Department of Health

Triennial Review of NHS Blood and Transplant (NHSBT)

Review Report

September 2016

Title: Triennial Review of NHS Blood and Transplant; Review Report
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Document Purpose: Corporate Report
Publication date: 15 September 2016
Target audience: Voluntary groups, Community groups, Charities, Civil society, Advocacy or support organisations, Clinicians, Managers, Commissioners, Directors of Public Health, Pharmacists, Doctors, Midwives, Healthcare scientists, Foundation Trusts, NHS Commissioning Board, Clinical Commissioning Groups, Regulatory body, Academic/ Professional institution, Trade union, General public, Patients, Patients, Service users, Suppliers.
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Published to gov.uk, in PDF format only.

www.gov.uk/dh

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Executive summary

The Department of Health (DH) Triennial Review (the review) of NHS Blood and Transplant (NHSBT) was conducted to provide assurance to DH and the public of the ongoing need for the functions currently performed by NHSBT, and the efficiency of the administration of these functions. This review forms one of a series of reviews conducted by the Department of its arm's length bodies (ALBs) between 2014-15 and 2016-17.

NHSBT is a Special Health Authority (SpHA) in England and Wales. Established in 2005 from the merger of the National Blood Authority and UK Transplant, it is sponsored by DH and the Welsh Government. For the purposes of the national accounts NHSBT is also classified as a public corporation. The review recommends that NHSBT maintains its current status as a SpHA.

NHSBT depends entirely on the altruistic donation of blood, tissues, solid organs and haemopoietic stem cells to fulfil its responsibility to provide a safe and sufficient supply of blood, organs, tissues and stem cells. NHSBT's functions in relation to blood apply to England only and those on stem cells to England and North Wales only. Wales, Scotland and Northern Ireland have their own blood services[1]. NHSBT supplies tissues across the UK and also has specific responsibilities across the UK with regard to organ donation and transplantation. As the UK Organ Donation Organisation, NHSBT is accountable to the four UK health departments, and works with each of them, as well as hospitals, to increase the number of organs available for transplantation. This report contains a more detailed discussion of NHSBT's functions, which the review concludes should be retained.

The evidence collected by the review team demonstrated that NHSBT has a strong organisational focus on the safe and efficient supply of blood and organs, which has included the innovative use of LEAN techniques and the adoption of strong governance processes. Declining demand for blood means creating efficiencies in relation to blood is a necessity for NHSBT, and has become ingrained in the senior management team's approach. The review contains some efficiency-related recommendations, which build on NHSBT's existing programme of work which has already delivered significant efficiencies.

In relation to organ donation and transplantation, NHSBT remains focused on the challenges of delivering the Organ 2020 Strategy, including funding in future years. The review recommends a specific piece of work to help NHSBT and DH (in England) consider the most suitable funding model going forward, noting that a change in the funding model will not in itself deliver the strategy.

In addition to services directly related to the blood and organ supply chains, NHSBT undertakes work that looks to make advances beyond improving the blood and organ supply chain. In particular the review makes the observation that NHSBT is uniquely placed to be a leader in the field of regenerative medicine. This is currently a small part of the organisation's business, but it has enormous potential for patients and could also be developed in a way that supports government strategies related to innovation and to growth. This field of work is still embryonic and NHSBT has some strong foundations, but the review recommends that NHSBT undertakes further work to develop its strategic approach to regenerative medicine.

[1] Until 1 May 2016 the Welsh Blood Service covered South, West and part of mid-Wales. From 2 May 2016, responsibility for the provision of the blood service in North Wales transferred from NHSBT to the Welsh Blood Service which covers all of Wales.

The review also makes a small number of recommendations that are intended to support NHSBT to continue to build its relationships with the Devolved Administrations. These recommendations are intended to support NHSBT to continue to deliver relevant services to all four nations as greater divergence in national policies potentially emerge.

1. Summary of Recommendations

Stage One - Function

Recommendation 1: The review team recommends that the range of functions currently undertaken by NHSBT continues. (paragraph 39, page 20)

Stage One – Delivery Model

Recommendation 2: The review team recommends that DH takes advantage of the opportunity presented by the end of the five-year strategy for stem cell transplantation to engage with NHSBT and Anthony Nolan and agree a way forward that addresses any infrastructure duplication and plays to the respective strengths of these two organisations in supporting DH objectives and priorities. (paragraph 65, page 26/27)
Action Owner: DH Genomics Science and Emerging Therapies Team; Timing: by end 2016/17

Recommendation 3: The review team recommends that NHSBT should remain a Special Health Authority (SpHA) in England and Wales. (paragraph 68, page 27)

Recommendation 4: The review team recommends that NHSBT adopts a stretch target for growth in Diagnostic and Therapeutic Services (DTS). (paragraph 68, page 27).
Action Owner: NHSBT Board; Timing: to be included in future business planning rounds

Recommendation 5: The review team recommends that NHSBT, working with DH and NHS England, and the Devolved Administrations, undertakes a specific project to develop a proposal on the future of Organ Donation and Transplantation (ODT) funding in England. (paragraph 74, page 28)
Action Owner: NHS England, DH, and NHSBT; Timing: by Summer 2017, to allow for incorporation into the NHS England Mandate 2018/19 if required

Stage Two – Governance and relationships

Recommendation 6: The review team recommends that NHSBT (for executive appointments) and DH Ministers (for non-executive appointments) should seek to use any upcoming appointments to consider strengthening specific skills and areas of knowledge on the Board. In particular donation from Black, Asian and Minority ethnic communities and individuals and Regenerative Medicine. (paragraph 83, page 30)
Action Owner: DH Public Appointments Unit and NHSBT; Timing: ongoing as existing posts become vacant

Recommendation 7: The review team recommends that NHSBT and Welsh Government Officials review information flow to assure themselves that they are systematically sighted on all key areas of work and upcoming developments. (paragraph 87, page 31)
Action Owner: NHSBT and Major Health Conditions Policy Team Welsh Government; Timing: with immediate effect

Recommendation 8: The review team recommends that NHSBT amends the Board pages on the NHSBT website to indicate which executive directors are full members of the Board and which are non-voting members. (paragraph 89, page 32)
Action Owner: NHSBT; Timing: with immediate effect

Recommendation 9: The review team recommends that the National Administrations Committee of the NHSBT Board works with government officials from each of the four nations, as well as the respective national commissioners, to identify and advise the NHSBT Board on future policy divergences. (paragraph 93, page 33)
Action Owner: NHSBT, DH Sponsor Team, and relevant officials in the Devolved Administrations; Timing: for next meeting of the Committee

Recommendation 10: The review team recommends that the relationship and expectations of each blood service in terms of contingency planning should be formalised, to guarantee that blood provision across the whole of the UK will be maintained in the event of a crisis in one or more of the four services. (paragraph 94, page 33)
Action Owner: NHSBT, DH Sponsor Team, and relevant officials in the Devolved Administrations; Timing: Q3 2016/17

Recommendation 11: The review team recommends that NHSBT continues to work to create greater and more consistent branding for its DTS products and services within the context of maintaining and developing the existing strong brand for blood and ODT. (paragraph 103, page 35)
Action Owner: NHSBT; Timing: ongoing with immediate effect

Recommendation 12: The review team recommends that the Department of Health coordinates arrangements to support the Care Quality Commission (CQC), Medicines and Healthcare Products Regulatory Agency (MHRA), Human Tissue Authority (HTA) and other health and care system regulators, plus the UK Accreditation Service (UKAS), to provide an even more joined-up regulatory framework, including to identify ways to improve their current information sharing arrangements. (paragraph 126, page 43)
Action Owner: DH Tailored Review Team; Timing: as part of the ongoing DH programme of reviews.

Stage Two – Strategic Leadership

Recommendation 13: The review team recommends that NHSBT should develop clear priorities for its role in the development of translational medicine, and gene and cell diagnostic therapies in healthcare, and actively seek partnerships with relevant organisations to promote this work. (paragraph 137, page 46)
Action Owner: NHSBT; Timing: to be included in NHSBT objectives in 2017/18 business planning round

Stage Two - Efficiency

Recommendation 14: The review team recommends that DH should consider NHSBT's expertise in LEAN and HR: for potential shared services for other ALBs. (paragraph 142, page 48)
Action Owner: DH Tailored Review Team; Timing: as part of the ongoing DH programme of reviews

Recommendation 15: The review team recommends that NHSBT's blood collection modernisation strategy be accelerated, but monitored through a phased plan, with key decision points reflecting analysis of the impact on donor behaviours (paragraph 143, page 48)
Action Owner: NHSBT, with agreement from DH; Timing: agreed programme of acceleration to be reached Q3 2016/17

Recommendation 16: The review team recommends that work to actively reduce blood use is included in the implementation of the Model Hospital proposed by Lord Carter's review of operational efficiency. (paragraph 144, page 48/49)
Action Owner: DH Carter Implementation team, with a view to transitioning to NHS Improvement with the overall Carter Programme; Timing: Integrated with the ongoing Carter Programme

Recommendation 17: The review team recommends that NHSBT and DH undertakes analysis to establish whether there is scope to drive behavioural change through alternative pricing structures for blood. (paragraph 145, page 49)
Action Owner: NHSBT and DH Public and International Health Directorate Analysis Team; Timing: analysis undertaken and tabled for consideration at November 2016 meeting for National Commissioning Group for Blood

Recommendation 18: The review team recommends that the Productivity and Efficiency Programme supports NHSBT to access appropriate data from providers to build a more effective business case, with specific case studies, to understand the levels of efficiency that hospitals could achieve. (paragraph 148, page 49)
Action Owner: DH Carter Implementation team, with a view to transitioning to NHS Improvement with the overall Carter Programme; Timing: Integrated with the ongoing Carter Programme

2. Introduction and background

Public Bodies Reform

1. Public bodies need to be responsive to an ever-changing landscape. They need to be efficient, effective and accountable. Any duplication of activity needs to be cut, and activities and functions no longer needed should be stopped. For functions that remain, the public has a right to be assured that they are effective, efficient and well governed. Regular challenge and review provides this assurance and is therefore central to the reform agenda.

