation by the R&D

Committee was required to deliver the programme within the available budget. It was noted that the blood price levy has been increased following the removal of Grant-in-Aid to support research. No funding was available from operations to fund research in stem cell and immunotherapies.

RB stated that good financial practice requires a forward view and indication of the planned requirements. The objective is to present a five year plan that will pre-empt blood price increases. There can be a degree of flexibility but this makes large changes difficult, especially as non-R&D areas are requesting large funds. The current R&D Plan, whilst satisfactory, must be considered alongside all other areas and a decreasing red cell usage.

NW gave a brief presentation covering successes of the 2010 - 2015 Strategy and proposals for 2015 - 2020. In discussion it was noted that:

- The proposals take advantage of the unique capabilities of NHSBT and its researchers, and identifies the key areas of question and investigation;
- There was a decrease in Research Capability Funding (RCF) of £168K in 2015/16 after budgets had been agreed and, with increased costs of £230K, if all proposals were approved, there would be a £400K predicted overspend for 2015/16;
- The £168K reduction in RCF would be supported, but the remaining £230K would not;
- Reducing all budgets by 3.4% to achieve a £230K saving was not considered a strategic response to the cost pressures;
- Pathogen inactivation may impact on the virology theme towards the end of the five year period;
- The proposals around long-term donor safety and developing a greater focus on donors are new and important areas, as is the use of Genomics and Big Data.
- The relevance of the proposals in stem cells and immunotherapies (SCI) (outside of the NIHR BTRU) to NHSBT's operational strategy were considered lower than in other areas; Action: LM to send Stem Cell Strategy to HK and EvdS
- As internal funding decreases, translational therapies will require increased support from organisations such as the MRC and Wellcome Trust. Both funders require an exit strategy as part of the application for research funding, and facility investment. There remains a gap for early phase clinical trials and the Cell Therapy Catapult (CTC) may be able to assist with this in the provision of manufacturing facilities;
- The Committee were impressed with the work that had been undertaken to develop the 2015 – 202 R&D Strategy and congratulated all of those involved;
- The Committee was not in a position to approve the 2015 2020 R&D Strategy until the Workpackage proposals were reviewed and prioritised.

The eight strategic goals were reviewed in detail, with the following being noted:

- Goal 4, Advanced blood components: Committee agreed that this goal should be broadened to include additional regenerative medicine therapies and reflect NHSBT's wider ambitions.
- Goal 5, Behavioural research: SJ advised the Committee that the challenge remains identifying the most appropriate area in the transplant pathway to

address . Health providers need to be brought on board and clinical leads for organ utilisation are being recruited. LW stated that there was scope for population level studies around donation and consent (funded through comms), as well as clinician behaviour. There is a current shortage/urgency around ODT, though later studies could focus on blood donation. In ODT, organ acceptance and the initial approach for gaining consent were the two areas identified as a priority for this work. NHSBT would need to work with external experts from academia and the commercial sector to deliver this goal. Due to the restrictions on funding it was felt that external funding should be pursued initially.

 Goal 6, Translational Data Science: Committee felt that translational outputs could be effectively delivered that would justify investment. The INTERVAL study was a good example of this as the data collected will be fed back to the blood donation services. RP informed the Committee that there is a need for bioinformatics expertise and for support to interrogate the data. Collaboration with partners might be useful.

#### 5a) Proposal for Tenure Track

NW presented proposals for developing a tenure track programme to assist with succession planning. The proposal was for £100k per annum over 5 years, in conjunction with the Wellcome Trust who will provide oversight but no funding. The initial proposal of £120K per annum was reduced to £100K per annum by the R&D SMT. The University of Cambridge is prepared to host the successful candidate, if required. Blood cell biology is the first area with need of bioinformatics expertise. In discussion it was noted that:

- For the NIH system, it is a relatively long process for both application to tenure track and a decision re tenured outcome. It is open nationally for applications and provides space, support and a mentor. There is no guarantee of a tenured post as these are competitive, but tenure success is good. It is difficult to support a post holder, however, if they do not obtain a tenured post. NIH fund posts from the department's budget, and a central tenure committee decide whether a candidate is qualified for tenure;
- Other blood services do not operate similar programmes;
- The proposal is good as it brings clarity at the start of the application process;
- NHSBT is not intending to increase the number of Principal Investigators overall and a planned reduction is expected over the duration of the 2015 – 2020 R&D Strategy;
- There are significant benefits in terms of reputation of working with an external grant awarding body;
- The post needs to be fully supported and resourced, with good mentoring but also with the ability to explore scientifically;
- There would be a need to assess the quality of any candidates rigorously against key performance indicators if they were to progress to a tenured position;

Outcome: The proposals were supported, subject to identification of savings elsewhere in the R&D Programme (see below)

Action: LW/NW to revise R&D Strategy and submit to the Board for final approval

6. Overview of workpackage and project progress reports

Recommendations from the R&D SMT in relation to project reports not escalated to Committee were accepted in full. It was noted that the report for PG08-3 (Isolation, characterisation and enrichment of human limbal stem cells prior to expansion by culture, Dr Carl Sheridan) had been received as a late submission.

#### Action: LM to feed back to project grant holders

<u>Detailed discussions relating to funding decisions for Items 7 – 12 are recorded in the</u> members only confidential section of the minutes.

#### 7. Theme 1: Blood Donor Health

#### 7a) 11-01-GEN: INTERVAL

LW stated that Phase II was requesting all participants to donate until June 2016, and that data was being collected. Twenty five thousand invites have been sent out and 54% have responded and agreed to continue donation at the randomised intervals. There has been a good commitment from donors, and both standard and randomised donor reminders are being used. The issue around the cognitive work has been resolved. LW suggested that RDC requests that a high level timetable be created for all projects within INTERVAL, and that a publication strategy was still required. This can also be applied to a wider range of studies with the samples provided to the Biobank.

GM stated that the 8, 10 and 12 week interval donors have the same adherence rate, and that there is a hope to transfer this level of adherence to the routine donations.

Outcome: The Committee accepted this report and agreed to continue support Action: NW to feedback to INTERVAL team that RDC is very happy with the progress being made and request a high level timetable for completion of specific projects within INTERVAL, a publications strategy and a summary of projects using the INTERVAL biobank.

8. Theme 2: Transfusion and Transplantation Virology/Microbiology 8a) WP15-01: Transfusion microbiology

Outcome: The Committee approved funding in full as part of the 2015 -2020 R&D Strategy

Action: NW to inform applicants of the outcome.

8b) vCJD screening update

Outcome: The R&D Committee agreed to fund the work until 30<sup>th</sup> September 2015.

Action: LW to discuss future funding with NHSBT's Chief Executive and representatives from the UK Forum.

9. Theme 3: Patient Blood Management9a) WP15-03: Innovation in hospital transfusion

Outcome: Decision on hold, pending clarification on the areas of concern raised in review

Action: LW to discuss with applicant; NW to send letter requesting the additional information; JM to visit Oxford to review project on behalf of RDC

#### 9b) 12-01-CSU: TREATT

A progress report on the TREATT trial was considered. The project is progressing well and open to recruitment. Erika Woods at Monash University will be a collaborator.

#### Outcome: The Committee accepted this report and agreed to continue support Action: LM to feed back to award holder

#### 9c) BS06-1: PlaNeT-2

A progress report on the PlaNeT-2 trial was considered. Committee congratulated the team for getting recruitment back on target.

#### Outcome: The Committee accepted this report and agreed to continue support Action: LM to feed back to award holder and implement annual reporting

#### 9d) BS08-3: HLA Epitope

A progress report on the HLA-epitope was considered. It was noted that 38 patients, of a target of 40, had been recruited. DC added that there are potentially another 4 more patients likely to be entered into the study and so the target of 40 should be met. It is hoped that analysis might be completed within 4 to 5 weeks post data collection.

#### Outcome: The Committee accepted this report and agreed to continue support Action: LM to feed back to award holder and implement annual reporting

#### 9e) 10-09-CSU: TRIGGER (Final report)

A final report for the TRIGGER trial, which had been completed successfully, was considered. The study demonstrated that cluster randomisation is feasible in this setting and a manuscript has been accepted for publication in Lancet. Future funding to move to a Phase III trial has not yet been identified; however, the data and outcomes will feed into gastrointestinal bleeding practices and guideline development.

Outcome: The Committee accepted this report and agreed to close the study. Action: NW to pass on congratulations to Professor Murphy, Dr Jairath and the study team

AT and CG were not present during discussions on Theme 4

# 10. Theme 4: Advanced blood components 10a) WP15-04: Manufactured red cells

Outcome: The Committee approved funding in principle as part of the 2015 -2020 R&D Strategy, subject to a review and agreement on the requested funds Action: NW to review funding requirements with applicant and include revised budget in Board submission

10b) WP15-05: Studies on erythropoiesis

Outcome: The Committee approved funding in full as part of the 2015 -2020 R&D Strategy

Action: NW to inform applicant of the outcome

10c) WP15-06: Production of platelets from stem cells

Outcome: The Committee approved funding in full as part of the 2015 -2020 R&D Strategy

Action: NW to inform applicant of the outcome

#### 10d) PG06-3: Alloimmunisation DNA bank (change request)

A change request from Dr Stephen Garner was considered. It was noted that:

- £48k remains unspent in the project;
- The results from the study could be generalised and could inform clinical staff about who is likely to form alloantibodies;
- There was a lack of clarity about how the remaining funds would support all of the genotyping required for the study;

#### Outcome: Approval deferred.

Action: NW to contact Prof Ouwehand to resolve issue relating to costs of genotyping and sample numbers. CC to take Chair's action on basis of information provided.

#### 11. Theme 5: Organ Donation and Transplantation

The minutes and recommendations from a pre-meet on ODT specific issues held on 13<sup>th</sup> May 2015 were accepted by the Committee. Specific actions relating to behavioural research and living kidney donors will be addressed as part of the 2015 – 2020 R&D Strategy. For living kidney donation it was agreed that greater information on the risks associated would be of considerable value. This work is currently being led by Dr di Angelantonio and will reported to the November 2015 meeting.

# Action: LM to request report on living kidney donation from Dr di Angelantonio for November 2015 meeting, to include comparisons between related and altruistic donors.

#### 11a) WP11-04: QUOD – report to Committee

RP reported that all sites are now recruiting and approximately 60% of Trusts are able to participate. There is variation in consenting and recruitment of QUOD donors in the different retrieval zones which is being managed by the QUOD National Management Team. A two step approach has been implemented to enable access to the samples in the BioBank. The first step assesses the feasibility of the study and alignment to the overarching QUOD objectives; the second step considers proposals in more detail

including time to replenish samples in the BioBank. Work to develop a cost recovery model for QUOD is underway.

It was noted that a library of proteomics and genomics data would be created as part of the QUOD Biobank.

Outcome: The Committee accepted this reported and agreed to continue support

12. Theme 6: Stem Cells and Immunotherapies12a) WP15-08: Optimising human HSC expansion

Outcome: The proposals were not approved. In light of this decision, the unsuccessful NIHR BTRU application from the University of Oxford and the cessation of funding to Prof Watt through NIHR Programme C, the R&D Committee recommended that steps be taken to close this work. In view of the BTRU, the need for this area of activity was questionable.

Action: LW to feed back comments to Prof Watt.

12b) WP15-09: Targeted therapeutics for childhood leukaemia

Outcome: The proposals were not approved.

Action: LW to feed back comments to Dr Blair and review requirements for animal studies to support the first-in-man clinical trial of manufacture red cells with Prof Anstee.

12c) WP15-11: Regulatory T-cells in stem cell transplantation

Outcome: The proposals were not approved.

Action: NW to arrange external peer review of the application. CC to take Chair's action on the basis of peer review.

12d) Additional Item: PG08-3: Isolation, characterisation and enrichment of human limbal stem cells prior to expansion by culture – Final Report (Dr Carl Sheridan)

The final report (received late) shows that the storage of epithelium has a detrimental effect on stem cells. The report has not yet been reviewed by Helen Gillan.

### Action: LM to send report to the Chair of the Tissues Strategy Group and return comments to RDC in November 2015

#### **13. Trust Fund Projects Annual Report**

It was reported that, following a review of available monies, the Trust Fund can consider funding two additional projects in 2015. Funding for additional pilot/preliminary studies would continue to be dependent upon corporate funds, but a process should be put in place to allow submission of applications. In order to increase scrutiny of applications an annual competition with presentations from applicants to R&D SMT will be maintained.

The Committee endorsed its support of providing flexible funding for pilot/preliminary studies as part of the 2015 – 2020 R&D Strategy.

#### 14. Clinical Fellows

LW presented an overview of current NHSBT Clinical Fellows, with all performing well and providing a mechanism for future leaders in transfusion medicine. Committee confirmed their continued support for these posts.

#### 15. Governance

#### 15a) Finance Presentation

CS presented the year end position for 2014/15, reporting a deficit of £393k, which was in large part due to costs associated with changes to NIHR funding. The worst case scenario for 2015/16 was an overspend of approximately £400k. With the further reductions in RCF predicted, the current position was considered too great a risk to carry forward into future years. The prioritisation of proposals was therefore essential to maintain the viability of the R&D Programme. It was noted that:

- Delivery of the full proposals in the 2015 2020 R&D Strategy would required significant additional funding with four critical projects (Clinical evaluation of dCELL dermis, Clinical trial to support patient blood management, Behaviour change research and Translational data science);
- An external funding application for a clinical trial of dCELL dermis in diabetic patients was being submitted to the Health Technology Assessment. If this application proved to be unsuccessful it has been agreed that the clinical trial can be funded by Diagnostics and Therapeutic Services;
- Dr Lise Estcourt, recently appointed as a Consultant and potential future PI, should be encouraged to seek external funding for a clinical trial in support of patient blood management in individuals with acquired coagulopathy;
- Commercial funding could be sought in some areas;
- International collaborations could facilitate larger, multi-centre studies which offer increased value for money;
- Dependency on external funding would increase the risk of failing to deliver the strategy if applications were unsuccessful and internal funding could not be identified;
- There are significant benefits in NHSBT continuing to fund research directly;
- There continue to be opportunities for NHSBT to support externally funded research driven by leading academics by making use of our unique capabilities;
- Activities in Translational Data Science would benefit from the renewed investment in IT;

# Outcome: The R&D Committee approved the prioritised budget for submission to the Board and agreed that costs associated with the changes could be funded from the Clinical budget in 2015/16.

Action: NW/CS to submit revised budget to Board.

#### 15b) Annual Intellectual Property Report

NW stated that the total IP expenditure has been reduced by £80K to £50K. Monthly calls were in place to review actions and decisions related to specific patents. It was noted that new patent applications were filled this year. Committee were supportive of the approach and accepted the report.

## Action: NW to increase efforts to identify new intellectual property that could be protected.

#### 15c) External R&D Funding and Research Outcomes

LM presented a summary of the figures reported by PIs in the annual returns, which showed significant level of external funding being obtained. CC stated that the results were pleasing, and asked HK how these compared to those at NIH. HK responded by stating that the figures for NHSBT were very high.

## Action: NW to feed back to PIs that the RDC is pleased with the level of external funding being sought and obtained

#### 15d) Review of Terms of Reference

CC stated that there is a requirement for an annual review of the Terms of Reference of the Committee. It was agreed that increasing the number of external experts would improve the ability of the Committee to assess proposals without the need for external peer review. Terms of reference to be amended to state that up to four external experts could be included on the Committee, with a minimum of 2 external experts required to make funding decisions.

#### Action: LM to update the Terms of Reference

#### 15e) Response to external review

LM gave a summary to the Committee. NW recommended closure of the external report with the remaining open recommendations to be reported separately in the future. The Committee accepted this proposal and formally closed the 2013 external review.

#### 16. Workplan for future RDC meetings

NW provided the Committee with a verbal summary of the workplan, including the ABO KPIs and the potential need for a call for the Behavioural Change research. Further updates to the workplan would be required following decisions at the Committee meeting. Standard progress reports will be provided at the November 2015 meeting. It was noted that results from the INTERVAL study would only be available once the study had completed as it was considered poor practice to assess data before the trial ends.