2. Triennial Reviews (TRs) provide a systematic approach for the regular review of public bodies operating at arm's length to Government Departments. TRs have two main stages:

   - **Stage One** tests the continuing need for the body, both in terms of the functions it performs and the model and approach through which those functions are delivered;
   - **Stage Two** considers the body's governance, performance and capability as well as exploring opportunities for efficiencies.

   All TRs are carried out in accordance with Cabinet Office guidance "Guidance on Reviews of Non-Departmental Public Bodies"[2], revised in 2014, and the principles laid out in that guidance of: challenge, proportionality, contextual, pace, inclusivity, and transparency.

3. The health and social care system reforms, set out in the Health and Social Care Act 2012 and the Care Act 2014, resulted in the devolution of functions and powers away from the DH to arm's length bodies and local health and care organisations. As steward of this evolving system, the DH is using Triennial Reviews to provide assurance that the system and the new and reformed bodies within it are fit for purpose.

4. To support DH in effectively delivering its stewardship function, the Department's programme of TRs extends to all Executive Non-Departmental Public Bodies, Advisory non-Departmental Public Bodies, Executive Agencies, and Special Health Authorities (SpHAs).

NHSBT Triennial Review – Governance, Methodology, and Stakeholder Management

5. The review was conducted by a DH lead reviewer working under the direction of a senior review sponsor (SRS), who was independent from both the review team and NHSBT.

6. In accordance with the Cabinet Office guidance that TRs should be proportionate to the size of the body under review, the two main stages (see paragraph 2 above) of the NHSBT TR were undertaken in parallel.

7. The scope of the review meant the team considered for Stage One of the review whether:

   - the current functions of NHSBT contribute to wider Government policy and constitute a justifiable use of public money;

[2] Copy available at: https://www.gov.uk/government/publications/triennial-reviews-guidance-and-schedule

- there are benefits to delivering the functions for users and stakeholders;
- NHSBT's status as a SpHA supports the organisation to deliver its objectives;
- NHSBT's current funding models remain appropriate;
- there is clarity in accountability and division of responsibility within the organisation.

8. For Stage Two of the review, the review team considered whether:

- NHSBT complies with Cabinet Office principles of good governance;
- internal processes are sufficiently lean, and whether further system wide efficiencies could be achieved through greater exploitation of NHSBT's assets and expertise;
- there are opportunities for NHSBT to exploit to improve growth or deliver innovation;
- NHSBT has effective relationships with its stakeholders and customers, including the Devolved Administrations;
- NHSBT collaborates effectively with partners across the health and care system;
- the management of NHSBT's strategic operating units is effective and/or could be improved;
- NHSBT is as efficient as possible;
- the regulatory landscape within which NHSBT operates is proportionate and appropriate.

9. In addition to the SRS, the review was overseen by a Project Board and supported by a Challenge Group. Project Board meetings were chaired by the SRS and attended by: NHSBT's Director of Finance; a Welsh Government official; a representative of the DH Sponsor Team for NHSBT; and the lead reviewer. The Challenge Group comprised three people with the necessary skills and experience to provide constructive additional challenge on the work of the review team and thereby to ensure the proportionality and robustness of the review. The members of the review team, the Project Board, and the Challenge Group are shown at Annex A. The review team also engaged extensively with officials from the Scottish and Northern Irish health departments throughout the review.

10. The review was subject to the wider scrutiny of the DH Triennial Review Steering Group led by the DH Director of Group Assurance. Ministerial clearance was granted by Department of Health Ministers with input from Welsh Government Ministers.

11. The start of the review was announced by written ministerial statement on 25 June 2015. A copy of the statement is shown at Annex B. Evidence was gathered through a variety of means, including desk-based research; material submitted during a public call for evidence and stakeholder workshop; and interviews with the NHSBT Chair, a number of NHSBT non-executive directors, all members of the NHSBT executive team including the Chief Executive, officials in each of the Devolved Administrations, and a range of other key stakeholders. The public call for evidence was run between 6 August and 10 September 2015. A list of those organisations informed in writing in advance of the launch of the public call for evidence is at Annex C. There were a total of 27 responses to the public call for evidence. Annex D contains the list of questions in the call for evidence and Annex E contains the list of respondents by organisation. Annex F details all the key stakeholders interviewed by the review team, and Annex G contains a quantitative analysis of the 27 responses received to the call for evidence.

Background on NHSBT

12. NHSBT is a Special Health Authority (SpHA) sponsored by the Department of Health, and the Welsh Government. It was established in 2005 from the merger of the National Blood Authority and UK Transplant. Unlike other types of Trust, SpHA's operate nationally rather than serving a specific geographical area. For the purposes of the national accounts, the Office of National Statistics classifies NHSBT as a public corporation.

13. NHSBT is responsible for the safe and sufficient supply of blood, organs, tissues and stem cells. In 2015/16, donors: donated nearly 1.8 million units of whole blood and platelets; provided 3,529 organs for transplant, made 13,000 individual tissue donations (including corneas); and added 1,950 cord blood units to the NHS Cord Blood Bank. NHSBT depends entirely on the donation of blood, tissues, solid organs and haemopoietic stem cells and therefore facilitates and promotes altruistic donation in England and across the UK.

14. NHSBT's functions in relation to blood apply to England only, and in relation to stem cells apply to England and North Wales only. Wales and Scotland and Northern Ireland have their own blood services[3]. However, NHSBT has responsibilities across the United Kingdom with regard to organ donation and transplantation.

15. NHSBT comprises three operating divisions: (1) Blood Components; (2) Organ Donation and Transplantation (ODT); and (3) Diagnostic and Therapeutic Services (DTS). DTS covers a range of specialist activities related to tissues, stem cells, red cell immunohaematology (RCI) including reagents, histocompatability and immunogenetics (H&I) and therapeutic apheresis services (TAS). Each of the strategic operating units within NHSBT (ie Divisions (1) and (2) plus each of the specialist services within DTS) has its own distinct supply chain and related strategies, which are supported by common group services. NHSBT also undertakes research and development in relation to all areas of its business.

16. Funding for Blood Components and DTS is mostly through recovery of costs from NHS hospitals, with the exception of cord blood banking, which receives a government subsidy. NHSBT is a sole supplier with regard to Blood Components (apart from plasma), but the organisation operates in a competitive market for each of the specialist services offered through DTS (apart from human skin in the DTS tissues sub-business unit, which is a monopoly). The National Commissioning Group for Blood (NCGB) sets the prices for Blood Components and the specialist services within DTS. Funding for Organ Donation and Transplantation is through direct subsidy from DH, along with contributions (on a population basis) from the devolved UK health departments. Table 1 below shows NHSBT planned income for 2015/16 across its three operating divisions. Table 2 below shows the direct subsidy to NHSBT for ODT from DH and the three devolved UK health departments.

[3] Until 1 May 2016 the Welsh Blood service covered South, West and part of mid-Wales. From 2 May 2016, responsibility for the blood service in North Wales transferred from NHSBT to the Welsh Blood Service which covers all of Wales.

Table 1: NHSBT Revenue Statement – 2015/16 plan	£m
Income – Blood/DTS/Other	342.2
Programme Funding from DH for ODT and Specialist Services[4]	61.9
Additional subsidy from DH for ODT	4.2[5]
Income from devolved UK health departments for ODT (Table 2 below shows breakdown by individual Dept)	12.2[6]
Total Income	**420.5**

Source: NHSBT financial plan as of 31 December 2015

Table 2: Direct subsidy to NHSBT for ODT from DH and the devolved UK health departments – 2015/16 plan	£m	£m
DH (Programme funding and additional subsidy for ODT)		61.8
Scotland	5.5	
Wales	4.6	
Northern Ireland	2.1	
Sub-total – devolved UK health departments		12.2
Total		**74.0**

Source: NHSBT financial plan as of 31 December 2015

17. NHSBT supplies critical biological products and related clinical services to the NHS, operating 24 hours a day, 365 days a year, within a highly regulated environment. The NHS Blood and Transplant (Establishment and Constitution) Order 2005/2529 is a joint England and Wales Order which provides NHSBT with a remit to:
    - collect, screen, analyse, process and supply blood, blood products, plasma, stem cells and other tissues to the health services;
    - prepare blood components and reagents;
    - facilitate, provide and secure the provision of services to assist tissue and organ transplantation; and
    - carry out any other such functions as directed.

18. NHSBT is also directed by the NHS Blood and Transplant (England) Directions 2005, and the NHS Blood and Transplant (Wales) Directions 2005, as amended, which govern the arrangements relating to England and Wales for blood, stem cell, tissue and organ donation and transplantation services. The Directions additionally direct NHSBT to:
    - conduct or commission research into the uses of, or development of, blood, stem cells and tissues,

[4] Funding in 2015/16 for ODT is £57.7m and for Specialist Services (primarily Cord Blood Bank) is £4.3m.

[5] Additional funding from DH to support expected increases to donor activity (£1.7m) and the running costs of the Organ Donor Register (ODR) (£0.9m) with the remainder being used to support prioritised change programme development work within ODT.