#### 17. AOB : None stated

#### 18. Date of next meeting: Monday 23rd November 2015

#### Twenty-fourth Meeting of the NHS Blood and Transplant REMUNERATION COMMITTEE held on Thursday 25 June 2015 at the West End Donor Centre

Present:	Mr S Williams (Chair)	SW
	Mr J Pattullo	JP
	Mr J Monroe	JM
In attendance:	Mr I Trenholm	IT
	Mr D Evans	DE

#### SUMMARY NOTES

At the meeting on 25 June 2015 the Committee discussed and agreed a number of matters which included the following:

- Executive Director Performance Review and bonus arrangements
- Changes to the Executive structure and the progress of new appointments
- Succession Planning
- Local awards for Medical Staff
- An update on the DH Review of the Very Senior Manager Pay Framework
- The annual report of the Committee
- The Committee agreed to meet again in the autumn.

Jane Minifie Minute Secretary

#### NHS BLOOD AND TRANSPLANT

#### 30 JULY 2015

#### REPORTS FROM THE UK HEALTH DEPARTMENTS

A report from Wales is attached.

July 2015

#### WALES UPDATE REPORT FOR NHSBT BOARD MEETING - 30 July 2015

#### **Organ Donation and Transplantation**

#### Human Transplantation (Wales) Act 2013

*Communications and engagement:* New TV and radio adverts were broadcast to coincide with a leaflet drop to all households in Wales which took place on 15 June. The new organ donor register was also opened to people in Wales from that date (see below). Traffic to the Organ Donation Wales website increased substantially. The Lap of Wales Challenge took place from 3 - 11 July, visiting many Welsh speaking communities along the way. A touring exhibition, specially commissioned drama, and musical entertainment also accompanied the celebrities as they travelled around Wales using a variety of modes of transport (tandems, zip wires, trams and steam trains, vintage vehicles, etc.)

*Register redevelopment:* The new register was launch fully across the UK on 9 July, although as stated above it had been available in Wales for several weeks before this date. It appears to be working well. As of 15 July, a total of 30,500 people had opted out, the vast majority from Wales. There has also been an increase of the number of people in Wales opting in to the register.

*Business change and training:* The Implementation Project Board meeting on 6 July received a paper from NHSBT on the training arrangements. SNOD teams and collaboratives across the UK have now received training on the new ODR. Specific training on the Welsh legislation and managing donation conversations will take place between September and November.

*Subordinate legislation:* The summary report from the consultation on three sets of regulations was published on 30 June. Some minor changes to the draft regulations will be made as a result of consultation responses. The regulations will be put before the National Assembly for Wales for approval on 6 October, together with the Human Tissue Authority's Code of Practice.

#### Taking Organ Transplantation to 2020 – Wales Action Plan

At next the Wales Transplantation Advisory Group (WTAG), in September, members will be peer reviewing health board plans.

The Towards 2020 - Organ Transplantation in Wales Conference is taking place on Thursday 24 September at Cardiff City Stadium, anyone interested can register at <u>https://tuag-at-2020-towards-2020.eventbrite.co.uk</u>. The morning session will focus on the practical implementation of the Human Transplantation (Wales) Act, and the afternoon session will focus on the 2020 Wales Action Plan with sessions on donation from the emergency department, paediatric donation, donation pathway and transplantation. The Minister for Health will be launching the first Towards 2020 Annual Report. Confirmed speakers include Luc Colenbie who will provide a Belgian perspective on organ donation legislation and a personal viewpoint from baby Teddy's parents, Jess and Mike.

#### All Wales Blood Service (AWBS)

Amendment Directions were made on 13 July to:

- revoke part of Direction 2 to remove the responsibility of NHSBT to provide blood services in north Wales from 2 May 2016 (the date that the AWBS comes into being);
- provide for transitional arrangements which direct NHSBT to share relevant donor data with the WBS; and
- instruct NHSBT to manage a legacy register of blood and bone marrow donors (that it holds as of 2 May 2016) and any associated services necessary for the treatment of patients and that this register is shared with WBS

NHSBT will not add new donor records as all new north Wales donors from 2 May 2016 will register through the AWBS.

While the AWBS will generally be self-sufficient from 2 May 2016, north Wales hospitals' demand for blood will be covered by contingency arrangements UK blood services have in place through a Memorandum of Understanding to ensure reciprocal support where needed.

The WBS and Velindre NHS Trust have worked closely with NHSBT and other key partners under the auspices of the AWBS Programme Board to develop proposals for the new services. There has been a considerable team effort in ensuring that the transition will be as smooth as possible – in terms of service provision; north Wales donors and clinics; and in the supporting communications developed.

Work continues on the Transition Plan that sets out in detail the key milestones and responsibilities in three phases: enabling activities (pre-transition); the actual cutover of services (legal transfer of staff and assets); and a supportive early adoption phase.

The Minister issued a Written Statement informing Assembly Members of the benefits being realised through the AWBS in terms of national resilience; jobs in Wales; local blood donation; product provision and pricing for north Wales hospitals; and increased scope for efficiency savings through an end-to-end management of the supply chain through a single body.

#### NHS BLOOD AND TRANSPLANT

#### 30 JULY 2015

The Board by this resolution give notice that representatives of the press and other members of the public be excluded from the remainder of this meeting having regard to the confidential nature of the business to be transacted, publicity on which would be prejudicial to the public interest (Section 1 (2) Public Bodies (Admission to Meetings) Act 1960).

The Board intend to consider certain commercial, research and development and policy items. The commercial matters relate to the purchase of goods/equipment/services. The research items are matters relating to named staff. The policy matters relate to organ donation and transplantation.

#### NHS BLOOD AND TRANSPLANT

#### 30 JULY 2015

#### ANNUAL REPORTS FROM THE BOARD COMMITTEES

Annual Reports from each of the Board Committees are attached.

July 2015



# **NHS Blood and Transplant**

# **Expenditure Controls Committee**

# Annual Report 2014/15

#### 1 PURPOSE OF THE REPORT

The Expenditure Controls Committee has prepared this report to the Board in order demonstrate how the Committee has satisfied its terms of reference during 2014/15.

#### 2 CONSTITUTION

The Expenditure Controls Committee was established by the Board in July 2011 to comply with Department of Health requirements regarding internal approvals for professional services expenditure. The Committee is an executive committee of the Board but has no executive powers other than those specifically delegated to it in the terms of reference.

#### 3 OVERVIEW

The duties of the Expenditure Controls Committee are:

- To approve and endorse expenditure on professional services within the limits established by the scheme of delegation.
- To review quarterly forecasts of professional services expenditure submitted to the Department of Health.
- To ensure that an audit trail is provided to demonstrate that authorisation of professional services expenditure has been applied in line with Department of Health requirements.
- To receive reports on all professional services expenditure and so ensure that approvals have been sought as required by Department of Health controls.

#### 4 MEMBERSHIP

The Expenditure Controls Committee membership in respect of the financial year 2014/15 was:

Lynda Hamlyn	Chief Executive, NHSBT and Chair (Q1 reporting only)
Ian Trenholm	Chief Executive, NHSBT and Chair (Q2 reporting onward)

Annual Report 2014/15

Andrew BlakemanNon-Executive DirectorRob BradburnDirector of Finance, NHSBT

The following individual(s) are normally in attendance at meetings:

Mark Taylor Assistant Director Planning & Performance NHSBT

#### 5 COMPLIANCE WITH TERMS OF REFERENCE

Formal meetings of the Expenditure Controls Committee were held on:

25<sup>th</sup> July 2014 7<sup>th</sup> November 2014 27<sup>th</sup> Mach 2015 27<sup>th</sup> April 2015

All meetings during 2014/15 were quorate.

#### 6 DUTIES AND FINDINGS

Over the 4 meetings held during 2014/15, the following matters were discussed and appropriate decisions taken by the Committee:

- The Committee received quarterly reports at each meeting detailing the type and value of expenditure incurred in the prior quarter(s) and also planned expenditure for the remaining quarter(s) of the financial year.
- Spend below £30k is reviewed and approved retrospectively by the committee, where it is over this level, ECC members are asked to provide approval off-line for prospective spend on each occasion.
- DH issued an update to the guidance in July 2013 (Government and DH Efficiency Controls Guidance for Arm's-Length Bodies), which supersedes the previous version of December 2012, however our previous delegations remain broadly unchanged and consistent with both our ToR and issued internal guidance.
- In line with Department of Health guidance issued to Arms-Length Bodies, Internal Audit have been engaged to undertake a review of Professional Services expenditure and confirm that expenditure was sourced from non programme funding formerly grant in aid funds (i.e. blood prices), at the end of each quarter.
- The information provided to the Committee is reviewed and discussed at the quarterly meeting and approval of the Committee is provided subject to assurance having been given that the expenditure incurred has been within the ambit and spirit of the guidance and advice received by the Authority. The Committee approved the findings at each of the 4 meetings during 2014/15.
- There have been four reports received from Internal Audit and on each occasion their findings did not identify any exceptions to the guidance from the Department, namely that where expenditure was incurred from Programme Funding sources it had been authorised in line with the standing arrangements issued by the Department (overall report rating for quarter 4 2014/15 was substantial).

#### 7 WORKPLAN 2015/16

The Committee will meet on an ad-hoc basis, but at least quarterly and will follow a standard agenda as per the meetings in 2014/15 (see Appendix A).

#### 8 CONCLUSION

The Expenditure Controls Committee has complied with its terms of reference during 2014/15.

Ian Trenholm Chair of the NHSBT Expenditure Controls Committee July 2015

#### APPENDIX A - EXPENDITURE CONTROLS COMMITTEE WORKPLAN / STANDARD AGENDA ITEMS 2014-15

Agenda Item	July 15	Oct 15	Jan 16	April 16
Review and approve expenditure report	Х	Х	Х	Х
Review findings of the Internal Audit Reports	Х	Х	Х	X



### NHS Blood and Transplant Governance and Audit Committee Annual Report 2014/15

#### 1 PURPOSE OF THE REPORT

The Governance and Audit Committee (GAC) has prepared this report to the NHSBT Board. It sets out how the Committee has satisfied its terms of reference during 2014/15 and seeks to provide evidence relevant to its responsibilities for the Governance Statement.

#### 2 OVERVIEW

The existence of an independent GAC is the central means by which a Board ensures effective control arrangements are in place. In addition, the GAC provides an independent check upon the executive arm of the Board.

The GAC independently reviews, monitors and reports to the Board on the attainment of effective control systems and financial reporting processes. In particular, the Committee's work focuses on the framework of risk, control, and related assurances that underpin the delivery of the organisation's objectives.

The GAC receives and considers reports from both Internal and External Auditors and also the Annual Report and Accounts.

#### 3 MEMBERSHIP

The GAC membership in respect of the financial year 2014/15 was:

Andrew Blakeman	Non-Executive Director and Chair of the GAC
Roy Griffins	Non-Executive Director
Shaun Williams	Non-Executive Director
Keith Rigg	Non-Executive Director

The Lead Director supporting the GAC was Rob Bradburn, Finance Director.

#### 4 COMPLIANCE WITH TERMS OF REFERENCE

The GAC is made up entirely of non-executive directors. All meetings during 2014/15 have been quorate with 100% attendance.

Page 1 of 7

The Committee has ensured that its terms of reference are in line with those recommended in the NHS Audit Committee Handbook, and its terms of reference have been approved by the Board and are reviewed annually by the GAC.

The GAC has regular attendees, these are:

John Pattullo Ian Trenholm	Chairman Chief Executive
Rob Bradburn	Finance Director
lan Bateman	Assistant Director, Quality
Eugene Cooke	Associate Director National Head of Procurement
Denise Dourado	Assistant Director Business Transformation
Christine Costello	Non-Executive Director
Louise Fullwood	Non-Executive Director
Linda Haigh	Assistant Finance Director
Ben Hume	Interim Assistant Director Transplantation Support Services
Sally Johnson	Director Organ Donation and Transplantation
Huw Williams	Director of Diagnostic and Therapeutic Services
Aaron Powell	Interim Director of ICT Interim (from October 2014)
Lorna Williamson	Medical and Research Director
David Evans	Director of Workforce
Clive Ronaldson	Director of Blood Supply
Katherine Robinson	Deputy Director for Human Resources
Mark Taylor	Assistant Finance Director
Huw Williams	Director of Diagnostic and Therapeutic Services
Mike Potter	Director of Business Transformation Services (until September 2014)
Ruth Adam	Assistant Director – Governance and Clinical Effectiveness (until July 2014)
Rachel Johnson	Assistant Director – Governance and Clinical Effectiveness –
	Interim (from August 2014 until March 2015)
Richard Rackham	Assistant Director - Governance & Resilience
Leonie Austin	Director of Communications
Ann Smith	Secretariat to the GAC and Senior PA to Ruth Adam & Rachel Johnson (Minutes)

The GAC is also regularly attended by representatives from both Internal and External Audit. Members meet with Auditors in private during the year.

#### 5 MEETINGS

Five meetings were held during the financial year:-

24 April 2014 13 June 2014 26 September 2014 28 November 2014 27 February 2015

#### 6 AUDIT PROVISION

Internal Audit was provided by PricewaterhouseCoopers and External Audit by the National Audit Office (in partnership with Deloitte). All parties regularly attended the GAC.

Page 2 of 7

Internal and External Auditors submitted annual audit plans, which were agreed and monitored by the GAC. Regular updates on the progress and outcomes of these were presented to the Committee during the year.

#### 7 GOVERNANCE AND AUDIT COMMITTEE OPINION

Members of the Board should recognise that assurance given can never be absolute. The highest level of assurance that can be provided to the Board is a reasonable assurance that there are no major weaknesses in the Authority's risk management, control, and governance processes.

The opinion of the Governance and Audit Committee, based on the issues set out in section 8 below, is that the Authority's risk management, control and governance processes are adequate and effective and may be relied upon by the Board.

#### 8 DUTIES AND FINDINGS

The GAC Terms of Reference were reviewed and updated in February 2015 and comprise five main areas of responsibility.

- Governance, including Clinical Governance, Risk Management and Internal Control
- Internal Audit
- External Audit
- Other Assurance Functions
- Financial Reporting

With agendas arranged under the following headings:

- Board Performance Report BPR (RBr) to look at the delivery of the Strategy from an assurance perspective, i.e. are controls in place to mitigate risks to delivery; it was for the Board to review performance against plan.
- Clinical Governance (LW)
- Quality Assurance (IB)
- Audit (Internal and External)
- Committee Business

#### 8.1 Governance, Risk Management and Internal Control

The Committee can give significant assurance that controls are being applied consistently through quality and thoroughness of investigations based on work that has been undertaken in 2014/15.

#### ODT

During 2014/15 the Committee continued to monitor the progress of the Duty Office action plan. As of June 2014 there remained only one open action, which was noted to be close to a resolution.

#### <u>Risks</u>

A meeting of stakeholders to discuss risk management input into a risk management proposal was held in August 2014. The process of risk management rather than individual risks is under review and the report was taken to the October 2014 Board meeting. The Information Governance Framework project, to develop a new, consolidated risk and

Page 3 of 7

incident management system was presented to the Transformation Programme Board (TPB), in April 2015. The project has been deferred until March/April 2016. The Risk Management Assessment Framework management process description (MPD) was approved in December 2014.

#### 8.2 Internal Audit

The GAC Committee receives recent internal audit work.

The Committee has overseen and supported the work of Internal Audit through:

- agreeing an audit plan;
- reflect the results of internal audit reviews;
- reviewing and agreeing the Head of Internal Audit Opinion

#### 8.3 External Audit

The GAC Committee is satisfied with the delivery of the external audit plan for 2014/15.

#### 8.4 Financial Reporting

The GAC has reviewed the Annual report and Accounts for 2014/15 and are assured the accounts comply with legal requirements.

#### 8.5 Other Assurance Functions

#### Site Resilience

The Committee were assured that many of the actions were completed following a review and it was noted that many of the actions were already in the workplan for 2014.

#### Business Continuity

Work continued in 2014/15 to expand the scope of certification to cover key NHSBT sites. The Committee are satisfied with the work completed and plans for 2014/15.