[6] Includes funding to support expected increases to donor activity (Scotland - £0.2m; Wales - £0.55m; NI - £0.3m) and the running costs of the ODR (Wales - £0.45m)

- promote, by advertising, marketing or otherwise, the donation of blood, stem cells and tissues, with a view in particular to maintaining an adequate supply of blood, stem cells and tissue,
- promote through advice and guidance, the appropriate use of blood, stem cells and tissue (having regard in particular to the need to promote the effective use of blood),
- conduct or commission research in connection with the field of organ donation and transplantation as NHSBT considers appropriate, and
- promote, by advertising, marketing or otherwise, the donation of organs and tissues with a view to maintaining an adequate number of organs and corneas for transplantation.

19. NHSBT operates from around 100 locations across the UK. Most of these facilities are operational in nature (for example, manufacturing centres, stock holding units and laboratories) and around 70 of them are fixed donation centres or mobile team bases in support of blood collection. Table 3 below shows the current NHSBT headcount broken down by organisational directorate.

Table 3: NHSBT Headcount – 2015/16 plan	**Whole Time Equivalent**
Blood Donation	1,534
Patient Services	830
DTS	794
ODT	387
Group (Communications, Finance, IT and HR)	1,219
Total	**4,764**

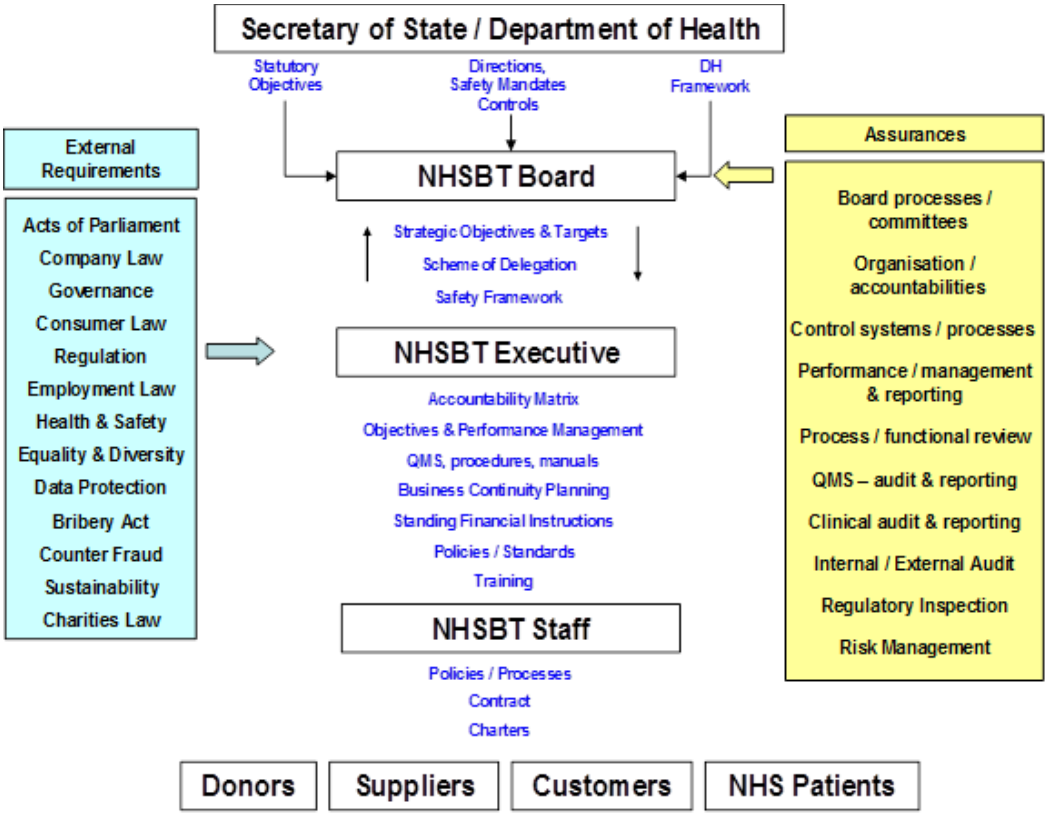
Source: NHSBT Business Plan 2015-2020

20. The NHSBT Board (as at November 2015) consists of an Independent Chair (John Pattullo) and seven non-executives, and a Chief Executive (Ian Trenholm) and 10 executive directors, who make up the executive team. The Chief Executive and five of the executive directors are full members of the board, and the remaining five executives attend the Board as non-voting members. Table 4 below provides further detail on these arrangements, and Figure 1 below illustrates the wider NHSBT governance framework within which the Board operates.

Table 4: NHSBT Board (November 2015)	
Non-Executives	**Executives**
John Pattullo (Chair)	Ian Trenholm (Chief Executive)
Andrew Blakeman **	Rob Bradburn (Director of Finance)
Dr Christine Costello **	Sally Johnson (Director of Organ Donation and Transplantation)
Louise Fullwood	Dr Huw Williams (Director of Diagnostic and Therapeutic Services)
Roy Griffins CB	Dr Lorna Williamson (Dr Gail Miflin from June 2016) (Medical and Research Director)
Jeremy Monroe	Leonie Austin (Director of Communications)*
Keith Rigg	Ian Bateman (Director of Quality)*
Shaun Williams	David Evans (Director of Workforce and Transformation Services)*
Notes *Non-voting members ** Charles St John and Prof Paresh Vyas from April 2016 when Mr Blakeman's and Dr Costello's appointment terms ended.	Peter Lidstone (Director of Blood Manufacturing and Logistics)
	Mike Stredder (Director of Blood Donation)*
	Aaron Powell (Chief Digital Officer)*

Source: NHSBT website

Figure 1: NHSBT Governance Framework



Source: NHSBT Integrated Governance Framework

21. The work of NHSBT has been the subject of a number of reviews in recent years, including the DH Commercial Review in 2011 and the National Organ Retrieval Service (NORS) Review, which was commissioned by NHSBT. In preparing this Triennial Review report the review team has been mindful of these foregoing reviews.

Stage One Report

3. Function

22. This section of the review focuses on whether the functions currently undertaken by NHSBT should continue, based on their contribution to the core business of government and the health and care system. The Stage Two report provides a more detailed consideration of the efficiency and effectiveness of the functions that Stage One of this report recommends should continue.

23. NHSBT's business is divided into three divisions: Blood Components (blood), Organ Donation and Transplantation (ODT), and Diagnostic and Therapeutic Services (DTS). There are synergies across the business and DTS provides a range of services that support safe and effective blood transfusion and organ/tissue and stem cell transplants.

Blood

24. NHSBT has a greater level of direct control over the blood supply chain than it does the supply chains involved in its other business areas. NHSBT is dependent on the donation of blood, which is beyond the organisation's direct control, but it does directly manage the collection of blood, blood processing, and the delivery of blood and blood products to hospitals. The supply chain is not 'vein-to-vein', as it does break once blood is delivered to hospitals: medical staff make decisions about the appropriate use of blood and blood products in the clinical environment.

25. On a day-to-day basis, NHSBT blood services currently cover England. Scotland, Northern Ireland and Wales each have independent blood services. NHSBT's relationship with the Devolved Administrations is discussed in more detail in the Stage Two report below.

26. The need for the continued supply of blood was not questioned in the responses to the call for evidence, and a compelling argument can be made for the continuation of this function. Put simply, there is a need for England to have a safe, reliable and consistent supply of blood in support of a wide range of clinical activities. This clinical work is, in many cases, lifesaving or significantly life enhancing. The World Health Organization (WHO) espouses a policy of promoting voluntary donation[7], arguing that such donations are more sustainable and promote a safer blood supply. In particular, donors are incentivised by their contribution to the health and welfare of others rather than financial remuneration, so are more likely to be open about any conditions that may disqualify them from donation or withdraw their donations during times of need. The WHO also argues that there is a financial case for voluntary donation, with it being the most economically sustainable way to achieve large-scale blood donation.

27. In addition to the direct processing and supply of blood, NHSBT does work to influence the use of blood and blood products in hospitals. In practical terms this work is undertaken by the patient blood management team in DTS. Ensuring that these products are used effectively, efficiently, and safely

[7] The WHO's approach is summarised in its 2010 report "Toward 100% Voluntary Blood Donation, A Global Framework for Action"

is consistent with creating a sustainable supply and promoting medical advances for the benefit of patients. The promotion of best clinical practice, which currently translates into a lower and more selective use of blood products, is not unique in the UK. While macro-level demand for blood in the UK is declining, in line with international trends, there are still areas where demand does not match supply; in particular O negative blood (which is potentially compatible with the majority of recipients) and blood types required for use by black and ethnic minority communities. Based on the arguments that the UK needs a robust and sustainable blood supply, and there is a need to manage costs effectively in the NHS, the review team believes that there is a strong argument for a function to exist that promotes the efficient use of blood products.

28. One ethical question raised with the review team was whether one organisation is able to be both dependent on the sale of blood and responsible for a reduction in its use. In response, NHSBT can point to a recent history of simultaneously reducing the price of blood and supporting the reduction in blood usage in the UK. These achievements are discussed in more detail in the Operational Performance section of this report, but they do provide evidence that one organisation can achieve both objectives. In deliberations, the review team again returned to the argument that there is a national need for robust supply, so it is counterproductive to reduce the use of blood to the extent that the current infrastructure becomes economically unsustainable. On this basis, the review team believes it is appropriate for the two functions to remain together, although does note the potential conflict between them. The review team also recognises that the National Blood Transfusion Committee (NBTC) has an important part to play in promoting good transfusion practice by providing information and advice to hospitals and blood services, including NHSBT, through its network of regional and hospital transfusion committees. Ways in which NHSBT could enhance its support to clinicians in the best use of blood products are considered in more detail in the Efficiency section of this report. At present, good clinical practice points to reducing blood usage, but the review team does recognise that, in future, clinical best practice could lead to an increase in the demand for blood, for example if blood transfusions become an essential part of other treatments. NHSBT therefore needs to remain responsive to any changes.