#### Transformation Project Board

The Committee were assured that the project was possible and was endorsed and it was endorsed by the Executive Team.

#### INTEGRATED GOVERNANCE

The Committee have reviewed, updated and approved the Integrated Governance Framework during 2014/15.

The Committee Terms of Reference and workplans have also been reviewed and amended during 2014/15.

During the year the GAC has been involved in examining governance arrangements for:

Board Assurance Framework and Map Board Committee self assessments and annual reports Board Performance Report Clinical Audit Clinical Claims

Page 4 of 7

Clinical Governance issues Committee workplan **Commercial Insurance** Care Quality Commission (CQC) Information Governance **DH Group Assurance** Directorate risk overviews by Specialist Services, Tissue Services, Organ Donation & Transplantation Draft and final accounts External Audit Financial Governance- losses and special payments, waivers Focus of the GAC in respect of Blood Supply/ODT Francis Report Action Plan Update Fraud Integrated Governance Framework Health and Safety Reports Infection Control Internal Audit IT Governance Organ Donation Register (ODR) Quality Management **Risk Management** Site Resilience Serious Untoward Incident's (SUI's) Sustainability Terms of Reference Transformation Programme/Information Technology (IT) risks Whistleblowing

The Committee has received risk presentations related to

- Diagnostic Services (Red Cell Immunohaematology (RCI) and Histocompatibility & Immunogenetics (H& I)
- Business Continuity
- Specialist Therapeutic Apheresis Services (TAS)
- Blood Supply Chain
- Clinical, Research and Development

The risk presentation timetable has been reviewed and updated for 2015/16

#### 9 CONCLUSION

The GAC has complied with its updated terms of reference in 2014/15 during which it has:

- reviewed and approved the financial statements for 2014/15;
- reviewed the Governance Statement for 2014/15 and confirmed that it is consistent with the GAC assessment of control;
- reviewed the Integrated Governance Framework;
- reviewed reports prepared by Internal and External Auditors along with the ensuing management actions, where appropriate;
- reviewed NHSBT plans to achieve financial stability

Page 5 of 7

The GAC will ensure that the Governance Framework supports the organisations' agenda and deliberations over the coming twelve months as NHSBT moves towards delivering the next stages of its service strategy.

#### Andrew Blakeman

Chair of Governance and Audit Committee June 2015

Page 6 of 7

WITN0643008\_0154

Page 7 of 7

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NHS Blood and Transplant

### **Remuneration Committee**

# Annual Report 2014/15

#### 1 PURPOSE OF THE REPORT

The Remuneration Committee has prepared this report to the NHSBT Board in order demonstrate how the Committee has satisfied its terms of reference during 2014/15.

#### 2 OVERVIEW

- The duties of the Remuneration Committee are:
- To exercise the authority delegated by the Board of NHSBT on the remuneration and other contractual arrangements for the Chief Executive and NHSBT Directors. This to be done with due regard to the provisions of the NHS Very Senior Manager Pay Framework and/or other relevant guidance and best practice, ensuring that they are fairly motivated and rewarded and their terms are reviewed and remain competitive and appropriate.
- Through the Chairman of NHSBT and the Chief Executive, to monitor and evaluate the performance of the Chief Executive and individual NHSBT Directors and to use the authority delegated by the Board to set performance bonuses, if appropriate and within guidelines and/or requirements set by DH.
- To oversee and advise the Board on termination and severance arrangements in relation to the Chief Executive and NHSBT Directors.
- To ensure that appropriate details of Board Members' remuneration and other benefits are published in the Annual Report.
- To consider and approve any individual redundancies with projected costs in excess of £100,000.
- To consider and approve redundancy proposals within organisational change exercises, where the total estimated redundancy cost exceeds £500k.
- To consider and approve proposals to establish management posts at Band 9 of the NHS national pay bands.

Annual Report 2011/12 and Workplan 2012/13

- To consider and approve recommendations for local Clinical Excellence Awards to NHSBT medical staff.
- To review the overall approach to NHSBT recommendations for national honours and to review the categories against which recommendations are made on an annual basis.
- At the request of the NHSBT Board, to undertake succession planning and any other appropriate duties to ensure that a stable, experienced and viable team is in place at executive at non-executive levels.

#### 3 MEMBERSHIP

The Remuneration Committee membership in respect of the financial year 2014/15 was:

Shaun Williams	Non-Executive Director and Chair
John Pattullo	Chairman NHSBT
Jeremy Monroe	Non-Executive Director

The following individuals were normally in attendance at meetings:

Lynda Hamlyn	Chief Executive, NHSBT (to July 2014)
lan Trenholm	Chief Executive, NHSBT (from October 2014)
David Evans	Director of Workforce, NHSBT

The Lead Director supporting the Remuneration Committee was David Evans, Director of Workforce.

#### 4 COMPLIANCE WITH TERMS OF REFERENCE

Formal meetings of the Remuneration Committee were held as follows:

8<sup>th</sup> April 2014 7<sup>th</sup> July 2014 1st October 2014 25th March 2015

All meetings were quorate, and the Committee complied with all aspects of its Terms of Reference.

#### 5 DUTIES AND FINDINGS

At formal meetings during 2014/2015 the Committee discussed and agreed a number of matters which included the following:

8<sup>th</sup> April 2014

**Remuneration Committee** 

Annual Report 2011/12 and Workplan 2012/13

- An update on the recruitment of a new Chief Executive for NHSBT
- A discussion of matters related to the Executive team structure and possible future changes resulting from possible future planned retirements
- A briefing on the planned DH review of the Very Senior Manger Pay framework.
- Arrangements for the future consideration of Executive performance.

#### 7th July 2014

- The outcomes of the Chief Executive's review of executive performance and agreed the approach to performance bonus awards for the 2013/2014 performance year, under the terms of the Very Senior Manager Pay Framework
- Consideration of other matters related to Executive pay
- An update on the DH review of the Very Senior Manager Pay Framework

#### 1<sup>st</sup> October 2014

- An update on the process to replace the Director of Business Transformation Services
- An update on the DH Review of the Very Senior Manager Pay Framework
- The Committee's Annual Report to the Board

#### 25<sup>th</sup> March 2015

- An update on proposed changes to the Executive structure
- Arrangements for the forthcoming Director Performance Review Process.
- An update on the DH Review of the Very Senior Manager Pay Framework.

### 7. REVISIONS TO TERMS OF REFERENCE

There were no revisions to the Committee's Terms of Reference during 2014/2015.

#### 6 CONCLUSION

The Remuneration Committee has complied fully with its terms of reference during 2014/2015.



# **NHS Blood and Transplant**

### **R&D** Committee

### Annual Report 2014/15

#### 1. PURPOSE OF THE REPORT

The R&D Committee has prepared this report to the NHSBT Board in order to demonstrate how the Committee has satisfied its terms of reference during 2014/15.

#### 2. OVERVIEW

The Board has delegated authority to the Committee to provide strategic oversight of an innovative, cohesive high quality programme of research and development (R&D) which includes a balance of short and long term research and meets the requirements of the Strategy Groups which link research, development and operational staff in each business area. The Committee aims for timely translation of research findings into new products and services, to deliver improvements to the efficiency, efficacy and safety of blood, tissues, cellular and organ products and services for donors and patients.

The Terms of Reference of the R&D Committee are:

- To approve, on an annual rolling basis, the R&D programme for presentation to the Board, having assurance of the quality, relevance and translation of the research, the facilities for its delivery, and the quality of the research staff.
- To make decisions on allocation of research and development funds, within the delegated financial limits of NHSBT.
- To receive annual reports and monitor progress on funded projects.
- To review, on an annual basis, the portfolio of external grants held by NHSBT's Principal Investigators.
- To review, on an annual basis, the portfolio of research projects funded by NHSBT's Trust Fund.
- To commission research from external sources where appropriate.
- To have assurance that appropriate arrangements are in place for staff development, research governance, agreements with academic and commercial collaborators, and protection and exploitation of Intellectual Property, reagents, and material such as cell lines.
- To determine the appropriate interval between external audits of NHSBT R&D, to commission the appropriate audit, to receive the report of the auditors and to ensure that such audits are properly conducted.
- To oversee the workplan of the R&D Senior Management Team.

These Terms of Reference were reviewed by the Committee at their meeting on 14<sup>th</sup> May 2015 and the following amendments were made.

- It was agreed that increasing the number of external experts would improve the ability of the Committee to assess proposals without the need for external peer review.
- The maximum number of external experts should be increased to four.
- A minimum of 2 external experts will be required to make funding decisions.

#### 3. MEMBERSHIP

The only change to the membership of the R&D Committee in the financial year 2014/15 was the replacement of Sarah McAllister, who was on maternity leave, by Lewis Matthews. The Membership at the end of the reporting period was:

#### Members

Rob Bradburn (NHSBT Finance Director) Christine Costello (Chair, Non-Executive NHSBT Board Member) Louise Fullwood (Non-Executive Director) Sally Johnson (NHSBT Director of Organ Donation & Transplantation) Harvey Klein (NIH, USA: External, expert assessor) Jeremy Monroe (Non-Executive Director) Clive Ronaldson (NHSBT Director of Blood Supply) Ellen van der Schoot (Sanquin, The Netherlands: External, expert assessor) Jonas Wadstrom (University of Stockholm, Sweden, External, expert assessor) Huw Williams (NHSBT Director of Diagnostic and Therapeutic Services) Lorna Williamson (NHSBT Medical & Research Director)

#### Observers

David Collett (NHSBT Associate Director Statistics and Clinical Audit) Cedric Ghevaert (NHSBT PI) Lewis Matthews (National Research Manager, Scientific Secretary) Rutger Ploeg (NHSBT PI) Chris Sims (Planning and Management Accountant, Group Services) Ashley Toye (NHSBT PI) Nick Watkins (NHSBT Assistant Director, Research & Development)

#### 4. COMPLIANCE WITH TERMS OF REFERENCE

Formal meetings of the R&D Committee were held on Friday 11<sup>th</sup> July 2014 and Monday 24th November 2014. Both meetings were quorate.

#### 5. DUTIES AND FINDINGS

- 1. The Committee agreed a workplan for future meetings.
- The committee noted the different levels of Research Capability Funding (RCF) associated with Programme Grants (41p/£) compared to Biomedical Research Units (19p/£). The transition from Programme Grant funding to Blood and Transplant Research Unit (BTRU) funding may be associated with a reduction in RCF.

- 3. The committee accepted the closing report of the Pricewaterhouse Coopers internal audit of governance of Strategy Group processes in Q4 2012/13. The committee noted that all actions were complete.
- 4. The committee made improvements to the quality of the PI annual reports by requesting that future annual reports capture unsuccessful funding bids.
- 5. The committee congratulated the INTERVAL Trial Steering Committee and Donor Centre Managers for their part in the successful recruitment of 50,000 interval donors.
- 6. The committee approved the £50k spend for the INTERVAL Study Administration Team (ISAT) to enable INTERVAL enhancements over two years.
- 7. The committee confirmed support for NHSBT's involvement in a vCJD population prevalence study should one go ahead.
- 8. The committee oversaw, reviewed and accepted the outcome of the NIHR BTRU application process.
- 9. The committee commissioned a process for pilot funding to be created to replace the Trust Fund which has now been exhausted. Subject to available funding, this will provide funding of up to £50k for pilot/spin-off studies.
- 10. The committee thanked Dr Lars Dölken, NHSBT PI, for his continued work with NHSBT, and wished him well for the future.
- 11. The committee supported NHSBT's involvement in the Alliance of Blood Operators International Working Group for R&D.
- 12. The Committee accepted reports on external grants held by Principal Investigators (PI) and recognised the ability of our PIs to attract external funding.
- 13. The Committee accepted an annual report on Intellectual Property.
- 14. The committee accepted an annual report on the status of the 22 active Trust Fund awards.
- 15. The Committee reviewed progress on 14 active workpackages within the reporting period. Progress on 12 was.ranked as Green and two were ranked Amber.
- 16. The Committee reviewed annual reports on all current research projects. Of the 19 projects reporting progress, 14 were ranked as Green, 4 as amber and 1 as red. The project ranked as red had ended and Committee wrote to the award holder and recommended that no further funding be awarded to them.
- 17. The Committee reviewed draft proposals for the 2015 2020 R&D Strategy, proposing a number of amendments.

#### 6. CONCLUSION

The R&D Committee has complied with its terms of reference from 1<sup>st</sup> April 2014 to 31<sup>st</sup> March 2015.

#### Christine Costello, NED NHSBT and Chair of R&D Committee, July 2015

**R&D** Committee

Page 3 of 3

Annual Report 2014/15



# NHS Blood and Transplant Transplant Policy Review Committee Annual Report 2014/2015

#### 1 PURPOSE OF THE REPORT

The Transplant Policy Review Committee has prepared this report to the NHSBT Board in order to demonstrate how the Committee has satisfied its terms of reference during 2014/2015.

#### 2 CONSTITUTION

The Transplant Policy Review Committee was established by the NHSBT Board to act on behalf of the Board to review and approve (where appropriate) all policies relating to selection and allocation policies relating to organ transplantation and those initiatives that have a significant impact on organ donation and transplantation. The Committee is an executive committee of the Board but has no executive powers other than those specifically delegated to it in the terms of reference.

#### 3 OVERVIEW

The duties of the Transplant Policy Review Committee are:

- To consider and approve, on behalf of the Board, those policies and standards developed by the solid organ Advisory Groups, the National Organ Donation Committee, and the National Retrieval Group and which relate to potential organ donor selection, organ donor management, patient selection and organ allocation.
- To ensure that the policies meet all legal, regulatory and ethical requirements and standards

#### 4 MEMBERSHIP

The Transplant Policy Review Committee membership in respect of the financial year 2014/2015 was:

Mr Jeremy Monroe	Non-executive Director (Chair)
Dr Christine Costello	Non-executive Director
Dr Lorna Williamson	Medical and Research Director
Ms Sally Johnson	Director ODT
Prof Chris Watson	Chair, Kidney Advisory Group
Prof John O'Grady	Chair, Liver Advisory Group
Prof Peter Friend	Chair, Pancreas Advisory Group
Mr Steven Tsui	Chair, Cardiothoracic Advisory Group
Prof Darius Mirza	Chair, Bowel Advisory Group
Mr Derek Tole	Chair, Ocular Tissue Advisory Group
Dr Paul Murphy	Chair, National Organ Donation Committee
Prof Rutger Ploeg	Chair, National Retrieval Group
Prof James Neuberger	Associate Medical Director, ODT (Secretary)
Prof John Dark	National Clinical Lead for Governance

#### 5 COMPLIANCE WITH TERMS OF REFERENCE

Formal meetings of the Transplant Policy Review Committee were held on:

1<sup>st</sup> July 2014 26<sup>th</sup> November 2014

A further meeting scheduled for 10<sup>th</sup> March 2015 was rescheduled to 16<sup>th</sup> April 2015 and is therefore not included in the report for the financial year 2014/15.

All meetings were quorate.

#### 6 DUTIES AND FINDINGS

Over the meetings held during 2014/2015, the following matters were discussed and appropriate decisions taken by the Committee:

The Committee reviewed and approved amendments to the following policies which are accessible at <u>www.odt.nhs.uk</u>

- Liver Selection Policy
- Liver Allocation Policy
- Kidney Selection Policy
- Kidney Allocation Policy
- Heart Selection Policy
- Heart Allocation Policy
- Lung Selection Policy
- Lung Allocation Policy
- Contra-indications to organ donation
- Intestinal Selection Policy
- Intestinal Allocation Policy
- Response to signals arising from audit of solid organ retrieval and transplantation outcomes
- Pancreas Selection Policy
- Pancreas Allocation Policy
- Ratification of changes to Kidney Selection and Allocation Policies re clarification of appeals process
- The Committee noted that one patient had so far been listed for the study of liver transplantation in selected patients with severe liver damage from alcohol (alcoholic hepatitis).
- The Committee discussed the implications of the management of listed liver transplant patients of highly effective directly active antiviral agents.
- The Committee noted progress made on the development of policies for use of organs from babies born with an encephaly and the policy for pregnancy testing on women of child-bearing potential who may become deceased organ donors.