ODT

29. On a typical day, three people die due to lack of a suitable organ. NHSBT is the UK Organ Donor Organisation that is tasked with maximising the number of organs available for transplant. Organ transplantation is a stand-alone activity, in contrast to the supply of blood, which is often an essential supporting component for a wider range of clinical activities. Organ transplantation is undertaken on the basis of clinical effectiveness, although arguments are also made on the basis of cost in relation to reducing the use of dialysis for kidney transplants. It is beyond the scope of this review to consider the policy behind continuing organ donation, but the call for evidence did strongly convey that respondents believed organ donation should be regarded as a public good, and is clinically effective.

30. NHSBT undertakes a number of specific activities to fulfil what is effectively an intermediary role bringing together donors, retrieval teams and transplant teams. The key functions that NHSBT undertakes are:

    - enabling and promoting organ donation. This includes, but is much broader than, being responsible for the organ donation register.

- maintaining the organ recipient list. NHSBT also owns the structure and processes by which the conditions for being on the organ recipient list are set, although setting these conditions is clinically led.
- maintaining a network of Specialist Nurses – Organ Donation (SNODs) in hospitals to support clinicians and families when a potential organ donation is identified;
- owning and running the Electronic Offering System by which NHSBT is informed by hospitals when organs become available, and running teams that match organ donations with potential recipients;
- commissioning 14 specialist surgical teams to retrieve organs from deceased donors in the UK. This national organ retrieval service is known as the National Organ Retrieval Service (NORS).

31. NHSBT does not have a decision-making role in commissioning organ transplants; this is undertaken by commissioning bodies in each of the four nations of the UK.

32. Broadly, the functions laid out above are conducted across the entire UK, although there are some policy divergences across the four nations in relation to organ donation, which do have an impact on NHSBT's operating environment. This is explored in more detail in Stage Two of this report, but the review team does not believe that this undermines the argument for the necessity of a donation and retrieval function across the UK.

33. As NHSBT plays a co-ordinating role in ODT, the challenges and range of activities that it undertakes to influence individuals, communities, and clinicians in making decisions about organ donation are different to those it undertakes in blood. However, the basic range of functions and the individual components of the wider supply are required as part of the organ supply chain, and the review team recommends that they should continue.

DTS

34. DTS comprises five main sub-business units, which each undertake a range of unique functions. Even when taken collectively, they are the smallest part of NHSBT's business. More detail on the specific work of the five main sub-business units can be found on NHSBT's website[8] and in the annual report[9], but in summary, they are:

- Tissue and Eye Services: NHSBT provides, skin, bone, arteries, heart valves, corneas and other tissues for implants.
- Diagnostic Services: red cell immunohaematology (RCI) supports complex blood cross-matching and histocompatability and immunogenetics (H&I) provides matching for platelets, organs, tissues and stem cells to support transfusions and transplants.
- Stem Cell Service and Cord Blood Bank: stem cell transplants from adult donors or umbilical cord blood are collectively known as bone marrow transplants. These are used to treat blood cancers such as leukaemia. NHSBT manages the British Bone Marrow Registry (BBMR) and the NHS

[8] http://www.nhsbt.nhs.uk/what-we-do/

[9] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/443179/NHSBT_report_2014-15.pdf

Cord Blood Bank (NHS CBB), and provides specialist services related to the provision of haematopoietic stem cells (stem cells that can turn into blood cells) for the treatment of blood cancers.

- Cellular and Molecular Therapies Services provided in support of developing the next generation of stem cell therapies (regenerative medicine).
- Therapeutic Apheresis Services (TAS): separates a patient's blood into component parts, and selectively removes or treats components. This service is directly patient-facing.

35. In addition, the DTS Director is responsible for Customer Services across blood and DTS, the Patient Blood Management function, and NHSBT Emergency Planning and Business Continuity. Customer Services and Patient Blood Management is the way in which NHSBT seeks to support NHS Trusts in managing their blood use effectively.

36. As well as dividing DTS into five component parts, there is also a useful dichotomy to be drawn between work which directly supports the use of blood and organs (for example compatibility testing), and work which looks to make advances beyond improving the blood and organ supply chain (for example the development of new cellular or regenerative medicines). To be clear, this dichotomy is not about innovation per se - as NHSBT has proved successful at delivering innovative improvements across the range of services and products (for example in compatibility testing) - but about the proximity of the work in DTS to NHSBT's blood and organ functions.

37. For functions in DTS that directly support the blood and organ supply chains there is a compelling argument for them to continue; they are necessary for the clinical effectiveness of blood and blood products and organ donations. In addition, most of the products and services DTS offers are not monopoly services so it can be argued that there is demand for these services in the health and care system, and hospitals are choosing to procure them.

38. For the work that is further removed from these key supply chains the argument is less clear. This is partly because the research work related to regenerative and cellular medicines is comparatively embryonic, so the wider benefits are not yet known. However, there is significant potential to deliver benefits to patients and NHSBT is in a unique position to support this research (this is discussed further in the section on Strategic Leadership below). Members of the Challenge Group expressed a strong view that NHSBT could and should play a much more leading role in translational and regenerative medicines. The review team believes that NHSBT should continue to develop its role in this field, within the context of a clear strategic direction, and in this review have tried to balance this against the practical challenges that face NHSBT in the short and medium term. This is explored in more detail in both the Delivery Models section below and the Strategic Leadership section in the Stage Two report, and is a key consideration in the discussion on DTS delivery models.

39. In summary, **the review team recommends that the range of functions currently undertaken by NHSBT should continue**. **[Recommendation 1]**

4. Delivery model

40. This section of the report focuses on whether NHSBT, in its current form as a SpHA in England and Wales, is the most effective delivery model for the function described above.

Current status

41. It is Government policy that ALBs should only be set up, or remain in existence, where the ALB model can be clearly shown to be the most appropriate and cost-effective model for delivering the function in question.

42. In designing the scope of this review, DH has set a specific parameter that any changes to the delivery model should not disrupt the altruistic donation of blood, organs, tissue and stem cells by UK citizens. DH and Ministers recognise the importance of the relationship between citizens and the blood and ODT services as one of the key principles behind the successful operation of the blood and organ supply chains in England. For the same reason the review team did not consider any delivery models that introduced direct payment for organs.[10]

43. NHSBT is currently a SpHA. This is a form of ALB only found within the health and social care landscape. SpHAs are NHS bodies, established for handling large, national, operational activities orientated towards the NHS. This model differs from Foundation Trusts, which are intended to make a specific link between local communities and decisions about the provision of healthcare. SpHAs are established through secondary legislation, and Ministers retain a formal power of direction that ensures ultimate control of SpHAs' actions. There are currently four SpHAs, the others being the NHS Business Services Authority, NHS Litigation Authority, and the NHS Trust Development Authority (the latter now comes under the banner of NHS Improvement).

44. NHSBT is also a public corporation, as it is a "market body that derives more than 50% of its income from the sale of goods and services"[11]. The independent Office for National Statistics determines whether a body is classified as a public corporation. In most respects public corporations are similar to executive decision-making non-departmental public bodies. They have substantial day-to-day operating independence and should be seen as institutional units separate from their sponsor departments.

45. NHSBT sits in an unusual position in the health and care system: it is a member of DH's family of arm's length bodies (ALBs), but its role is highly operational compared with those of other DH ALBs. The closest parallels are the other SpHAs that interact directly with NHS organisations. In this context, the benefit of NHSBT's status as a SpHA status in part lies in its association with the NHS. This helps to convey to donors of blood, organs (and their next of kin), tissue and stem cells that NHSBT operates within the principles of the NHS, not seeking to make a profit from donations, and embodying an ethos of serving the public.

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[10] Not disrupting the altruistic donation of organs was the primary reason for this parameter. Charging for organs is prohibited under primary legislation - Human Tissue Act 2004 (Eng, Wales and NI) and Human Tissue (Scotland) Act 2006 (Scot).

[11] Classification is laid out in the Cabinet Office Guidance Public Bodies: A Guide for Departments, Chapter 2: Policy and characteristics of a Public Body

Barrier presented by SpHA status

46. As the review wishes to avoid any unnecessary disruption to donations of blood and organs, the starting point for the team's analysis was to consider what barriers NHSBT's current status presents.

47. SpHA status does provide a positive constraint in the sense that it creates an obligation and clear accountability for the safe, robust, and consistent supply of blood, stem cells, tissues and organs. From this perspective, the UK has an assurance that blood and organs will be supplied that could not be guaranteed by provision through the private sector. The consequence of this is that NHSBT will prioritise these functions directly related to the supply of blood and organs over, for example, the development of regenerative medicine.

48. NHSBT's ability to vary the blood price is limited by its status as a public body. NHSBT blood component prices are set nationally by the National Commissioning Group for Blood (NCGB). The prices that NHSBT proposes to the NCGB include a small amount for development work, but this is restricted. While this seems like a barrier created by SpHA status, in practice, restrictions on cross-subsidisation from blood to other parts of the business (see discussion below on Managing Public Money) are a more real concern for NHSBT.

49. In relation to organs, the largest issue is related to the funding model. At present there is a block subsidy provided by each of the four nations of the UK on a population basis to cover ODT activity, including NHSBT reimbursing hospitals for the costs associated with organ donation. This model is out of step with the wider commissioning approach in the NHS (especially in England where funding is provided by DH rather than NHS England). Additionally, it does not incentivise a growth in organ donations, as any spend above the agreed level of subsidy requires NHSBT to request extra funding from the health departments. It would be possible to move to a different commissioning model in England (the pros and cons of this argument are discussed later in this section), but fundamentally this could be achieved within the boundaries of a SpHA.

50. DTS is the area where the SpHA status appears potentially most restrictive. While blood and organs are monopolies in England and the UK respectively, DTS services compete in more open markets. Excluding the Customer Services and Patient Blood Management sub-unit, which largely concerns demand management, a high-level summary of the markets the DTS sub-business units operate in is as follows:

    - Tissue services: NHSBT is a supplier of skin, bone, arteries, heart valves, tendons, and corneas. Competition comes from a range of commercial and NHS suppliers but NHSBT focuses on niche areas and unmet NHS need, and has a substantial market share in these segments.
    - Diagnostic services: NHSBT services approximately 50% of the UK demand for histocompatability and immunogenetics (H&I) and the majority of demand for red cell immunohaematology (RCI), and has a growing market share. The remainder of the RCI and H&I markets mainly comprises individual hospital labs.
    - Stem Cell Services and the Cord Blood Bank: services in England and Wales. The vast majority of services are provided by NHSBT and Anthony Nolan. Delete Blood Cancer UK is part of the German-based DKMS, the world's leading stem cell donation organisation - over time this organisation has extended operations into the United States, Poland, Spain and now the UK.
    - Therapeutic Apheresis Services (blood treatment): NHSBT has around 40% UK market share; the other 60% mainly comprises individual hospital provision of such services.

51. Each of the strategies for the business units within DTS, agreed with DH, has an ambition to achieve a greater market share (ie seeking consolidation across the NHS) and to deliver economies of scale. The review team believes this is the right approach, as growth will enable greater innovation whereas standing still runs the risk of a decline in the service offering. In achieving growth, NHSBT needs to be able to operate with a commercial approach. To be clear, a commercial approach does not need to translate into a profit motive. Indeed, the review team does not believe that a model that looks to make a profit is appropriate. The main constraint for NHSBT is that it is unable to systematically use funds from one part of its business to support another part, as detailed in HM Treasury's "Managing Public Money" (MPM)[12]. In particular, NHSBT cannot use funds from the sales of blood to invest in DTS and vice versa. In practice, NHSBT does not aim to make a surplus from blood, and revises its blood prices each year in line with the cost recovery principle, but variations in demand, and progress against transformational projects with uncertain timing, mean that in-year surpluses can be generated and hence small amounts of investment in DTS can be possible. Under MPM, public corporations can borrow funds commercially provided that this is in their foundation documents, which is not the case for NHSBT.

52. There are other restrictions related to being a SpHA, for example delegated limits on spending such as communications, but NHSBT has not found these to be a serious constraint on its activities, with a few exceptions (in particular, communications spending). As such, while the review team notes these restrictions, it does not believe they are a compelling argument for a change of delivery model.

53. It is not consistent with wider Government policy to create a monopoly where there are existing or potential markets, so DTS services do need to compete where there is competition. However, the restraints on NHSBT mean that its ability to compete is limited and the potential benefits of a more open market are curtailed. Commercial decisions to attract additional contracts to expand market share, where the motivation is creating overall saving to the NHS through economies of scale and rolling out process improvements, would be consistent with the objectives for DTS that have been agreed.

Delivery model options

54. There are a range of potential delivery models that Cabinet Office guidance suggests review teams consider. A list is included in the table below, with a brief initial analysis of which options were considered and which discounted in this review. There was no strong consensus in the responses to the call for evidence about delivery models, with only a small number of respondents expressing a view. As such, for the delivery model options that were not discounted, the review team made an assessment based on the supplementary evidence gathered and drawing from Cabinet Office best practice.

[12] "Managing Public Money" can be accessed at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/454191/Managing_Public_Money_AA_v2_-jan15.pdf

Table 5	
Delivery option	**Initial Assessment**
Abolish	Consider – the review team considered whether NHSBT's functions were required.
Move out of central government	Consider – NHSBT is already outside central government. The review team considered whether other organisations in the health and care system offered appropriate delivery models.
Commercial model	Consider – the review team did consider models outside government that could operate on a not-for profit basis.
Bring in-house	Consider – the review team discounted bringing the services into the DH, partly because NHSBT provides services to all four nations in the UK and DH has an England-only remit, and partly as DH does not have the infrastructure to support a large operational delivery business.
Merger with another body	Consider – the review team gathered evidence on synergies with other organisations in the health and care system and wider government but found no organisation with sufficient synergies to explore further.
Less formal structure	Reject – the Cabinet Office Categories of Public Bodies list a number of options for less formal advisory bodies: Temporary Advisory Bodies, Task Forces and Reviews, Stakeholder Groups/Forums, Public Sector Working Groups and Internal Advisory Committees. All were rejected given the nature of NHSBT's current functions.
Delivery by a new Executive Agency	Consider – the review team gathered evidence on the appropriate level of independence for NHSBT
Continued delivery as a SpHA	Consider – the review team considered whether the NHSBT met one or more of the 'three tests' (see footnote 12 below).

55. To address the remaining options the review team considered Cabinet Office guidance on: the "three tests"[13] for NDPB status; and 'Triennial Reviews: Guidance on Reviews of non-Departmental Public Bodies[14]'.

[13] The Government's presumption is that if a public function is needed then it should be undertaken by a body that is democratically accountable at either national or local level. A body should only exist at arm's length from government if it meets one of 3 tests: it performs a technical function; its activities require political impartiality; and/or it needs to act independently to establish facts.

56. The review team focused on a range of specific delivery models within the categories above:

- Executive Non-Departmental Public Body[15] (ENDPB): the key feature of an ENDPB is that is has a role in the processes of national government, but is not a government department or part of one. As such, it operates to a greater or lesser extent at arm's length from ministers. In DH, Ministers do ultimately remain accountable for the health and care system and hold DH's ENDPBs to account for the delivery of their objectives.
- Moving outside the health and care system, primarily as a charity or mutual (as defined by the Cabinet Office)[16]. The key features of a 'mutual' are: it originated in, but has left the public sector (also known as 'spinning out'); it continues to deliver public services; and it has staff control embedded within the running of the organisation. An organisation could be both a mutual and a charity.
- Foundation Trust (FT): FTs are independent legal entities and have governance arrangements that make them accountable to their constituents (which in the case of FT hospitals means local people). FTs have a range of financial freedoms from central government and can raise capital from both the public and private sectors within borrowing limits. FTs do remain within the DH's consolidated accounts, and consequently are unable to aim to make a profit or loss.

57. The review team also considered whether a single organisation or multiple organisations would be best placed to deliver each of the functions described above.

58. For blood and organs the review team concluded that there was scope to resolve the barrier identified above within the existing delivery model. Mindful of the importance of minimising the risk to the levels of donations, SpHA status was regarded as the best viable option. The review team also considered as part of this conclusion that risks to the supply of blood are so fundamental to the operation of significant parts of the NHS that the state would be unable to transfer fully the risk to organisations outside the state sector.

59. The three tests were not sufficient to enable the review team to reach a definitive conclusion on the delivery model for DTS services. While the functions need to continue, there is a more obvious question about whether they need to do so within NHSBT. There is a clear benefit in having the expertise required to run DTS within the health and care system, as it can be deployed on behalf of Government both in the UK and internationally. Additionally, DTS currently provides many services and products that are low volume and it is unclear whether there would be significant interest from third parties in being engaged in running these business units. However, the products and services provided by DTS are services that are saleable, and structurally they are run as largely independent business units.

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[14] For more details on different types of public bodies, see the Cabinet Office Categories of Public Bodies: A Guide for Departments (Dec 2012), available at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/80075/Categories_of_public_bodies_Dec12.pdf

[15] Greater detail can be found in the Cabinet Office "Classification for Public Bodies" guidance, at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/80075/Categories_of_public_bodies_Dec12.pdf

[16] More information about 'mutuals' can be found at https://www.gov.uk/government/groups/mutuals-information-service

60. The review developed an additional framework to further consider whether DTS functions should continue within NHSBT or whether an alternative delivery model should be explored further:

61. *Promoting growth and innovation*: the government has a strategy to promote growth and innovation, in particular supporting small and medium sized enterprises. This is captured in the government document "Our Plan for Growth, Science and Innovation". There are two aspects to this strategy for NHSBT.

62. The first is whether there is more NHSBT should be doing to promote innovation and growth. NHSBT does have a unique infrastructure and capabilities that would allow it to support the development of cellular medicine and innovation in blood and ODT in the UK. Taking an organisational perspective, growing DTS services would support NHSBT to manage its business in the face of increasing declines in demand for blood. Additionally, a number of stakeholders have expressed the view that innovative medical and technological advances mean that growth is required simply for the business to 'stand still' as the wider environment changes. NHSBT's role as a leader in promoting growth and innovation is considered in more detail in the Strategic Leadership section of this report, but the review team's analysis does support increased growth of DTS.

63. The second aspect of 'promoting growth and innovation' is whether NHSBT, as a public sector organisation, is creating any barriers to other organisations delivering services. There are other providers for tissue services (apart from skin), diagnostic services, stem cell services and Therapeutic Apheresis Services (TAS). In most cases these providers are private companies. While there does not appear to be a wide range of suppliers for some services and products, there is evidence that hospitals do exercise choices about where they purchase DTS services. For the work undertaken in DTS the review team has noted that there are a range of products provided by the DTS sub-business units that are essential for a small number of patients. The quality of these products needs to be maintained but they are unlikely, in many cases, to be scalable. While the review team does not believe that growing DTS would currently present a barrier to other organisations delivering services, it does believe that successful future growth within NHSBT may change the benefits of alternative delivery models and the potential for DTS to promote wider growth in the economy.