#### 7 WORKPLAN 2015/2016

The Committee will meet at least six monthly and will follow a standard agenda as per the meetings in 2014/2015.

#### 8 CONCLUSION

The Transplant Policy Review Committee has complied with its terms of reference during 2014/2015.

#### Jeremy Monroe

Chair of the Transplant Policy Review Committee

June 2015



#### NHS BLOOD AND TRANSPLANT

#### **TRUST FUND**

#### ANNUAL REPORT 2014/15

#### 1 PURPOSE OF THE REPORT

The Trust Fund Committee has prepared this report to the NHSBT Board. It sets out how the Committee has satisfied its terms of reference during 2014/15, and seeks to provide evidence relevant to its responsibilities, in accordance with the powers delegated under the Standing Orders and Standing Financial Instructions.

#### 2 OVERVIEW

The NHS Blood and Transplant Trust Fund comprises a single General Fund, plus the Howard Ostin Fund, and the British Bone Marrow Donor Appeal (BBMDA) which are special funds with specific objectives. The Trust Fund Committee administers these funds on behalf of the Board which is the Corporate Trustee. The funds are registered under an Umbrella registration No. 1061771 with the Charity Commission, in accordance with the Charities Act 1993. The Charity receives income from investments and donations from members of the public, which are mainly credited to the General Fund. Donations in support of Organ Donation are 'earmarked' within the General Fund for that purpose.

The Committee controls and manages the use of all the funds resources. It monitors the investments of the Charity and oversees all expenditure. Acting for the Corporate Trustee the Committee ensures that 'best practice' is followed in conducting the affairs of the Charity, that all legal responsibilities are met, and that monies are spent in accordance with fund objectives as outlined below; challenging when it considers that funding should first be sought from other sources.

**The General Fund** is an unrestricted income fund and the property therein may be used at the discretion of the Trustee for charitable purposes, wholly or mainly for the services provided by NHS Blood and Transplant. The General Fund receives donations that can be used for any charitable purpose relating to the NHS. This flexibility has been used to fund recognition awards for those staff members with over 20 years' service with NHS Blood and Transplant (including service with the National Blood

Authority), and staff winter celebrations. Staff recognition awards for those staff working in the Birmingham area are charged to the Howard Ostin Fund.

**The Howard Ostin Fund** is a restricted fund and the object is to further such charitable purposes of NHS Blood and Transplant as the trustee thinks fit. 'In furthering such purposes the trustee shall first consider and have regard to the needs in the area of Birmingham and the surrounding district".

**The British Bone Marrow Donation Appeal** (BBMDA) is a restricted fund. The objective of this fund is to improve the infrastructure for searching and accessing the British Bone Marrow Registry by clinicians, registry managers and patients.

The overall value of the funds at 31 March 2015 was £1.141m (subject to audit).

#### 3 MEMBERSHIP

The Trust Fund Committee membership in respect of the financial year 2014/15 included:

Roy Griffins	Chair and Non-Executive Director
Andrew Blakeman	Non- Executive Director
Lorna Williamson	Medical and Research Director
Rob Bradburn	Finance Director

Other NHSBT staff in regular attendance are:David EvansDirector of WorkforceLinda HaighAFD (Operations) and Secretary to the Committee

#### 4 MEETINGS

Four meetings were held during the financial year 2014/15, all chaired by Roy Griffins. Attendance at these meetings is shown below:-

Committee Attendance	Apr- 14	Jul-14	Nov-14	Feb-14
Roy Griffins (RG)	1	1	1	1
Andrew Blakeman (AB)	1	1	1	1
Rob Bradburn (RB)	1	1	1	1
Lorna Williamson (LW)	1	sent Deputy	1	1

#### 5 COMPLIANCE WITH TERMS OF REFERENCE

The Terms of Reference for the Trust Fund Committee have been approved by the Board and are reviewed annually by the Trust Fund Committee.

The Committee approved an annual budget for 2015/16 and a workplan for the year. The finances of the funds have been reviewed at each Committee meeting, with all income and expenditure monitored against the approved budget for each of the funds. During the year the Committee approved funding amounting to £331,065 in support of the following projects:

- Platelet transfusions in the Absence of Bleeding in Critical Care (£20,100).
- Bedside platelet function testing to guide the use of platelet transfusion in neonates (£48,974).
- Improving database of outcomes after stem cell transplant recipients and short and long term follow-up of donors from British Blood and Marrow Registry (£119,601).
- Behavioural change in Blood Component prescribing using smartphone applications at point of care (£46,980).
- Study of the significance and genetic determinants of hepcidin levels in blood donors (£46,150).
- Study of the significance of T regulatory cells in the outcome of allogeneic HSCT (£49,260).

Recognising that the high standards and high quality of the services provided by NHSBT is dependent on the contribution, effort and loyalty of our staff, the Committee continues to fund loyal service awards which amounted to £18k for 2014/15. In reviewing the reserves policy, the Committee has taken into consideration the need to ensure that there are sufficient funds available to provide support for these awards over the longer term.

In addition, for the forth year running, funding for the annual 'winter celebrations' (increased to £10 per head from £7) for staff has been provided from Trust Funds, amounting to £32k for 2014/15.

#### 6 GOVERNANCE ARRANGEMENTS

The Chairman of the Committee on behalf of members has reviewed the investments of the Charity at each meeting. In 2014/15 all meetings were held face to face after the GAC, making best use of time and keeping costs to a minimum.

At the start of the year the Committee reviewed the reserves of the Charity and agreed an annual budget against which expenditure has been monitored at each meeting. All applications for research grants are first reviewed by the R&D Senior Management Team and all applications for funding require an Executive sponsor. In addition, the Committee receives reports on the status of all projects from the R&D Senior Management Team. Annual progress reports are also received for all on-going projects, with a final closure report required highlighting project outcomes for projects which have completed. The R&D Committee of the Board reviewed a paper summarising the successes in obtaining subsequent research funding based on preliminary studies supported by the Trust Fund. This resulted in agreement that, subject to availability of funds, there should be a '50k' funding stream for new projects in the 2015-2020 R&D strategy.

The Secretary has made Committee Members aware of forthcoming changes to the charities SORP and the new options for the legal status of charities. Members have also been provided with a website link where Charity Commission Newsletters, giving updates on legislative changes and topical issues, are published

The annual report and accounts for 2013/14 were reviewed by the Trust Fund Committee in November 2014 following appropriate review and clearance by the external auditors Deloittes. These were registered with the Charity Commission within the required timeframe.

#### 7 TRUST FUND COMMITTEE OPINION

Members of the Board should recognise that assurance given can never be absolute. The highest level of assurance that can be provided to the Board is a reasonable assurance that there are no major weaknesses in the governance arrangements, risk management and internal control processes in the Management of the NHSBT Trust Fund.

The opinion of the Trust Fund Committee, based on the activities set out in section 8 below, is that the NHSBT Trust Fund's risk management, control and governance processes are adequate and effective and may be relied upon by the Board.

#### 8 CONCLUSION

The Trust Fund Committee has complied with its terms of reference during 2014/15 during which it has:

- set and approved an annual budget against which performance is reviewed
- set and approved an annual workplan for 2014/15, monitoring that this was adhered to
- reviewed and updated the Charity's Procedure & Guidance notes
- considered the investment strategy and monitored performance of investments
- received and approved applications for funding/grants supported by the R&D Senior Management Team, challenging applications when appropriate to do so
- ensured that all expenditure was within the objectives of the respective fund
- reviewed the position for the funding of Winter Celebrations
- received and discussed progress/closure reports for all live projects
- received and approved the annual report and accounts for 2013/14
- reviewed reserves policy in light of the current economic climate and spending plans.

Roy Griffins Chair of Trust Fund Committee July 2015

#### NHS BLOOD AND TRANSPLANT

#### 30 July 2015

#### 2014/15 ANNUAL REPORT AND ACCOUNTS

#### **EXECUTIVE SUMMARY**

The NHSBT Annual Report and Accounts for 2014/15 were reviewed by the Governance and Audit Committee and formally approved, on behalf of the NHSBT Board (as allowed by section 4.3.2 of the NHSBT Scheme of Delegation) at the meeting on 26 June 2014.

The final results were consistent with the March 2015 Board Performance Report (see operating surplus reconciliation reported in Note 2). The final reported income surplus at £15.7m was equivalent to the result reported in the management accounts submitted as part of the March 2015 Board Performance Report. This reflects a year end audit that, again, went extremely well with no adjustments no control issues raised.

#### RECOMMENDATION

The Board is asked to note the approval of the NHSBT Annual Report and Accounts for 2014/15 by the GAC.

#### ATTACHMENTS

- Explanatory note to describe and reconcile the differences between the "Net Operating Expenditure" basis of reporting in the Annual Report and Accounts and the "Income & Expenditure" basis of reporting in the NHBST management accounts that are reported to the Board.
- Electronic or hard copy of the 2014/15 Annual Report available on request.

Rob Bradburn Finance Director, NHSBT July 2015

#### **BRIEFING NOTE**

#### **Reconciliation of the Management Accounts to the Statutory Accounts**

#### Background

The term **Capital Charges** comprises **depreciation** on fixed assets and a **notional cost of capital** (calculated as 3.5% of average net assets employed, excluding cash balances).

We are required to include these items in our pricing calculations and we therefore recover the costs as cash from our customers.

In the absence of any other action, we would build up a substantial cash balance of approximately £17 million per year (£10 million depreciation and £7 million cost of capital). We are therefore required to make a cash payment to the Department of Health based on the amount we have included in our prices for the two items.

The payment is based on our initial budgets and pricing models. The cash payment is not amended to reflect the actual calculations of depreciation and cost of capital.

#### **Management Accounts Reporting**

In our management accounts our Income & Expenditure account includes actual depreciation and the calculated cost of capital amounts as expenditure.

The relevant accounting entries for the calculated depreciation and actual cost of capital are:

- DR Depreciation expense (I&E)
- CR Fixed Asset Provision for Depreciation (Balance Sheet)
- DR Cost of Capital Expense (I&E)
- CR General Reserve (Balance Sheet)

The accounting entry for the cash payment to the Department of Health is (calculation based on budget):

- DR General Reserve (Balance Sheet)
- CR Cash (Balance Sheet)

#### Statutory Accounts Reporting

The Statement of Comprehensive Net Expenditure treats the cash payment to the Department of Health and the (non-cash) depreciation charge as expenditure. This implies that **depreciation is effectively included twice within Net Expenditure** (actual depreciation *and* the budgeted depreciation that is paid as cash).

There is no requirement to show a notional cost of capital charge with Net Expenditure. It is therefore added back to General Reserves within the Statutory Accounts.

Note that within the Statutory Accounts we treat Department of Health funding as direct funding to the General Reserve whereas the management accounts treat the funding as income. Funding provided by the other UK Health Departments is treated as income in both the statutory and management accounts.

#### **Reconciliation of Management Accounts and Statutory Accounts**

The relevant figures for 2014/15 are:

Department of Health funding	£63, 048k
Cash Payment to Department of Health for depreciation	£10,314k
Cash Payment to Department of Health for cost of capital	£6,600k
Actual depreciation charge	£9,628k
Actual notional cost of capital	£6,703k

The reconciliation between **Net Expenditure** (statutory) and **I&E Surplus** (management) is:

Net Operating Expenditure per Statutory Accounts	<u>- 56,954</u>
Add in Department of Health (DH) funding Treated as income in management accounts	63,048
Add back Cash Payments to DH (10,314 + 6,600) Excluded from management accounts as they already include actual depreciation and notional cost of capital	16,267
Deduct actual notional cost of capital We are not required to include cost of capital within Net Expenditure but it is a cost within our management accounts	- 6,703
Surplus per Management Accounts	1 <u>5,658</u>

#### NHS BLOOD AND TRANSPLANT

#### 30 July 2015

#### **REGISTER OF SEALINGS**

#### **EXECUTIVE SUMMARY**

The Board are asked to note the attached extract from the Register of Sealings relevant to NHSBT for the period 17 March 2015 to 22 July 2015.

An updated Register of Sealings is maintained by myself and is available to the public for inspection on request.

Rob Bradburn Finance Director 22 July 2015

#### Register of Sealing's

#### Under the Authority's Standing Orders, a report of all sealing's made should be reported to the Board .

#### A central register of sealing's is kept at Head Office in Watford.

							Review &		
Seal No	Date	Description	Location	Value	Term	End	Break option	Signed	Witnessed
187	01/04/2015	Lease on Nottingham Blood Centre, Trinity Square.	Nottingham	£67,000	15 years	2030	Rent Reviews at 5 & 10 years.	Rob Bradburn	Becki Sambrook
188	13/04/2015	Licence to Alter Re: Nottingham Donor Centre	Nottingham	N/A	N/A	N/A	N/A	Rob Bradburn	Becki Sambrook
189	18/05/2015	Licence to Alger Re: Blood Donor Centre, Cathedral Court, Sheffield	Sheffield	N/A	N/A	N/A	N/A	Rob Bradburn	Mark Taylor
190	18/05/2015	Lease renewal Re: Team base at Northampton.	Northampton	£8,000 pa	9 years	2029	Tenants Break option years 3 and 6	Rob Bradburn	Mark Taylor
191	18/05/2015	Lease renewal Re: Exeter Team Base.	Exeter	£28,900 pa	9 years	2029	Tenants Break options years 3 and 6	Rob Bradburn	Mark Taylor
192	17/06/2015	Deed of Variation Re: Stoke on Trent Team Base.	Stock on Trent	£10,000	N/A	N/A	Rent reduction from £11,500 to £10,000 for not exercising a lease break option.	Rob Bradburn	Becki Sambrook
193	20/07/2015	Surrender of the Lease for the Barnstaple Team Base. Surrender premium of £16,565 including dilapidations	Barnstaple	£16,565	N/A	N/A	N/A	Rob Bradburn	Becki Sambrook
194	20/07/2015	Lease renewal on Morecambe Team Base.	Morecambe	£26,635	9 years	2029	Tenants break at 3 yearly intervals.	Rob Bradburn	Becki Sambrook

### NHS BLOOD AND TRANSPLANT

### 30 JULY 2015

#### FORWARD AGENDA PLAN

September 2015				
For decision				
Networks and Telephony Contract Renewal (AP)				
ODT Hub Stage 2 and beyond (SJ)				
For discussion				
ODT Performance Management Review (SJ)				
Workforce Transformation Functional Review (DE)				
Communications Functional Review (LA)				
For information				
Annual Health & Safety Report (DE)				
NORS implementation progress report (SJ)				
Seminar				
Board Effectiveness, Progress on Themes (IT)				
November 2015				
For decision				
ABO Risk Based Decision Making Framework (LW)				
0				
New Desktop Delivery Options (AP) For discussion				
IT Strategy Process/Applications (AP)				
DTS Performance Management Review (HW)				
Clinical R & D Functional Review (LW)				
Finance Procurement Functional Review (RB)				
For information				
Nursing Annual Report (LW)				
Business Continuity half year report (HW)				
January 2016				
For discussion				
Blood Performance Management Review (CR)				
Workforce excluding L&D Functional Review (DE)				
March 2016				
For decision				
Annual Review of Standing Orders (RB)				
For discussion				
ODT Performance Management Review (SJ)				
Quality Assurance Functional Review (IB)				
Finance Finance Functional Review (RB)				
Employee Survey (DE)				
May 2016				
For discussion				
Clinical Clinical Functional Review (LW)				
NHSBT's Engagement Programme – Update (LA)				
July 2016				
For discussion				
Workforce L&D/Shine Functional Review (DE)				
September 2016				
For discussion				
CI/Lean Functional Review (CR)				

WITN0643008\_0175

#### NHS BLOOD AND TRANSPLANT

#### The Sixty-eighth Meeting of NHS Blood and Transplant will be held on Thursday 30 July 2015 in U6/7 the Novo Nordisk Suite at the Royal College of Obstetricians and Gynaecologists 27 Sussex Place, Regent's Park, London NW1 4RG

### AGENDA – Confidential

1	Minutes of the last meeting (attached)	13.05
2	Matters Arising (P15/24 attached)	
	For Decision	
3	Hepatitis E Virus (HEV) Testing (P15/25 attached)	13.10
	For Discussion	
4	IT at NHSBT (P15/25a attached)	13.30
5	Appendix to Minutes of R & D Committee 14.05.15 (P15/26 attached)	13.50
6	Minutes of Transplant Policy Review Committee 18.06.15 (P15/27 attached)	
7	Any Other Business	
	For information	
8	Notes of the Seminar held on 28.5.15 (P15/28 attached)	
9	Contracts over £1m and under £3m (P15/29 attached)	
10	NHSBT Major Contracts Pipeline Report (P15/30 attached)	

#### DRAFT

#### Minutes of the Sixty-seventh Meeting of NHS Blood and Transplant held on Thursday 28 May 2015 at the Royal College of Obstetricians and Gynaecologists 27 Sussex Place, Regent's Park, London NW1 4RG

Present:	Mr J Pattullo Mr A Blakeman Mr R Bradburn Dr C Costello Ms L Fullwood Mr R Griffins Ms S Johnson	Mr J Monroe Mr K Rigg Dr C Ronaldson Mr I Trenholm Dr H Williams Mr S Williams Dr L Williamson
In attendance:	Ms L Austin Mr I Bateman Mr D Evans Mr A Powell Mr G Brown	Ms P Vernon Mr E Webb Ms J Minifie

#### CONFIDENTIAL

#### P15/22 MINUTES OF THE LAST MEETING

The minutes of the previous meeting were agreed.