64. *Use of government funds*: there is direct funding from the DH for collecting cord blood, but other DTS services are delivered on a cost recovery basis, with prices set by the National Commissioning Group for Blood. As such, the decision for hospitals to purchase DTS products and services does not have a direct impact on public finances. In fact, the review team believes that the growth of DTS could potentially create a virtuous economic circle. With public corporation status, products and services that are not a monopoly should be sold at a market rate: in the case of DTS, this could position NHSBT to have greater capacity to invest in and support ever better technologies and research. If realised in combination with NHSBT's work with the clinical community, DTS could be a greater component of NHSBT's future functions in bringing improvements to patients that reflect the strategic direction set by the government in relation to developing and, crucially, adopting leading medical technologies.

65. One specific point does emerge from the use of government fund criterion, which relates to stem cells. The DH has provided additional programme funding over six years to support improvements in the delivery of stem cell transplantation services. A five-year strategy was completed in March 2015, designed to deliver more efficient and effective services and resulting in better patient care. Discussions are currently being held between DH and delivery partners on future priorities. NHSBT

and the Anthony Nolan charity work together in the field of cord blood. While the five-year strategy has delivered streamlining in many areas - especially the bone marrow register - an overlap remains in terms of infrastructure; the physical cord banks in particular were highlighted to the review team. **The review team recommends that DH takes advantage of the opportunity presented by the end of the five-year strategy for stem cell transplantation to engage with NHSBT and Anthony Nolan and agree a way forward that addresses any infrastructure duplication and plays to the respective strengths of these two organisations in supporting DH objectives and priorities. [Recommendation 2]**

66. *Impact on wider organisation delivery:* would NHSBT's other objectives be more effectively delivered if NHSBT undertook fewer functions under DTS? There is little evidence to support this idea and NHSBT is focused on and highly aware of its statutory responsibilities to ensure the safe and effective supply of organs and blood. NHSBT is able to use its existing 'in house' services to support blood and transplant, many of which it would otherwise have to buy in order to maintain delivery in its other business areas. In practice, if DTS were to become a significantly bigger part of NHSBT's business the risk is likely to be to DTS services, as NHSBT has statutory responsibilities in relation to blood and ODT, which must remain its senior team's priority.

67. *Relationships with health authorities*: NHSBT has a remit that, with regard to ODT, covers all nations of the UK. As such, any change in status would need to enable NHSBT to continue to provide services across Wales, Scotland, Northern Ireland and England. While there was no particularly strong attachment to SpHA status across the health departments, there was a clear message that any change to an alternative type of public body should be justified and be able to create a demonstrable improvement in service levels.

68. Based on these criteria the review team believes that the DTS functions should continue within NHSBT, and that **NHSBT should remain a SpHA in England and Wales [Recommendation 3]**. In addition, the review team believes that NHSBT should continue to grow DTS, and **recommends that NHSBT adopts a stretch target for growth in DTS [Recommendation 4]**. This target should be set by the NHSBT board and designed to capture the long-term trajectory for DTS, rather than immediately attainable short-term performance targets.

69. SpHA status does create some limitations on the tools that NHSBT can deploy to grow the DTS aspect of its business; in particular the safe supply of blood and organs must take precedence over other activities due to the statutory nature of those activities. As a public body NHSBT is also limited in terms of its capacity to take on debt to fund growth in the way a private sector company would be able to. As such, looking forward, NHSBT must remain mindful of the potential of alternative delivery models as a mechanism to promote both innovation and growth. Greater growth and the potential to market products and services internationally, for example, may open greater opportunities for joint venture partners who could bring additional investment and management capacity without compromising NHSBT's statutory obligations in relation to blood and ODT. While the review team is not making a specific recommendation at the time of writing this report, the team does note that both DH and the Cabinet Office are able to offer ongoing support in respect of alternative delivery models as DTS develops within NHSBT.

Organ donation funding model

70. The discussion on the consideration of status mentions the current funding model for organ donation. There are two key features of the current block subsidy arrangement that call its effectiveness into question. The first is the fact it is anomalous in the sense that DH acts as the commissioner in

England, when NHS England was specifically established to fulfil this function. The second is that while growth in organ donation (either through more organs or better use of the same number of organs) is regarded as being a positive trend, the funding structure does not incentivise this. This argument is compounded by concerns around the affordability of the Organ 2020 Strategy, especially in relation to investment in technology.

71. The review team believes that in England there is an argument to move the commissioning role currently played by DH to NHS England, but it is not clear cut. Such a move would align funding for donation with funding for transplantation and would mirror the transfer of the commissioning role in Wales from Welsh Government to Welsh Health Specialised Commissioning planned for 2016-17. However, this cannot be a simple transfer of functions to NHS England, and there are associated risks. These risks need to be addressed by NHSBT and DH more fully before a decision on the structure of ODT funding should be taken. In terms of achieving NHSBT's Organ 2020 Strategy, there are no current examples of NHS England providing ring-fenced funding through specialised commissioning. As such, ODT would need to be prioritised alongside the other business cases that NHS England is managing, against a background of significant overspends in specialised commissioning based on figures in NHS England's consolidated accounts. While it would be possible to provide some safeguards to transfer ownership of the strategy to NHS England, part of the benefit of the transfer of commissioning would be to enable NHS England to make priorities about the most effective use of its total funding. As such, simply transferring funding at this point would provide no greater guarantee of delivery of the organ strategy than the current funding arrangement.

72. Additionally, funding flows in relation to ODT can be complicated and difficult to track. Currently NHSBT reimburses hospitals for costs associated with organ donation but testing costs, for example H&I testing, are covered by an in-house pathology laboratory in some hospitals and the reimbursement does not reflect the true cost. NHSBT, supported by the DH sponsor team and finance colleagues, will need to ensure that there is a clear proposal for NHS England's responsibilities. Otherwise there is potential for misunderstanding of what funding should be transferred.

73. The review team also notes that an ODT commissioning model would need to be designed to ensure that NHSBT was able to deliver organs to all four nations. While it would be feasible for NHSBT to receive a block subsidy in relation to three nations (Northern Ireland, Scotland and Wales), NHSBT is developing a model that lays out fixed and variable costs that could offer a compromise which is acceptable to all health authorities. NHSBT is uniquely placed to manage this co-ordination, and the review team believes this work should be completed before any transfer of functions occurs.

74. In summary, the **review team recommends that NHSBT, working with DH and NHS England, and the Devolved Administrations, undertakes a specific project to develop a proposal on the future of ODT funding in England**. In developing this proposal NHSBT will need to engage with DH and the Devolved Administrations to ensure that any future funding model enables the effective management of ODT across the whole of the UK. **[Recommendation 5]**

75. Moving the responsibility for commissioning from DH to NHS England would make decisions more 'arm's length' from DH and Ministers in England. The review team notes that such a change in accountability should be agreed by Ministers.

Stage One Conclusion

76. The review team concludes that all of the functions identified in this section of the report should continue, and NHSBT should deliver them as a Special Health Authority.

77. The recommendations are designed to build on the strengths of NHSBT, and also help to clarify some of the complexities that it faces, for example funding for ODT. The Stage One review also makes the observations that as NHSBT grows and adapts, for example expanding DTS and managing the declining demand for blood, the recommendations related to delivery models should be revisited. In terms of setting the scene for any future discussions on delivery models, from the preparatory stage of the review right through the evidence collection phase, the importance of the altruistic nature of donation (from individuals or their next of kin) was a common theme. An altruistic approach to donations is strongly supported by international organisations as the most sustainable and cost effective model. The review team believes this factor should be a central feature of any future discussions about delivery models for NHSBT.

78. A summary of the recommendations made in the Stage One report can be found on pages seven and eight.

Stage Two Report

79. The Stage Two report explores whether NHSBT adheres to principles of good governance, and considers performance and potential efficiencies.

5. Governance and relationships

Governance of NHSBT and Capability

80. Good corporate governance is central to the effective and efficient running of all public bodies. NHSBT broadly complies with the requirements of good governance set out in the Cabinet Office Corporate governance in central government departments: Code of Good Practice. A full 'comply or explain' analysis against the principles of good corporate governance, defined by the Cabinet Office, is provided at Annex H.

Principles of Good Corporate Governance

Good corporate governance is central to the effective operation of all public bodies. As part of the review process, therefore, as an Arm's Length Body of the Department of Health, the governance arrangements in place in NHSBT should be reviewed. As a minimum, the controls, processes and safeguards in place in the ALB should be assessed against the principles and policies set out in this guidance. These reflect best practice in the public and private sectors and, in particular, draw from the principles and approach set out in the ***Corporate Governance in Central Government Departments: Code of Good Practice*.**

81. Against a background of strong internal governance, this section of the report focuses on areas of particular note or where recommendations are required in light of the review team's in-depth analysis.

82. Senior colleagues in the Department of Health and stakeholders largely felt that the NHSBT Board provided strong leadership, especially in relation to the management of blood and ODT. Although there were no consistent themes that emerged from the evidence, there were a small number of potential improvements in Board composition that were suggested, and where bringing in expertise to the executive team, or challenge from non-executives, could strengthen NHSBT's position.

- Black, Asian and Minority Ethnic (BAME): NHSBT and DH recognise that there are no BAME members on the Board either as an executives or non-executives. This fact is especially stark given that BAME communities are some of those least likely to donate blood and organs. A more diverse Board could help strengthen NHSBT's work to increase donations.
- Specialist in regenerative medicines: if NHSBT is to develop its role in regenerative medicine it is important that it is able to translate its infrastructure and capabilities into the needs of the private sector and academic institutions that are developing therapies based on regenerative medicine.