#### P15/23 MATTERS ARISING

Papers P15/16 and P15/16a were received. The Board ratified the decision of the Chairman to (i) Exercise a discretionary power, as described in Section 4.2 of NHSBT's Standing Orders, to approve the recommendation of the NAT Board Paper (ii) To award the contract to the winner of the tender as recommended by the NAT Board paper. As required by NHSBT's Standing Orders the Chairman had consulted with, and obtained support from, Ms Fullwood and Mr Monroe for his action.

#### P15/24 MODERNISATION OF MANUFACTURING IN NHSBT

Stuart Penny, Assistant Director for National Operations Blood Supply, attended for this item and supported Dr Ronaldson in presenting paper P15/17.

The Board supported in principle further work to invest in, and further consolidate, manufacturing operations as proposed in the paper. It was agreed that a more detailed proposal would be brought to the next meeting. The Board requested that this address i) the matter of the capacity of the new Centre being built in Scotland and (ii) the issue of working to the same SOPs at all three manufacturing sites.

#### DRAFT

Mr Webb agreed to take soundings on the Northern Powerhouse concept to check that the proposal would not encounter any obstacles related to Government policy for the Region.

#### P15/25 NHSBT PRICING POLICY: BLOOD COMPONENTS AND DIAGNOSTICS & THERAPEUTIC SERVICES

Dr Williams presented paper P15/18 and the Board noted the current approach to pricing in blood and DTS.

#### P15/26 DIAGNOSTIC & THERAPEUTIC SERVICES BOARD PERFORMANCE REVIEW

It was agreed to defer this item to a future meeting.

#### P15/27 INTERNAL AUDIT REPORT ON THE NAT PROCUREMENT

Mr Bradburn presented paper P15/20. The Board reviewed the internal audit findings and recommendations made by PwC and noted the moderate assurance opinion that had been provided and the management response.

#### P15/28 MINUTES OF TRANSPLANT POLICY REVIEW COMMITTEE MEETING 16.04.15

The minutes were noted.

#### P15/29 ANY OTHER BUSINESS

There was no other business.

#### P15/30 CONTRACTS OVER £1M AND UNDER £3M

Paper P15/22 was noted.

#### P15/31 NHSBT MAJOR CONTRACTS PIPELINE REPORT

Paper P15/23 was noted.

TW

### Matters Arising from meeting held on Thursday 28 May 2015

Agenda	Issue	Lead	Action Taken
item no.			
	MODERNISATION OF MANUFACTURING IN NHSBT		
3	Mr Webb agreed to take soundings on the Northern Powerhouse concept to check that the proposal would not encounter any obstacles related to Government policy for the Region.	TW	Mr Webb spoke to the Estates Lead in the Department of Health who did not foresee a problem with NHSBT's proposal and said it fitted with the Government's aim to reduce and consolidate estate.

1	Date / title of meeting	30 July 2015 Board	
2	Title of paper	Hepatitis E Virus (HEV) Testing	
3	Status	Commercially sensitive	
4	Tweet (max 140 characters)	Hepatitis E blood donor screening implemented in response to emerging concerns on its effect on susceptible recipients	
5	Executive Summary		
	Hepatitis E virus (HEV) infections are increasing in the UK population. Most infections are from pork products, but HEV has emerged as a threat to recipients of blood, stem cells and organs. Estimates suggest 400 transmssions/year from NHSBT blood components. Most recipients have no symptoms and clear the infection completely, but in stem cell and transplant recipients, there is evidence that infection may become chronic and lead to liver damage within several years. At meetings in April and 7 <sup>th</sup> July, SaBTO considered options for selective and universal blood donation screening, and recommended testing of blood components for provision to recipients of solid organ and allogeneic (donor) stem cell transplants. To ensure a ready stock of all blood groups and short shelf life products at all SHUs, 286,000 tests would have to be performed. Meeting the requirements for platelets and granulocytes for stem cell and organ transplant patients would generate surplus red cells which could be manufactured for neonatal use. Thus providing all tested components for neonatal use. Thus providing all tested to be £286k/year; if all neonatal components are included, costs are £357k/year. These costs are based on indicative prices supplied by the current NAT supplier. The cost per transmission prevented is approximately £13,000 but due to limited information regarding frequency of chronicity, a cost/QALY cannot yet be calculated. Testing of all donations would require 1.78M tests/year at an annual cost of £3.37M.		
	seperately tendered. In view of the new is proposed that we seek an agreemen 1-year contract to Roche for the pr platform. This will then provide the tir	f the testing services will need to be ed to implement without delay, however, it nt with potential suppliers that we award a rovision of tests via their existing NAT me during which a formal tender can be efore commence in January 2016, and a	

[	project group will be formed to every	implementation RIII SE and OROS con				
		e implementation. PULSE and OBOS can s can changes to donor literature and				
	Considering legal and reputational risks of not testing for HEV, it is recommended that NHSBT move rapidly to take a precautionary and proportionate approach, which is supported by evidence, by providing HEV- tested components for solid organ and stem cell transplant patients. This strategy will allow us also to provide tested components for neonates at modest extra cost (subject to the procurement approach described above).					
		pader patient groups can be added as t studies to add to the state of knowledge				
	Additional actions for NHSBT are:					
	<ul> <li>to raise clinician awareness or community</li> </ul>	f HEV, commencing with the transplant				
	<ul> <li>to promulgate dietary advice to PHE/Food Standards Agency</li> </ul>	transplant recipients when available from				
	<ul> <li>to review information leaflets for</li> </ul>	donors and transfusion recipients.				
		ategies to protect transplant recipients at clude consideration of testing organ/stem g of recipients.				
6	Action requested	<ul> <li>To approve £357k/year funding for the selective screening for HEV of blood components for organ and stem cell transplant recipients, plus all neonates.</li> </ul>				
7	Background and customer					
-	promise					
		BACKGROUND				
	The SaBTO HEV Working Group repor	t of April 2015 identified that:				
	with 700 clinical cases in 2013 an symptoms (genotype does not cau unlike the genotypes seen in South	easing in the UK population sincce 2010, d up to 70,000 infections with no clinical use fulminant hepatitis in healthy people, Asia). The rate of new cases in the UK is es from eating processed pork products.				

- 2. HEV is also transmitted via blood components, with an NHSBT/PHE study showing that 1:2848 NHSBT donations are carrying HEV infection. An estimated 40% of those will transmit to patients, resulting in an estimated 450 transmissions/year. There have been 4 transmissions of HEV reported to SHOT (3 since 2011); FFP has been the source of these last 3.
- 3. Most recipients have no immediate symptoms and clear the virus, but stem cell/organ recipients are at particular risk of chronic hepatitis E infection and liver disease. There has also been one affected case with underlying liver disease before the transfusion. Chronic infection can be treated with ribovirin, with a success rate of 80%.
- 4. There is also an ongoing (and numerically greater) risk to transplant recipients from diet (processed pork products). For example, a liver transplant patient in the first year after transplant is 17 times more likely to become infected via diet than through the transfusions. A cross-government meeting was held in June 2015 to consider the overall risks, and updated dietary advice will be produced by PHE and the Food Standards Agency.

SaBTO considered these issues at a meeting in April 2015, and requested UK Blood Services to provide a costed plan for both selective and universal blood donor screening. This was considered at an extraordinary meeting of SaBTO on 7 July, which recommended testing of blood components for provision to recipients of solid organ and donor stem cell transplants. It was also recommended that testing samples in pools of 24 would be adequate to identify donations with high enough virus levels to transmit to patients.

### CONTEXT FOR DECISION MAKING.

### 1. Legal/reputational risks.

A legal opinion on HEV testing (Mills and Reeve plus QC) concluded that NHSBT has civil liability under Product Liability legislation for providing 'defective' components. It should be noted that a claim can be made for harm caused by a transmission, but not for a transmission that causes no material harm. It is also advised that we add information re HEV to information provided to potential blood recipients. In criminal law, we may have liabilities under section 3 of the Health and Safety Act 1974; public policy making is excluded from Corporate Manslaughter legislation.

We have no absolute duty to introduce a safety measure regardless of cost. However, the opinion reminds us of the use of the Precautionary Principle to make proportionate decisions in the face of uncertainty. In addition, The Penrose Inquiry highlighted the need for vigilance and prompt actions where emerging transfusion transmitted infections are identified.

### 2. International situation.

Other UK Blood Services are preparing plans for selective testing as per the SaBTO recommedations. SNBTS will request government funding for this. The Irish Blood Service has requested government funding for universal testing for five years in the first instance; no decision has been taken yet.

France test plasma for Octaplas manufacture, and FFP for liver disease recipients. Consideration is being given to testing other components and for other patient groups but no decisions have yet been made.

Due to their very high population incidence, the Netherlands are considering using antibody screening rather than NAT. This would identify donors with previous cleared infection whose components would be directed to high risk recipients. The incidence of HEV in the UK is much lower and the saBTO working group concluded that this strategy would not yield sufficient donations to be viable.

Elsewhere, there is monitoring and surveillance studies, but the recent rise in population incidence seems confined to Europe.

### 3. Commercial.

The European Medicines Agency held a meeting in 2014 to consider licenced plasma products, including Octaplas. It is likely that there will be a requirement for Octaplas to be manufactured from tested plasma. If NHSBT does not provide tested FFP, hospital uptake of Octaplas may increase.

### 4. Pathogen inactivation (PI) as an alternative to testing.

There are no licenced PI methods for red cells. There are no data yet to establish that any PI method for FFP or platelets would be effective against HEV; indeed there have been transmissions outside the UK from untested Octaplas and Intercept-treated FFP.

### PROPOSAL

It is proposed to provide HEV NAT negative components as follows:

- 1. Red cells, platelets, FFP and cryoprecipitate for all patients during organ or stem cell transplants, and for as long afterwards as they remain on immunosuppression.
- 2. All granulocytes, as most recipients have had stem cell transplants.
- 3. Red cells and platelets for neonates. (The imported FFP from Austria is

already tested at source).

### RATIONALE FOR PATIENT GROUPS SELECTED

- 1. Solid organ transplantation. The literature review performed by the SaBTO working group provided evidence of failure to clear HEV in a proportion of patients post-organ transplant, some of whom went on to develop liver damage (60% in one series). However, immunosuppression after organ transplantation is life-long, so once chronic carriage is established, spontaneous clearance of virus is unlikely.
- **2. Stem cell transplant recipients.** There are also case reports of HEV transmission and prolonged viral carriage after stem cell transplantation.
- **3. Neonates.** There are no reports of transfusion-acquired HEV in neonates; however, cases may be missed as clinical awareness of the condition is low and HEV is not yet a routine part of the investigation of abnormal liver function in this age group. In the context of providing HEV negative components for transplant recipients, a case can be made for including all neonates, as follows:
- (a) Most neonates who are transfused are premature, sometimes as early as 26 weeks gestation. These babies have both an immature immune system and an immature liver.
- (b) Most mothers will not have protective antibodies, and even if present the babies are born too early to benefit.
- (c) Newborns are not at risk of HEV from diet; transfusions are their only source of infection.
- (d) Premature babies who survive the first few weeks of life generally have a normal life span so will be at risk of long term effects of infection.
- (e) Blood components for neonates are a separate product line and would all be tested, so there will be no need for a dual inventory either in NHSBT or in hospitals.
- (f) One adult donation is split into 4 or 6 'paedi-packs'. These may be given to more than 1 baby thus spreading infection more widely.
- (g) In the context of manufacturing components for transplant recipients, red cells for neonates can partly be obtained without extra cost, so the extra cost/infection prevented is low.

Other patient groups were considered during the SaBTO work, including those with chronic liver disease and patients with various diagnoses receiving a range of treatments with immunosuppressive properties. It was considered that the evidence for harm caused by transfusion-transmitted HEV was less strong than for transplant patients, and that because these are large numbers of patients, it would be important to gather evidence quickly to inform subsequent decision making.

### **OPERATIONAL PLAN**

### 1. Testing strategy.

Testing would be performed using a CE marked HEV NAT test at the same time as other routine NAT tests. To provide components for solid organ and stem cell recipients plus neonates, 109,000 tests would need to be performed; a sample pool size of 24 was recommended by SaBTO. Implementation would be relatively straightforward, with testing and donor handling integrated into current established systems; only an additional 0.5 WTE would be needed at each testing site, and this cost is included in the figures. Prior to the launch of the tested components, a small stockbuild would be required. Tested components would be labelled as HEV negative, and will be able to be ordered in the normal way. By testing more units than will be required for transfusion, we can ensure that an adequate group mix is held at stock holding units. Hospitals with a transplant unit are likely to want to hold a small stock for emergencies.

There are 2 suppliers with CE marked tests - Grifols and Roche. The NAT contract for NAT testing for HIV, HCV and HBV was recently awarded to Roche. Consideration has therefore been given as to whether we can build the requirement for HEV NAT as an additional service under the Roche NAT contract. Legal advice is that we should, on balance, tender for the new requirement. However, as this would introduce at least 6 months delay it is proposed that we seek an agreement with the potential suppliers that we award a contract to Roche for 12 months and conduct a tender exercise during this time. This not without riks but is considered to be a reasonable and defendable course of action under procurement law.

**2. Impact on blood component supply.** Testing for transplant recipients and neonates would result in an expected 36 confirmed positive donors per year. Confirmatory testing will be performed at our micrbiology laboratories at Colindale, and the costs are included in the figures. The donors could be reinstated after 6 months – the tests required at the point of reinstatement are under discussion. Experience from the study with PHE suggests that >90% of suspended donors would return, but even if this is much lower, overall impact on

component supply will be minimal.

**3. Donor management and lookback.** Donors found to carry HEV at the time of their donation will be informed and offered information about the infection. HEV is a notifiable infection in England and Wales, so the local Health Protection team will be advised of all positive donors. JPAC is currently revising deferral guidance so that HEV NAT positive donors could be re-instated after six months, with discretionary earlier re-instatement of apheresis, HLA matched and rare group donors provided NAT is negative and HEV antibodies are present.

As HEV is a short lived infection in healthy individuals, testing of archive samples will be required only for any donations in the previous four months. This would primarily affect apheresis platelet and INTERVAL red cell donations. The need for lookback to recipients of these donations will be determined by the microbiology team on an individual case basis, depending on the viral load of the archive sample. Should a donation be considered at risk of having transmitted, the hospitals receiving the components will be contacted and a decision taken with the patient's clinican regarding further investigation.

**4. Donors of tissues, organs and stem cells.** The SaBTO HEV working group report concluded that tissue recipients were low risk and did not recommend screening of tissue donors. Because organ and stem cell recipients are also at risk from diet, overall strategies for the protection of these patients will be further considered by SaBTO. This may include testing of stem cell/organ donors and/or recipient monitoring eg by annual testing.

### COSTS

Indicative costs are shown for different patient groups, with samples tested in pools of 24 as recommended by SaBTO.

1,771,000
3.373.046

Predicted reductions in transmissions are shown for these patient groups,

	Recipient group	Transmissions prevented	Incremental benefit i.e. reduced transmissions	Incremental cost	Cost per (additional) transmission prevented
	1. SOT+SCT +	18	18	£357,000	£13,000
	2. SOT+SCT+CLD	58	40	£516,000	£12,900
	3. Universal	543	485	£3,373,000	£7,000
	patient harm. RESEARCH AND R		oderstanding of	the changing	opidomiology
	Research activities f and the impact of H during 2015/16 as p May 2015. These ind a) monitoring the ch monitoring strategie acquisition and se neonates, multi-tran associated with vira budget.	EV on susceptible part of the NHSB clude: anging incidence es in transplant quelae in specif nsfused, and chi	in the population recipients c) c fic patient grou	programmed to approved by on; b) trailling of determining ra ups (transplar ase) and d)	different HEV ates of HEV nt recipients, determinants
3	and the impact of H during 2015/16 as p May 2015. These ind a) monitoring the ch monitoring strategie acquisition and se neonates, multi-tran associated with vira	EV on susceptible part of the NHSB clude: anging incidence es in transplant quelae in speci nsfused, and chi al persistence.	e recipients are T R&D Strategy in the population recipients c) of fic patient grout ronic liver disea Funding for thi © Recipient © Legal resp © Public cor	programmed f approved by determining ra ups (transplar ase) and d) s is included safety ponsibility, dut nfidence maximum saf	to commence the Board in different HEV ates of HEV nt recipients, determinants in the R&D
3	and the impact of H during 2015/16 as p May 2015. These ind a) monitoring the ch monitoring strategie acquisition and se neonates, multi-trar associated with vira budget.	EV on susceptible part of the NHSB clude: anging incidence es in transplant quelae in specif nsfused, and chi al persistence.	<ul> <li>recipients are T R&amp;D Strategy</li> <li>in the population recipients c) of fic patient grout ronic liver disease Funding for thi</li> <li>Recipient o Legal respondent o Ensuring recipients</li> <li>SaBTO working of Thomas wall relevant</li> </ul>	programmed f approved by determining ra ups (transplar ase) and d) s is included safety ponsibility, dut nfidence maximum saf HEV Bloo group led by with NHSBT in	to commence the Board in different HEV ates of HEV nt recipients, determinants in the R&D y of care fety for organ d Services Dr Stephen nput covering

-		1			
1 1	Significant next Actions	<ul> <li>Establish a project through BS CPB/TBP</li> </ul>			
		<ul> <li>Communicate implementation plan for new HEV negative components with all stakeholders</li> </ul>			
		<ul> <li>Communications to transplant centres to raise awareness of HEV</li> </ul>			
		<ul> <li>Review of donor and patient information to include HEV</li> </ul>			
		<ul> <li>Work with cross governmental group i.e. PHE; FSA; DEFRA to agree communication of dietary advice</li> </ul>			
1 2	How does this impact on Equality and Diversity?	No major impacts.			
1 3	What is the impact on sustainability?	N/A			
1 4	Employee impact?	Testing and donor handling integrated into current systems, staff impact is minimal.			
		Stock Holding Units will be required to manage the HEV negative supply chain, so training will be needed.			
		The Hospital Services team will be			
		required to work with hospitals to			
		provide education on the use of the HEV negative inventory.			
1 5	Donor/Patient/Customer impact?				
	<ol> <li>The need for HEV testing will be added to donor literature and consent forms modified as needed. We will develop a positive communication plan to all donors to ensure that addition of HEV testing does not deter potential or current donors.</li> </ol>				
	<ol> <li>Overall impact on supply will be minimal. Evidence from the NHSBT/PHE study suggests that &gt;90% of donors identified as HEV RNA positive will return to donate. Apheresis platelet, HLA matched and rare group donors can be offered the option to provide a sample for HEV screening sooner than six months to maintain their commitment and to assure stock levels</li> </ol>				

	of these vulnerable components		
	of these vulnerable components	<i>б.</i>	
	negative units for their patients; education will be required by di professional societies. All neon tested so no new actions will be	centres will be required to order HEV ; this has been the case for CMV but rect communication and through atal components will be labelled and e required by clinical staff. We will ensure through the customer services team/joint	
	above. There has been the cas	s will have to manage a dual inventory as se for CMV negative components so lowever, work will be required by the hospitals make the change.	
	<ol><li>Publicising this safety measure the safety of the blood supply.</li></ol>	with help to maintain public confidence in	
1 6	Taxpayer impact?	See section 7 for costs	
1	Authors	Jo Tossell, Safety Co-ordinator	
7		Stephen Thomas, Interim AD –	
		Manufacturing Development	
1 8	Responsible Director	Dr Lorna Williamson, Medical and Research Director	
		Clive Ronaldson, Director of	
		Manufacturing and Logistics	
1	NED input	Christine Costello	
9		Keith Rigg	
2	Additional Documentation	1. SaBTO HEV Working Group Reports	
0	Available on Request	<ul> <li>April and July 2015</li> <li>2. Detailed option appraisal and costings</li> <li>3. Legal opinion on testing – Mills and Reeve 25<sup>th</sup> June 2015</li> <li>4. Legal opinion on Procurement situation – Mills and Reeve.</li> <li>5. Safety framework</li> </ul>	

## IT at NHSBT

Reflections on current position of IT within NHSBT

lan Trenholm, NHSBT Chief Executive, 9th July 2015

### 1. Introduction

- 1.1. Following the Board Away day on 27<sup>th</sup> May 2015 a concern arose about our culture of risk management around IT, following the reporting of some high profile failures. This paper covers our current position, what we do well, areas of risk, and an overview of what we are doing to avoid being in the same position again.
- 1.2. This paper is my view, based on what I have seen as Chief Executive, over the last year. The report is aimed at the current board and I have attempted to explain some computing concepts in fairly simple terms, which may make the report longer than ideal. It should be read as an opinion piece rather than an extensively evidenced report, or definitive prescription for success.

## 2. History

- 2.1. The NHSBT IT estate is something of a product of its time with much of the design and installation stretching back to the period 2000-2005. The main design of the desktop is so called 'thin client'. The computing calculations are largely done in the servers in central server rooms, with no capacity for computers on desktops to buffer demands on computing power. This means that the network cannot balance load across itself very well and performance issues within the servers, or in the network, are immediately visible to users, and this manifests as a slowing down of functionality. At the time of installation this design was cutting edge.
- 2.2. When the system was designed NHSBT owned BPL and services were shared. When BPL was sold off most services were easily split and we have operated as separate enterprises since. However the lack of action in resolving the location of our server room on the BPL site was a mistake which we are now having to correct. As noted below the movement of the servers will overshadow everything else we do in IT for the next 12 months. This move has been further complicated by the need for geographic proximity with the back-up site.
- 2.3. There have been a range of short term, supposedly safe, decisions which at the time each was made may have made sense but when taken together have resulted in a tide of issues which now need to be resolved. This speaks to a lack of overarching strategy in respect of IT and lack of wider market trend awareness.

Risk associated with IT Page 1 of 9

### 3. Current status

- 3.1. The way in which computing is now used is significantly different from even a few years ago. When our network was built neither the iPhone nor the iPad were available and the concept of mobile working was fairly immature. We now have a single user accessing the network through multiple devices in multiple locations. The perception of 'what good looks like' has also changed beyond recognition. The threats to security have also increased exponentially. In short, our performance expectations have overwhelmed the design of our network and we are attempting to operate it way beyond its original design capability.
- 3.2. Whilst some components have been upgraded to try and cope, in reality the overall systems configuration *design* is the rate limiting step. We have also not maintained the applications and operating systems we have got adequately, with a number of them well behind on patches and versions. In effect, we are operating an old car, in modern traffic, and haven't serviced it properly we should therefore not be surprised if it breaks down occasionally.
- 3.3. It is now recognised that using 'thick client' computing power and the cloud is an effective way of running enterprise wide IT. Cloud computing is a design whereby servers are managed and run by a third party and computing power is effectively rented on a pay as you go basis. The computing power available can be flexed easily. Our newer systems, such as the ODR, are delivered using this approach, but core applications, such as Pulse, NtXD and the desktop use old technology.
- 3.4. As a universal service provider to a diverse range of constituents we need to have systems capable of servicing everyone, which calls for levels of flexibility, security and transparency unseen in most enterprises this is a significant challenge.
- 3.5. Whilst there are clearly issues with our current network and applications we have achieved some significant success in recent years. At a strategic level our platform strategy, an approach whereby we aim to replace pieces of functionality a piece at a time, is a pragmatic and lower risk means of upgrading our systems than a more traditional 'like for like' replacement strategy. Importantly this approach also forces a rethink of what we *really* need.
- 3.6. In terms of costs we spend relatively little on IT, with desktops costing around £500 per employee, which compares to the Cabinet Office's new desktop provision of £1600 per employee (plus £11mn implementation costs). The average across Whitehall departments is estimated at over £2000 per employee.

Risk associated with IT Page 2 of 9

- 3.7. We have invested approximately £3mn over the last 5 years on our servers. Our data centres cost about £1.6mn pa to operate.
- 3.8. Our platform strategy envisages spending in the range £24-31mn to replace the entirety of the current estate and migrate to the cloud. Desktop costs are likely to be an additional £5-6mn.
- 3.9. On a day to day basis our current IT works, validating and tracking in excess of 2mn products a year, albeit not to world class standards and costs per transaction higher than they could be. There are a number of bright spots. Examples of services which work well include:
  - The booking service around blood donation using our 'App' is admired across government and we are currently the only Health body to have passed the Government Digital Service (GDS) Service assessment, in effect the kite mark for usability of government services. The App was used nearly a million times last year and enhancements planned in the coming year should increase that number further and offer additional functionality aimed at driving donor loyalty.
  - The organ donor register has just passed 21mn registrants, using the old technology, and has been migrated to a new platform during June 2015. The service is now based on a re-purposed Housing Benefits system, hosted in the cloud and serves all 4 UK nations.
  - Browser based blood ordering services and lab result presentation systems mean that most of our interactions with hospitals are done electronically despite wildly varying hospital systems. I believe we are the only organisation who has an electronic relationship with every English Hospital.
  - EOS Mobile allows transplant surgeons to see organ offers on a range of mobile devices 24/7.

### 4. Why are we here?

- 4.1. There is no single event or reason for our current position. This lack of a single negative *event* meant that a creeping loss of confidence was never collectively apparent to the board, with the point of moving from *unconscious incompetence* to *conscious incompetence* occurring at different times for different members of the top team.
- 4.2. Our overall strategy has not been clear and this has been combined with a number of specific technical decisions and issues which have meant we have attempted to maintain the status quo of "manage locally + bespoke", set against a fast moving external IT landscape moving towards "manage in the cloud + commoditise".

Risk associated with IT Page 3 of 9

- 4.3. Pulse is a good example of a system which is old and managed by a relatively small business for whom we are the main client. NtxD is similarly old and bespoke. As NHSBT came together from multiple organisations a few years ago we have never really attempted to systematically bring the IT together into a single enterprise.
- 4.4. Our IT providers have been mixed in terms of performance. Whilst systems do generally work system changes have been difficult to deliver and have taken a long time, with some problems seemly intractable. The use of external strategy consultants such as Gartner doesn't seem to have been particularly effective in prompting a single enterprise view.
- 4.5. We have taken a somewhat conservative and internally focussed view of risk around IT in the past. The view has been that change carries risk and a governance overhead, so technical changes have been avoided in back end systems. Some changes have been delivered to customer facing systems. There was also a view that we had no money for investment. It is unclear if this ultralow risk/no money approach was ever 'decided' in any clear way, it has just found its way into the water supply and colours day to day decisions.
- 4.6. A specific problem appears to be that over the last few years the core network software and the desktop software has not been patched or upgraded. It should be recognised that patching in an enterprise context is a significant undertaking. However we should also see this as part of the overall business as usual activity of a well-run service i.e. it should not require senior board level approval to trigger the work.
- 4.7. It is right to say that doing nothing has eliminated the risks of patching, it has however exposed a much less obvious risk of now being so far behind current levels of patching that we are now faced with a significant job simply to get up to date.
- 4.8. There have been problems with the performance of Pulse, particularly at lunch time or at times when there are large numbers of people trying to access the external portal and blood appointment booking app. It is clear that decisions were made as external facing technology was installed that 'hardwired' the external facing elements of our technical estates to back office systems and we have not been able to manage unexpected demand easily.

Risk associated with IT Page 4 of 9

## 5. Conclusions

- 5.1. #Today. Issues of transition. We are in something of a transition phase managing our way out of some old thinking into a new more modern way of operating with IT. One of our challenges is to look for ways to offer value added services that people can see, without destabilising the prioritised legacy system management. It will not feel comfortable for a while yet.
- 5.2. *#Today. NHS IT.* There has clearly been a polarisation of IT within the NHS in recent years with some of the better hospitals making large investments and moving towards 'paperless'. Other hospitals have been overtaken by events and not managed to make anything like enough investment. We have had to try and service both ends of that spectrum at the same time and have probably tended to aim to serve the lowest common denominator and not attempted to raise the bar. This one size fits all approach is unsustainable.
- 5.3. #Customers. Users. We need to be much more focussed on users, both in the design of the systems and the way they are operated. Whilst donors deal with us on the app, etc. these are occasional small transactions carried out in large overall volumes. We also need to ensure we are offering our employees and hospital customers a richer experience, as they are complex customers currently receiving a poor service which is potentially leading to safety issues. Genuinely digital *services* for all segments of our customer base will undoubtedly enable us to offer value adding services to hospitals, reduce errors, change faster and open up new markets/forms of value to the NHS in areas such as data manipulation. We need to define 'customer' more broadly.
- 5.4. *#People. Employees.* It is clear we don't have the depth, or volume of skills in house to do everything we need to at the pace we need to do it. We have made some recent recruitments and I expect to try and continue to attract new people with expertise in modern computing landscapes. We may need to expand the IT team and /or bring in more external support to help us in the short to medium term. We need to invest in modern IT skills.
- 5.5. #People. External support. The current stabilisation activity is being supported with external partners being given very specific briefs to provide advice and then execute changes in conjunction with our teams. We will however have to have more structured use of external partners to ensure we have the right skills available on a consistent basis. I don't see this as a single 'outsourcing of IT' but probably a handful of strategic partners who we charge with running elements of our services, and perhaps bring in others as needed to deliver specific work. Importantly though we do need to recognise the need to be good at managing

Risk associated with IT Page 5 of 9

multiple partners. We need to make more and better managed use of external support.