83. While recognising many of these skills are present below board level in the organisation, the **review team recommends that NHSBT (for executive appointments) and DH Ministers (for non-executive appointments) should seek to use any upcoming appointments to consider strengthening specific skills and areas of knowledge on the Board.** NHSBT needs to ensure

that the Board maintains an appropriate range of skills, but additional expertise in the areas highlighted would increase the level of challenge to the executive team on these key aspects of NHSBT's business. **[Recommendation 6]**

84. One respondent highlighted that the NHSBT Board does not have a member who is engaged on a working basis with making clinical decisions about organ donations (although there is a transplant surgeon amongst the non-executives). At the root of this observation is the fact that the number of potential donors who become actual donors is relatively low, which is a recognised challenge for ODT. However, NHSBT has access to expertise through a network of 'clinical leads' that provides regular and up-to-date advice to the director of ODT. The review team notes that such advice is important, but does not believe NHSBT would garner sufficient benefit from bringing these skills onto the Board to merit inclusion in Recommendation 6.

85. The review team received a number of comments on NHSBT's policies on the criteria for donation of blood and organs, in particular regarding men who have sex with men. There is a wider point related to the safety behind this evidence, which is that NHSBT follows the advice of the independent Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO), which looks at blood safety. NHSBT is compliant with, and bases its working policies on, the advice of SaBTO, as well as relevant EU Directives and UK legislation[17]. Whilst it is beyond the scope of this review to consider the criteria for those who can't donate blood, and other safety issues, the representations received by the review team have been passed on to the relevant policy officials in DH.

86. NHSBT is unusual across DH ALBs in that its Board members are required to pass the 'fit and proper persons test'. This arises from the fact that NHSBT is registered with the Care Quality Commission (CQC) as a service provider (for example for TAS) under the Health and Social Care Act 2008 (regulated activities) Regulations 2014. NHSBT has effective processes in place for complying with this requirement.

87. NHSBT is also unusual in its status as a Special Health Authority for England and Wales. This means that NHSBT must comply with the directions in place in both nations. In evidence given to the review team, Welsh officials considered there was scope to introduce more systematic communications, as there were a small number of examples of them being engaged late, or feeling unsighted, on areas of work (in particular in relation to DTS). However, both officials in the England and Wales health departments were broadly content with the existing arrangements. **The review team recommends that NHSBT and Welsh Government officials review information flow to assure themselves that they are systematically sighted on all key areas of work and upcoming developments.** This is intended as an improvement to the existing system rather than a fundamental change. **[Recommendation 7]**

88. NHSBT's remit does cover all four of the UK nations for ODT, and there is a sub-committee of the NHSBT Board (the National Administrations Committee) that considers issues related to the Devolved Administrations. Wales, Scotland, and Northern Ireland officials agreed that this was a useful structure, but felt unclear on the remit and the sub-committee. The current terms of reference of the sub-committee are at Annex I. The review team believes that the advisory function of this sub-

[17] See Table 7 below for further details on the relevant legislation.

committee could be a useful governance tool, and it is discussed in more detail in 'Relationships with the four health departments', below.

89. The final governance point relates to the running of the NHSBT Board. The Board holds public meetings and publishes its papers, which is good practice that is designed to improve transparency. To improve transparency still further **the review team recommends that NHSBT amends the Board pages on the NHSBT website to indicate which executive directors are full members of the Board and which are non-voting members. [Recommendation 8]**

90. The Board is also a key mechanism for engaging with the four UK health departments and the public more generally. The Board has a practice of asking two non-executive directors to review each paper prior to the meeting. While this is an effective challenge it does mean that a significant proportion of that challenge is conducted prior to discussion and decision-taking at Board meetings. The review team accepted the rationale for this approach, but considers NHSBT needs to be mindful of the need to manage the potential for this way of working to be perceived to bypass full Board decision making.

Relationship with the four health departments

91. In terms of service delivery, structures, and accountabilities, NHSBT has an individual relationship with each of the four health departments in the UK. DH operates a full sponsorship model, following the standard principles and processes used for all its major arm's length bodies; this includes the standard accountability structures, which are based on NHSBT's status as a Special Health Authority. NHSBT is also a Special Health Authority covering Wales, although the range of services it provides in Wales are smaller than those it provides in England, given the move to a separate all-Wales blood service in May 2016. Welsh health officials have lower levels of contact with NHSBT but reported that they were broadly content with the arrangements in place (some potential marginal improvements are discussed below). Scotland and Northern Ireland cannot hold NHSBT to account as a Special Health Authority but there are income generation agreements and associated governance arrangements in place. These arrangements mean that NHSBT is held to account differently by each of the four nations, even where they are providing very similar services, but importantly, the arrangements are seen to work and no practical examples of accountability breakdowns under the current structure were identified.

92. One of the features of devolved powers is that each Devolved Administration makes its own policy decisions, to best serve the needs of the nation it represents and the political mandate it has. This is an important principle, which underpins the value of devolution, but through the lens of a UK-wide body providing services to all four nations, it can create additional burdens.

93. A recent example is that as of December 2015 Wales operates an 'opt-out', rather than 'opt-in', system of organ donation. At the time of writing this report there were also live private members bills in Scotland and Northern Ireland proposing a move to opt-out schemes similar, but not identical, to that set out in the forthcoming Welsh legislation. At a practical level NHSBT has adapted the organ donor register to manage the change in Wales. However, the nature of devolved powers means that NHSBT could end up effectively running four different systems within the organ donor register, at a time when the register is taking on increased importance as a list of those people who explicitly do not wish to be organ donors. While this is a specific example of policy divergence across the UK, the underlying point is that NHSBT needs to ensure it is able to understand areas of divergence and

factor any resultant additional costs into its business planning (such as the need for NHSBT as a public body operating in Wales to comply with Welsh Language Act requirements). Building on the discussion about the Board committee in the governance section of this report **the review team recommends that the National Administrations Committee of the NHSBT Board works with government officials from each of the four nations, as well as the respective national commissioners, to identify and advise the NHSBT Board on future policy divergences.** Such an approach will strengthen the NHSBT's non-executive's ability to advise on and challenge the executive team's work in relation to the Devolved Administrations. **[Recommendation 9]**

94. As well as the organ donor register, the transition to the Welsh Blood Service covering all of Wales brings about a further change in NHSBT's relationship with the health department in Wales, and potentially the commissioners of healthcare in Wales. While there is a specific point about NHSBT and the Welsh Blood Service being clear on their relationship, there is also a wider point concerning the relationship of the four blood services across the UK: at present the blood services do co-ordinate and provide support and assistance to each other as required. This often materialises largely as NHSBT providing support to Scotland and Northern Ireland, simply because of the relative scale of NHSBT compared with the other blood services. As the services are likely to become increasingly different in their approaches **the review team recommends that the relationship and expectations of each service in terms of contingency planning should be formalised, to guarantee that blood provision across the whole of the UK will be maintained in the event of a crisis in one of more of the four services. [Recommendation 10]**

95. All four of the health departments were least clear on the parameters of the DTS component of NHSBT's business, in particular in relation to regenerative medicines. While DTS is a comparatively small part of the NHSBT's business and is still developing, the review team considers that NHSBT should continue the work it has already started to help health departments to understand DTS-related work, including enabling officials to promote NHSBT and make the appropriate links across government. Taking a recent example, NHSBT could potentially have been engaged earlier with the Accelerated Access Review in England.

Relationship with others in the health and care system

96. NHSBT, NHS England, and health commissioners in each of the Devolved Administrations have responsibility for different components of organ supply, and while there is some co-ordination related to the commissioning of organ transplantation, their interactions are otherwise comparatively limited. The key question about this relationship is the funding of organ donations, which is discussed in the 'Delivery model' section of this report. NHSBT does engage with other health ALBs, for example it has provided significant input to NICE guidance, and co-operates fully with the relevant regulators (NHSBT's relationship with regulators is discussed in more detail in the Regulation section below).

97. NHSBT blood product prices are set nationally by the National Commissioning Group for Blood. However, decisions about the use of blood and DTS services are taken at a local level by individual hospitals. This model means that NHSBT is operating in a fragmented market with every hospital having the scope to make its own decisions about procurement. Undoubtedly traction with hospitals is one of the areas where NHSBT encounters barriers, most notably in the DTS markets, although they do have an extensive network of interactions with individual institutions (including the blood supply chain, NHSBT/NHS joint consultants, and laboratories). As there are markets for almost all DTS services, albeit each with their own specific characteristics, it is possible to construct an argument that the level of provision of service currently seen represents the preference of the market.

98. NHSBT does face two apparent obstacles. The first is that it must seek departmental approval for any novel and contentious activities, or significant changes in the scale of their operations of funding of initiatives. This means, for example, partnerships with private sector organisations would require DH or even ministerial approval. While there are processes to achieve this, it does reduce the agility of the organisation, for example if NHSBT wanted to pursue a joint venture in relation to DTS services similar to the joint venture model Guys and Thomas' have developed with SERCO[18]. The second is that where services are produced in house by hospitals (for example through pathology labs) the comparative prices of a product or services can be hard to assess, which can make it difficult for NHSBT to demonstrate that they are offering better value for money, this is considered in more detail in relation to the Carter review in the 'Efficiency' section below.

99. Given that DTS services are sold in a more competitive market than blood, NHSBT does practice prices differentiation, although still within the constraints of cost pricing. As discussed in the 'Delivery model' section above, NHSBT is unable to use funds from one part of its business to subsidise another. This has an impact on the investments NHSBT can make into DTS services including, for example, the size of the team it maintains to promote these services to hospitals. The team is currently only seven people. Although it is not a perfect analogy, as NHSBT does have extensive knowledge and networks into the NHS, NHSBT is running DTS as a stand-alone business rather than as part of a larger business. NHSBT's current strategy is not to compete with larger private sector organisations, but to look for niche unmet needs. However, NHSBT does not have the same options for expansion as an organisation of an equivalent size not governed by HM Treasury rules (Managing Public Money).