- 5.6. *#People. Board knowledge.* We are not a technology business per se and so don't need a board full of technologists. However almost every modern organisation is technology enabled and so we individually and collectively need to increase our understanding of current and future trends in this fast moving area. Because of the diversity of our business we need to be alive to big and small developments in everything from social media to Big Data. The board could consider 'associate' board members and greater use of specialists in advisory roles. In the short term the IT Advisory Board will give us a sense of the value in external challenge to us all. <u>The board needs to understand IT and digital service trends better</u>.
- 5.7. *#Management. IT operations.* IT operations involves a number of small decisions each day, any one of which can cause an application to fail, or slow down. This issue is exacerbated in bespoke applications, or where complex systems are run by in-house people with limited exposure to managing system wide problems. Our systems are extensively bespoked and we have a relatively small in-house team. Modern systems offer simpler configuration and, if we make the right choices, we can minimise the maintenance overhead. We need to ensure we buy (and then manage) simpler systems with lower maintenance overhead.
- 5.8. *#Management. Change control.* It has not been clear who is responsible within the operations structure for authorizing and managing day to day changes. <u>This is now clear and working well</u>.
- 5.9. #Management. Assurance. We haven't been using external assurance particularly effectively. My view is that external assurers have generally been giving opinions at too high a level around the shape of the market, rather than whether a given tender is properly specified and likely to lead to a cost effective outcome. We need to make more targeted use of assurance.
- 5.10. #Management. Supplier performance. We have had mixed performance from some of our suppliers and have probably tolerated mediocre service in some quarters longer than we should. In part this is a lack of internal confidence / knowledge, with our default position tending towards "we didn't spec it properly" rather than "you, supplier, need to deliver". Recent leadership changes and some successes in off-loading poor performers has given the business as a whole more confidence in this area. We need to be intolerant of poor supplier performance.
- 5.11. #Management. Government. IT and digital services across government have received a great deal of scrutiny in recent years and our strategy is not

Risk associated with IT Page 6 of 9

completely within our own gift to control. In order to secure Department of Health financial support we will need to ensure we are compliant with the overall digital strategy, via the Government Digital Services (GDS). We need to stay consistent with GDS standards

- 5.12. *#Future. Strategy.* Our platform strategy makes sense given our context and should enable us to move in managed, safe steps to a position whereby we are directly managing much less, if any, of our infrastructure and have a much more flexible set of applications. We need to execute against the strategy.
- 5.13. *#Future. The IT market.* The market is increasingly moving to offering services which are more fragmented and assume agile development techniques and an ease of configuration not seen from large hard coded systems of the past. Government pressure on the market is also forcing a direction of travel towards clusters of suppliers on short term contracts. We are catching up fast but not there yet. We need to build skills in this area.
- 5.14. #Future. Intelligence. Organisations such as NAO, Cabinet Office et al produce reports on IT as seen in government, and we don't systematically consider them. It is also not clear that we view trends in IT more broadly. Our 2000-2005 network design was contemporary for its day but now looks dangerously dated. We need to ensure that our current contemporary strategy is reviewed and challenged over coming years so we don't find ourselves in 2030 looking foolish. We need to all keep on top of digital service trends not rely on 'IT' to do it.

### 6. The Future and next steps

- 6.1. My view is that we have not kept our aged IT infrastructure up to date and we are having to deal with the problems which have resulted. In part we have overwhelmed the original design of the architecture and in part we have not maintained what could have been a workman-like system in the short term. The IT market has moved on and 'what good looks like' is very different from even five years ago. At the same time change in expectations from the public, customers and employees have created expectations we can't effectively meet at the moment.
- 6.2. Looking forward, we have got a sound IT strategy which is consistent with wider strategies across government. We have had some success with some applications. We have a clearer view of problems and are dealing with them with very clear work packages using internal and external teams.
- 6.3. Over the next three years the numbers of problems emerging will decrease but incompatibility between old and new versions of software will continue to be an

Risk associated with IT Page 7 of 9

issue which will take up time and we need to be ready to make re-prioritisation decisions smartly. We also need to recognise that this re-prioritisation may mean that boring but important (servers/operating systems) trumps interesting but less critical (application changes) and we will need to re-set expectations constantly which may not always be comfortable, particularly with internal teams.

- 6.4. It is clear that recent leadership focus on IT is paying dividends. Server outages have reduced to zero in recent weeks and the backlog of calls to the service desk have reduced considerably. A change control process is now being used routinely and again this means we are now managing our landscape more effectively.
- 6.5. Specific actions current actions include:
  - The most important project at present is the movement of the server room away from the BPL site at Elstree. We are planning for a change freeze in the autumn to ensure that we have absolute focus on a managed transition.
  - We have recently worked with third parties to offer us a managed service to carry out a short term piece of work to upgrade the server estate, and then to move the servers to a new location. This process will result in stable servers sitting in a new location. It should stabilize the current landscape rather than offer any new functionality.
  - Some software changes have been made and more are in train which we hope will de-link some transactions, placing firebreaks in the system to try and make it easier to manage peaks in demand for Pulse. Again our platform strategy will accelerate this process, and actively turning off functionality within Pulse and turning on different services on different (but linked applications), e.g. the management of donors and their appointments will be on a different system from the manufacturing of blood. We will also be running these new systems in the cloud, hosted by a third party, with them taking responsibility for upgrades of operating systems.
  - > We have started work on replacements for Pulse and NtXD.
  - We are splitting the networks contract into more coherent bundles which will add value in areas like 4G on all mobile phones, increases in bandwidth to all sites by factors of around 10x, etc. This work is setting us up to use more cloud based applications more easily.

Risk associated with IT Page 8 of 9

- 6.6. We arrived where we are as frogs in a slowly boiling pan and have probably turned off the gas in time. The team doing the work also have a new found confidence to stop and make course corrections if things are not working as intended.
- 6.7. The last year has been uncomfortable, but has not broken the business. We have undoubtedly used up some goodwill, with donors, customers and employees. However the new strategy, investment in new people and introduction of external support in IT, combined with visible leadership attention in this area have seen improving performance and emerging confidence.
- 6.8. The positive movement is not yet baked in and we, as a board, need to be prepared to challenge whether the current configurations of resources, expertise and assurance are delivering our outcomes in the short and long term.

Risk associated with IT Page 9 of 9



## **Research and Development Committee Meeting**

### 9 a.m. Thursday 14<sup>th</sup> May 2015 The King's Fund, London

### **CONFIDENTIAL APPENDIX – FOR MEMBERS ONLY**

# 8. Theme 2: Transfusion and Transplantation Virology/Microbiology 8a) WP15-01: Transfusion microbiology

A proposal to fund work in partnership with Public Health England led by Professor Richard Tedder on blood and tissue safety was considered. It was noted that:

- The work has the full support of the microbiology strategy group;
- The current priority area is Hepatitis E Virus (HEV). There is a SABTO Working Group to decide whether selective or universal testing is required;
- Additional proposals include work on Chikungunya virus (Chik V), Hepatitis B, the provision of convalescent plasma and CMV for Club 96 donors;
- The technical transfer mechanisms to the National Transfusion Microbiology Reference Laboratories (NTMRL) are in place.

## Outcome: The Committee approved funding in full as part of the 2015 -2020 R&D Strategy

### Action: NW to inform applicants of the outcome.

### 8b) vCJD screening update

LW informed the Committee that eQuIC is unlikely to deliver its intended outcomes and development has ceased. The current focus is on establishing whether or not the vCJD screening assay developed at the MRC Prion Unit and owned by D-GEN is suitable for use in a population prevalence study. The Prion Working Group is due to meet during the week commencing 18<sup>th</sup> May 2015 to review progress.

Discussions focused on the impact of a decision to cease funding for this work, during which it was noted that:

- The additional work agreed by ACDP relates to assessment of the D-Gen assay;
- There is potential for reputational risk to the organisation if the work is terminated prematurely;
- The UK Forum could decide to continue to support this work;
- A recommendation on the performance of the assay would support the decision making process on future population studies;
- A future test would need to be CE marked;

Outcome: The R&D Committee agreed to fund the work until 30<sup>th</sup> September 2015.

Action: LW to discuss future funding with NHSBT's Chief Executive and representatives from the UK Forum.

### 9. Theme 3: Patient Blood Management

#### 9a) WP15-03: Innovation in hospital transfusion

A proposal from Professor Murphy on the use of electronic systems to improve patient blood management was considered. It was noted that:

- The proposal is supported by the Patient Blood Management Strategy Group;
- There was limited detail on who would be undertaking the health economic analysis;
- The benefits and focus of the work remain within the Oxford University Hospitals environment and attempts to roll it out to the wider setting have had limited success;
- The applicant has an excellent track record in this area;
- Oxford University Hospitals had co-invested in the project in kind, but would not fund the support post;
- Further information was required to understand the benefit of the SEND project;
- Given the long-term concerns from Committee in relation to this work, it would be beneficial for a member to visit Prof Murphy in Oxford. JM offered to visit.

## Outcome: Decision on hold, pending clarification on the areas of concern raised in review

Action: LW to discuss with applicant; NW to send letter requesting the additional information; JM to visit Oxford to review project on behalf of RDC

### 10. Theme 4: Advanced blood components

#### 10a) WP15-04: Manufactured red cells

A funding application from Prof Anstee focusing on the manufacture of red cells from stem cells was considered. It was noted that:

- The proposals are supported in full by the component strategy group;
- The work is complementary to the NIHR BTRU in manufactured red cells;
- Continuation of baseline funding for Prof Anstee is a condition of the NIHR BTRU offer;
- Manufactured red cells have the potential to improve transfusion support for hard to match patients;
- The proposal comprises four work streams: GMP manufacture of cRBCs, animal modelling, storage optimisation, and cord unit typing;
- There was uncertainty about the requirements for animal work to support the first-in-man clinical trial and further information was required (see WP15-09);
- A detailed review of the proposed budget was required.

Outcome: The Committee approved funding in principle as part of the 2015 - 2020 R&D Strategy, subject to a review and agreement on the requested funds Action: NW to review funding requirements with applicant and include revised budget in Board submission

### 10b) WP15-05: Studies on erythropoiesis

A funding application from Dr Toye aimed at improving the manufacturing of red cells through understanding aspects of the basic science was considered. It was noted that:

- The proposals are supported in full by the Component Strategy Group;
- The work is complementary to the NIHR BTRU in manufactured red cells;
- Continuation of baseline funding for Dr Toye is a condition of the NIHR BTRU offer;

## Outcome: The Committee approved funding in full as part of the 2015 -2020 R&D Strategy

### Action: NW to inform applicant of the outcome

### 10c) WP15-06: Production of platelets from stem cells

A funding application from Dr Ghevaert aimed at maximising the production of platelets from stem cells was considered. It was noted that:

- The proposals are supported in full by the Component Strategy Group;
- Work in this area has previously been funded through NIHR Programme B;
- An NIHR BTRU application was submitted but was unsuccessful;
- Funding is for two post-doctoral scientists and consumables;
- The work aims to identify ligands to maximise the production of platelets, and to create universal platelets;
- The proposal is largely basic science but aims to move towards a first-in-man trial by 2020;
- The work is complementary to other activities in Advanced Blood Components;
- The applicant has demonstrated readiness and the required knowledge for a clinical trial of cellular therapies and has the potential to fill a gap in the NHS where there is a lack of readiness for translation of regenerative medicine based therapies;

## Outcome: The Committee approved funding in full as part of the 2015 -2020 R&D Strategy

### Action: NW to inform applicant of the outcome

### 12. Theme 6: Stem Cells and Immunotherapies

### 12a) WP15-08: Optimising human HSC expansion

A funding application from Prof Watt on the development of protocols to expand cord blood derived haematopoietic progenitor cells (HPC) was considered. At the request of Committee, the application had been undergone external peer review. In discussion it was noted that:

- The proposal did not have the support of the Stem cells and immunotherapies strategy group;
- The proposals were considered fragmented without an overarching objective;

- The external referees considered the application to be of good quality but raised concerns about the likelihood of translating the approach into clinical practice in a 2 – 3 year timeframe;
- Multiple HPC expansion protocols are currently undergoing evaluation in clinical trials and NHSBT does not have a leading position in this field;
- The focus of the translational research Programme in stem cells and immunotherapies had shifted to the NIHR BTRU at UCL;
- The funding stream for these activities (RCF) had reduced by £168k and there was no funding available from operations to replace this.
- The funding application did not include the salary for the PI;
- Changes in clinical practice have led to a reduction in activity in cord blood transplantation, mainly because haplo-transplantation is increasing;
- Gene-editing protocols make use of adult rather than cord stem cell populations;

Outcome: The proposals were not approved. In light of this decision, the unsuccessful NIHR BTRU application from the University of Oxford and the cessation of funding to Prof Watt through NIHR Programme C, the R&D Committee recommended that steps be taken to close this work. In view of the BTRU, the need for this area of activity was questionable.

Action: LW to feed back comments to Prof Watt.

#### 12b) WP15-09: Targeted therapeutics for childhood leukaemia

A funding application from Dr Blair focused on the validation of CD200 as a potential therapeutic target in childhood leukaemia and described animal studies in support of the manufacture of red blood cells was considered. It was noted that:

- The proposal is supported by the Stem cells and immunotherapies research strategy group;
- The work is closely linked to the NHIR BTRU at UCL and describes the activities of a post-doctoral fellow who will be funded via the BTRU for 12 months in the first instance;
- There remain concerns about whether CD200 is a valid therapeutic target because of tissue distribution;
- The focus on activities should be a rapid validation of CD200 as a target with a clear Go/No-Go decision;
- Dr Blair's work using animal models is complex but in other NHSBT funded laboratories these activities are undertaken successfully by more junior staff and therefore the proposals do not represent value for money;
- In other studies, animal work is contracted through University animal houses rather than by funding full-time staff. This approach supports focussed studies and reduced animal husbandry costs;
- Only 0.15 FTE of Dr Blair's time is required to support work on the preclinical evaluation of manufacture red cells;
- The exact requirements from the MHRA for pre-clinical validation and toxicology studies for manufacture red cells are not yet known;
- Some pre-clinical validation of manufactured red cells could be conducted in an *ex-vivo* kidney model;

Outcome: The proposals were not approved.

Action: LW to feed back comments to Dr Blair and review requirements for animal studies to support the first-in-man clinical trial of manufacture red cells with Prof Anstee.

### 12c) WP15-11: Regulatory T-cells in stem cell transplantation

A funding application from Prof Roberts on the regulatory T-cells in stem cell transplantation was considered. It was noted that:

- The proposals were supported by the stem cells and immunotherapies strategy group;
- The application had been received late and therefore it had not been possible to undertake peer review;
- Evidence suggests a lower mortality is associated with increased counts of Tregs in the graft and that T-reg levels are correlated with vitamin D;
- The initial findings had been submitted for publication but had not yet been accepted because of the confounding effect of the high incidence of use of CAMPATH in UK transplant recipients;
- If funded, this proposal would provide a potential redeployment opportunity for a member of staff currently at risk through changes to NIHR funding;

### Outcome: The proposals were not approved.

Action: NW to arrange external peer review of the application. CC to take Chair's action on the basis of peer review.

**TPRC(M)(15)2** 

### NHS BLOOD AND TRANSPLANT

### MINUTES OF THE FOURTEENTH TRANSPLANT POLICY REVIEW COMMITTEE MEETING HELD AT 12.30 PM ON THURSDAY 18<sup>TH</sup> JUNE 2015 AT THE UNIVERSITY OF LONDON, MALET STREET, LONDON

PRESENT:Mr Jeremy Monroe, Non-Executive Director (Chair)<br/>Dr Christine Costello, Non-Executive Director<br/>Prof John Dark, National Clinical Lead for Governance, ODT<br/>Ms Sally Johnson, ODT Director, NHSBT<br/>Dr Paul Murphy, National Organ Donation Committee Chair<br/>Prof James Neuberger, Associate Medical Director, ODT<br/>Prof John O'Grady, Liver Advisory Group Chair<br/>Prof Rutger Ploeg, National Retrieval Group Chair<br/>Mr Steven Tsui, Cardiothoracic Advisory Group Chair<br/>Prof Chris Watson, Kidney Advisory Group Chair

IN ATTENDANCE: Mrs Kathy Zalewska, Clinical & Support Services, ODT (Secretary)

ACTION

### 1 WELCOME AND APOLOGIES

1.1 J Monroe welcomed everyone to the meeting and apologies were reported from:

Prof Peter Friend, Pancreas Advisory Group Chair Prof Darius Mirza, Bowel Advisory Group Chair Mr Derek Tole, Ocular Tissue Advisory Group Chair Dr Lorna Williamson, Medical & Research Director, NHSBT

### 2 DECLARATIONS OF INTEREST – TPRC(15)13

There were no declarations of interest.

### 3 MINUTES OF PREVIOUS MEETING & MATTERS ARISING

- 3.1 **Minutes of the meeting held on 16<sup>th</sup> April 2015 TPRC(M)(15)1** The minutes of the previous meeting were agreed as a correct record.
- 3.2 Action points TPRC(AP)(15)2

**Item 1: Pregnancy policy revision** – Deferred awaiting report from UK DEC.

- Item 2: Completed
- Item 3: Completed
- Item 4: Completed
- Item 5: In hand Changes are currently being made to the policy
- Item 6: In hand
- Item 7: Completed

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#### ACTION 3.3 Matters arising not separately identified Minute 4.1: A meeting with surgeons and intensivists and others on organ donation and transplantation from children less than 2 months of age is scheduled for 17<sup>th</sup> July 2015. The outcomes of this meeting will be used to J Neuberger/ inform the draft NHSBT position statement which will be presented to the P Murphy NHSBT Board. J Neuberger and P Murphy will prepare an update for J J Monroe/ Monroe and C Costello to take to the September Board meeting. C Costello FOR CONSIDERATION 4.1 Update on the Pregnancy Policy revision P Murphy reported that a revision to the policy was proposed in that permission should no longer be sought for a pregnancy test as the test should be undertaken as part of donor characterisation. A sub-committee of The Royal College of Obstetrics and Gynaecology asked that the policy be sent to the UK Donation Ethics Committee for their view. Formal feedback from UKDEC is due following their meeting to be held on 19<sup>th</sup> June 2015; J Neuberger will ask A Clarkson to remind SNODs to maintain the current **J** Neuberger policy. P Murphy agreed to provide a further update for members at the P Murphy next meeting in September. S Johnson was asked to review the need for S Johnson escalating this to the CMOs of all four Departments of Health and NHS England. 4.2 Review of TPRC Terms of Reference – TPRC(15)14 Members reviewed the TPRC Terms of Reference. It was clarified that nonquorate meetings can continue provided no material decisions are made by those present. To date, all TPRC meetings have been guorate. Minor changes were agreed to item 8 'Duties' and item 10 'Reporting' to J Neuberger/ clarify the duties of the Committee and to include production of the Annual **C & SS** Report to the Board POL189 – Cornea Allocation Policy – TPRC(15)15 Revisions to the policy were noted and approved subject to a minor revision clarifying that the number of corneal transplants quoted as undertaken each year is at the time of writing in 2015. POL190 – Cornea Selection Policy: TPRC(15)16 Revisions to the policy were noted and approved. MPD1100 – Donor Organ Photographs – TPRC(15)17 Following an incident where the accepting surgeon requested a photograph

of a rash on a potential donor to enable him to reach a decision about the use of the organs, changes to the Guidance and Principles for Donor Organ Photographs were requested to allow appropriate pictures of tissues to enable safe donation to take place. The changes were approved subject to the omission of Appendix B (List of identifiers that should be avoided).

#### 8 ANY OTHER BUSINESS

There were no other items of business.

#### 9 Date of next meeting:

Thursday, 17<sup>th</sup> September 2015 at a London venue to be confirmed.

June 2015

**J** Neuberger

P15/28

### NHS BLOOD AND TRANSPLANT

### 30 JULY 2015

### NOTES FROM THE SEMINAR HELD ON 28 MAY 2015

### DIRECTORS' RESPONSIBILITIES

I presented an overview of the legal and regulatory landscape relating to Directors' duties and corporate governance, including recent updates. The Board welcomed this reminder of its responsibilities and obligations in this area.

Louise Fullwood Non-Executive Director June 2015

### NHS BLOOD AND TRANSPLANT

### 30 JULY 2015

### CONTRACTS OVER £1 MILLION AND UNDER £3 MILLION

# FRAMEWORK AGREEMENT FOR THE SUPPLY AND SUPPORT OF FLOW CYTOMETERS

Based upon a submission by Huw Williams, I have approved the award of a framework agreement for the provision of flow cytometers. The value of the agreement is £1.8m over 4 years. The submission was approved by Andrew Blakeman and Keith Rigg.

### **BRISTOL EYE BANK**

On the basis of a submission made by Huw Williams, I have approved a business case for the construction of an eye bank at NHSBT's Filton premises, with associated internal changes. This was reviewed by Shaun Williams and Louise Fullwood. The value of the business case is £956,000.

lan Trenholm Chief Executive May 2015

## NHSBT Major Contracts Pipeline Report July 2015

### **CONFIDENTIAL - SOME UPDATES RELATE TO LIVE TENDER EXERCISES**

## Strategic Goods Team

Contract Reference	Contract Title	Estimated Total Value (ex VAT)	Approval by	Details
NHSBT0466	Perfusion Fluid	£5m	Board Sept 2015	<ul> <li>Finalising evaluation by 24<sup>th</sup> July 2015</li> <li>Moderation of scores by panel – 28<sup>th</sup> July 2015</li> <li>Award recommendation to ODT SMT by 18<sup>th</sup> August 2015</li> <li>Award recommendation to Board – 24<sup>th</sup> Sept 2015</li> <li>New service starts – Oct 2015</li> </ul>
NHSBT717	Labels: Gamma and X-ray indication	£1m	NED scrutiny September 2015	<ul> <li>Current agreement ends November 2015.</li> <li>Option to continue supply from incumbent supplier, Biotest UK, under the managed service provided by Williams Lea – bids currently in evaluation by Procurement and customer.</li> <li>Validation may cause delay to award should the competitor, RadTag Tech be considered further however sufficient supply available for duration of 2016.</li> </ul>
NHSBT0436	Pathogen Inactivation of Platelets	£15m (detection) £35m (reduction)	Board Nov 2015 & Mar 2016	<ul> <li>New requirement. The Board will need to make a decision in November 2015 with regard to continuing with the Pathogen Inactivation tender on the basis of the technical and commercial evidence presented.</li> <li>The final recommendation paper will be issued to the Board in March 2016.</li> </ul>
NHSBT0649	Blood Weigher/ Agitator	£1.5m	NED scrutiny November 2015	<ul> <li>Maintenance only following a roll out of new ASI equipment in 2011/12.</li> <li>Tender exercise resulted in approval May 2015 (NED reviewed). Subsequent challenge from unsuccessful tenderer (ASI) led to decision to abandon and re-tender.</li> <li>Re-tender process to begin August 2015. Interim arrangement with ASI in place to provide maintenance until contract award in 4-6 months time.</li> </ul>

Contract Reference	Contract Title	Estimated Total Value (ex VAT)	Approval by	Details
NHSBT0765	HLA Allelic, Rapid, Routine typing and HLA Antibodies	£10m	Board November 2015	<ul> <li>Procurement Strategy Approval: March 2015.</li> <li>Deadline for receipt of Tenders: 31 July 2015.</li> <li>Framework Agreement Commencement Date: 01 January 2016.</li> <li>Framework Agreement Expiry Date: 31 December January 2020.</li> <li>Split into five lots</li> <li>10 potential suppliers have responded to the OJEU PIN and supplier engagement completed April 2015. Site visits taking place July 2015.</li> </ul>
NHSBT0787	Rapid plasma freezers	£1m	NED scrutiny January 2016	<ul> <li>Procurement strategy and specification development – Aug 2015</li> <li>Supplier engagement day – w/c 10<sup>th</sup> August 2015</li> <li>OJEU advert – 1<sup>st</sup> Sept 2015</li> <li>Evaluation and Validation – 16<sup>th</sup> Oct – Dec 2015</li> <li>Award recommendation to Board – end Jan 2016</li> <li>Start of new service – 1<sup>st</sup> April 2016</li> </ul>
NHSBT0758	Centrifuges: Processing	£1.9m	NED scrutiny Jan 2016	<ul> <li>EU Compliance raised for January '15 – January '16 for maintenance.</li> <li>A tender exercise for supply and maintenance was performed in 2014 but received only one suitable bid.</li> <li>New tender exercise to be started August 2015</li> <li>15 units requiring replacement before 31<sup>st</sup> March 2016 to be called off LUPC framework.</li> </ul>
NHSBT0559	Low Density Lipoprotein (LDL) Apheresis Systems	£1m	NED scrutiny January 2016	<ul> <li>Supplier engagement underway. Trials being conducted of current technology to help inform NHSBT procurement. Due to complete July 2015.</li> <li>Expected tender issue August 2015.</li> <li>Award due March 2016.</li> </ul>
твс	Secondary blood grouping	£3m	Board March 2016	<ul> <li>Currently aware of only one supplier in the market place.</li> <li>NHSBT to undertake an EBA survey to establish if there are any other suppliers or types of technology used for this purpose.</li> <li>Current contract expires 31<sup>st</sup> March 2016</li> </ul>
NHSBT0761	Enumeration of White Blood Cells in Leucodepleted Blood	£1m	NED scrutiny March 2016	<ul> <li>Strategy paper approved May 2015.</li> <li>Expected tender issue 30 September 2015.</li> <li>Award due 1 May 2016.</li> </ul>
NHSBT0675	Blood Presses	£2.5m	NED scrutiny March 2016	<ul> <li>Supplier engagement day held October 2014, 4 companies attended.</li> <li>Specification in draft, tender process to commence August 2015.</li> <li>Between 125 and 173 presses to be replaced over 4 year agreement</li> </ul>

Contract Reference	Contract Title	Estimated Total Value (ex VAT)	Approval by	Details
				term, exact figure pending decision on consolidation of manufacturing sites.
NHSBT0788	Pathogen Inactivation (PI) of Plasma	£2.8m	Board May 2016	<ul> <li>The option of purchasing finished PI plasma has been explored and the decision taken to continue importing untreated plasma (SaBTO). There is an urgent requirement to start this tender and the specification is currently under development.</li> <li>A request for 6 month extension of current contract has been authorised by the FD.</li> <li>A new tender timetable in place, with OJEU advert scheduled for Oct 2015 and new service date of July 2016.</li> </ul>
ТВС	Extracoporeal photopheresis	£1m	NED scrutiny July 2016	<ul> <li>Strategy paper commenced May 2015.</li> <li>Expected tender issue February/March 2016.</li> <li>Award due 1 October 2016.</li> </ul>
TBC	Bacterial arm cleansing	£3m	Board Sept 2016	Project to commence Sept 2015
ТВС	DNA extraction	£1m	NED scrutiny Sept 2016	<ul> <li>Current contract expires 14 October 2016</li> <li>Strategy paper to commence September 2015.</li> <li>Pre-tender activity commenced April 2015.</li> </ul>
твс	Multifunctional apheresis devices	£3m	Board Nov 2016	<ul> <li>Current contract expires 31 January 2017</li> <li>Strategy paper to commence November 2015.</li> <li>Pre-tender activity to commence August 2015.</li> </ul>
твс	Eurobloodpack	£48m (or circa £80m with collaboration)	Board Nov 16 Mar 2017	<ul> <li>1<sup>st</sup> Supplier engagement meeting took place on 3 July.</li> <li>Scoping meeting with Dragon Sourcing took place 16 July.</li> <li>Strategy paper (draft) to be circulated August 2015</li> <li>Nov 16 Framework agreement approval</li> <li>Mar 17 Supplier(s) award</li> </ul>
ТВС	Primary Blood Grouping Equipment	£3m	Board May 2017	<ul> <li>Current contract expires Jan 2018</li> <li>Strategy paper to commence May 2016.</li> </ul>

## Transformation / IT

Contract Reference	Contract Title	Estimated Total Value (ex VAT)	Board Approval	Details
NHSBT0728	Connectivity and Network Services	£7m	September 2015	It has been agreed by Crown Commercial Services (CCS) that we will conduct 6 telecoms related procurements (and a potential 7 <sup>th</sup> for N3) replacing the single contract we currently have with Vodafone. After tendering via the existing PSN Connectivity framework for Connectivity we received two responses: Vodafone and Easynet. We are in the process of evaluating these and are working closely with Finance to fully understand and evaluate the financial details / costs The supplier presentations were held early June 2015. The Detailed Business Case (DBC) is expected to be presented to the September Board; this will also incorporate the Telephony and Firewall requirements.
NHSBT0723	Integrated Telecommunications Services	£3.3m	September 2015	We have now conducted a tender via the existing PSN Connectivity framework for Telephony and received two responses: Vodafone and Capita. We are in the process of evaluation. The supplier presentations were held at the end of June 2015. The Detailed Business Case (DBC) is expected to be presented to the September board; this will also incorporate the Connectivity and Firewall requirements.
NHSBT0775	Co Managed Service / Firewall Hardware	Up to £2.1m	September 2015	Currently evaluating 2 supplier responses (from BT and Dimension) following PSN tender. The Detailed Business Case (DBC) is being prepared by project lead Cat Ongers. If we proceed with one of the tender submissions the DBC will be expected to be presented to the September board; this will also incorporate the Connectivity and Telecoms requirements. Contract will be for 2 years plus 2, 1 year extension options.

Contract Reference	Contract Title	Estimated Total Value (ex VAT)	Board Approval	Details
NHSBT0782	Modern Paperless Donor Journey Hardware & Software	£2.5m	September 2015	<ul> <li>This is a requirement for tablets, laptops, servers and software.</li> <li>Early pre tender discussions held with Project Team to discuss requirements, timescales and possible routes to market.</li> <li>Supplier Technology Meetings to be held with manufacturers of hardware in Autumn 2015 to help us identify what hardware is on the market.</li> <li>Routes to Market – CCS Technology Products Lot 1 Technology Hardware (Hardware) and Digital Services Framework (Software).</li> </ul>
Not yet assigned	IT Specialists (Interim resources)	£1-3m	November 2015	Project to access IT Specialists on an ad-hoc basis, potentially via a managed service approach. Procurement route to market yet to be decided. The Board date provided is an estimate only as project timescales are yet to be agreed.
NHSBT0709	Transformation Discovery / IT Platforms	£31m over 4 – 5 years (of which £6- 7m is predicted for software acquisition)	The Board date is to be confirmed as timescales are yet to be agreed.	<ul> <li>The aim of this project is to take the existing portfolio of applications (a mix of COTs and bespoke) and consolidate under 7 potential platforms e.g. Scheduling, CRM, Finance etc.</li> <li>As part of the formulation of the functionality of the platforms a further supplier is required to help with the conceptual design of the platforms. This is to provide skills that NHSBT does not possess. This is principally in the areas of Automated Testing Services, Automated Testing Tools and lower-level Agile Delivery Management.</li> <li>After conducting an objective selection process via Gcloud we have selected Engine Partners who are the lowest priced supplier for the two GCloud contracts for the IT Platforms and Testing and Selection. We have also contracted with them on this project previously.</li> <li>We have already engaged with Cabinet Office (CCS) regarding potential procurement routes. There will be a formal meeting early September with CCS to help formulate the procurement strategy.</li> </ul>

## Estates & Services

Contract	Contract Title	Estimated Total Value (ex VAT)	Approval by	Details
NHSBT402	Leasing of Commercial Vehicles	£8.4m	Board September 2015	Mini competition to be undertaken against a CCS framework upon award of Framework in May 2015.
NHSBT0594	Liquid Fuel	£2.8m	Noted to board November 2015	CCS Framework Agreements. CCS currently undertaken procurement exercise. CCS will undertake a direct award on behalf of NHSBT
NHSBT0001	Courier Services	£10.8m	Board January 2016	Final extension decision contract expiry 31 <sup>st</sup> January 2017. Tender process to commence November/December 2015.
NHSBT0309 NHSBT0310 NHSBT0311	National Cleaning and Portering Services	£6.7m	Board May 2016	Authorisation to extend to 31 <sup>st</sup> March 2017. Maximum extension period 31 <sup>st</sup> March 2020
NHSBT0189 NHSBT0190 NHSBT0426	National Planned Preventative Maintenance	£6.1m	Board May 2016	Authorisation to extend to 31 <sup>st</sup> May 2017. Maximum extension period 31 <sup>st</sup> May 2018. Commence re tender process June 2017, however CCS are currently procuring a facilities management framework agreement which we may mandated to use.
NHSBT0455	Clinical Waste	£3m	Board November 2016	Authorisation to extend to 31 <sup>st</sup> May 2018.
NHSBT0401 NHSBT0401a NHSBT0401b	Contingent Labour Lots 1, 2 and 3	£12m	Board January 2017	Contract expiry 4 <sup>th</sup> June 2016. Authorisation to extend to 4 <sup>th</sup> June 2017.
NHSBT0536	National Contact Centre	£10.2m	Board July 2017	Contract expiry 31 <sup>st</sup> August 2017. Current contract from a CCS Framework Agreement. CCS to retender Framework Agreement 2016. NHSBT mandated to undertake mini competition of the framework.
NHSBT0243	Vehicle Maintenance	£2.7m	Board November 2018	Maximum extension current contract 31 <sup>st</sup> March 2019, commence retender process January 2018