100. While the greatest barriers in terms of relationships with the wide health and care system relate to DTS, the break in the blood supply chain (once blood is in hospitals) creates a challenge for NHSBT. NHSBT's role in driving the effective use of blood is discussed elsewhere in the report, but the review team notes that NHSBT is developing a vendor management inventory. The rationale behind this approach is that it reduces stock holding at hospital level and wastage, and raises standards and consistency in blood transfusion clinical practice. While recognising that decisions, and risks, rightly sit with the clinician in relation to the use of blood, the review team believes that minimising the impact of breaks in the blood supply chain is the right direction of travel for NHSBT.

101. NHSBT is also developing a proposal for integrated transfusion services (ITS), in partnership with hospitals and the transfusion community. The intention is to: combine expertise across these stakeholders; better utilise technology; hold an appropriate buffer stock; and lead innovation. Innovations can be achieve through training, regulatory compliance, technological innovation and better blood transfusion. While this approach will not be mandatory for hospitals, greater standardisation and economies of scale are in line with the approach being suggested by the Carter Review. Additionally, advice from the European Blood Alliance is that efficiency, patient safety, and engagement from donors are improved the fewer breaks there are in the vein to vein supply chain.

[18] Viapath is a joint venture between Guy's and St. Thomas' and King's College Hospital NHS Foundation Trusts and Serco plc. Majority owned by its NHS partners, Viapath provides pathology services to over 400 NHS trusts, GP practices and private health clinics.

102. NHSBT has a range of established networks into the clinical community. This includes jointly employing clinicians with trusts, the National Blood Transfusion Committee (supported by regional transfusion committees), and Regional Collaboratives and local donation committees in relation to OTD. The challenge group noted that NHSBT could look wider than it currently does in terms of the clinical practice that it influences, in particular the group discussed the impact that better treatment of anaemia could have on patient demand. The review team has drawn this to the attention of NHSBT as an areas for future consideration which should not be lost but notes that the focus of their work in the short term, in relation to demand management for blood, should be on increasing the traction they have with clinicians and hospitals.

103. The final point in relation to interactions with the wide health and care system relates to NHSBT's branding. While there is a strong brand for blood and organ donation this is not always used. For example the Board papers, which are designed to enhance transparency and are published, are not branded. There is also an issue that NHSBT's brand does not fully convey its work in DTS. This issue was discussed with executives and non-executives during the review process and is recognised within NHSBT. The review team appreciates the risk of over complicating messages to the NHSBT's wide range of stakeholder and customers, and the risk of losing the strong brand that does exist, but **recommends that NHSBT continues to work to create greater and more consistent branding for its DTS products and services, within the context of maintaining and developing the existing strong brand for blood and ODT**. **[Recommendation 11]**

Relationship with donors and patients

104. Engagement with donors for blood, living donors for ODT, and potential donors and next of kin for ODT and the relevant DTS services, is key to NHSBT's work. NHSBT has a range of mechanisms, such as targeted communications, to promote donations from target groups as well as the SNOD network already discussed. NHSBT clearly understand the importance of this work, and they have a communications strategy which looks across all areas of their business.

105. The review did receive evidence from a small number of blood donors, which was largely positive. Even where there were specific issues raised, donors felt that the complaints process was effective. One theme that did emerge was the number of walk in sessions had been reduced, which conflicts with the perception that some donors held that they have a right to donate. This is discussed in more detail in the 'Efficiency' section in the report.

106. In relation to blood, NHSBT is increasingly sophisticated in focusing communications to address shortage of specific blood types, while in relation to ODT the focus is on promotion of the organ donor register. In cases where specific groups can be appropriately targeted NHSBT uses local or even 'micro-local' campaigns. The most prominent example of where campaigns can be targeted is BAME communities. This links back to recommendation 6, where specific expertise on the Board could be effectively deployed. However, there is a clear challenge NHSBT faces in that there is no way to know the blood type of an individual until they have come forward to donate, so there are practical limitations on targeting communications. In relation to ODT, NHSBT is conscious of the risks posed by the comparatively low number of potential donors who become actual donors (i.e. achieving next of kin agreement for donations). This is recognised in the ODT strategy.

107. Much of the work NHSBT has undertaken in relation to blood and ODT is regarded as highly innovative by DH and other DH ALBs. For example, NHSBT work closely with local communities as

well as running national campaigns. For example, the 'missing type' campaign in June 2015 which secured more than 1000 partners, Transplant Week, and the Rugby World Cup 2015 'Bleed for England' campaign. NHSBT has made significant advances in its use of digital technology, for example making it easier for blood donors to make appointments. Although this is just one of the channels NHSBT used, they do have a strong social media presence, with much campaign activity led from social media.

108. NHSBT does face the same challenges as other ALBs, in that there is not a guaranteed funding flow for marketing, as this is dependent on government wide restrictions at any given time.

109. NHSBT has a direct interaction with patients through therapeutic apheresis. They also have a range of indirect impacts beyond the provision of supplies to hospitals. In particular, NHSBT manages the structure and process that determines the rules underpinning the allocation of organs.

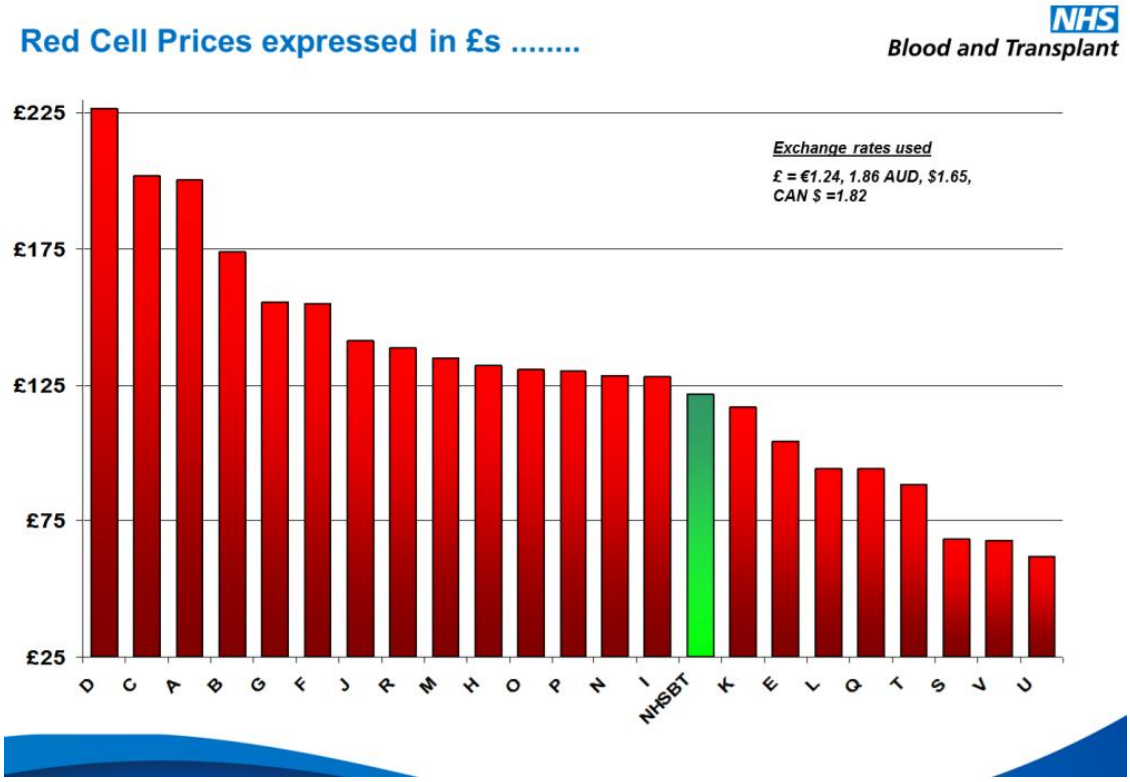
Operational performance

110. The context over the next two years for NHSBT operational performance is that the organisation will be undertaking a major IT development and change programme. This should bring performance improvements, but there is also a significant aspect of this work that quite rightly is about resilience. The NHSBT Board has plans in place, which have clear ownership, and a developing set of KPIs. There is also a structured approach to the management of the programme, which will be critical in mitigating risks to NHSBT delivery. However, the review team does want to highlight explicitly the scale of the challenge faced by NHSBT in delivering its programme of IT change, and the level of associated risk.

111. Evidence gathered in the course of the review confirms NHSBT has done a lot of work in recent years to reduce an over capacity and related costs within the blood supply chain. This has been passed on to hospitals. For example, a year on year drop in blood price from 2008-15 (from £140 per unit of red blood cells to £120 per unit of red blood cells), whilst maintaining consistency, quality and safety of supply, and in the context of falling demand (9.5% reduction in last three years). As part of that NHSBT has also started to introduce LEAN processes across its activities. Stakeholders recognised and applauded NHSBT's strong performance to drive down the blood price and thereby pass on cost savings to the wider NHS.

112. International benchmarking data, including but not limited to the European Blood Alliance, confirms this is a good performance when compared with blood services in other countries. For example, Figure 2 below illustrates NHSBT's red cell blood price is now in the top third for low prices when compared with 22 other countries in Europe and North America. Red cells, platelets and plasma related components are derived as co-products from whole blood. Platelets are also specifically sourced through apheresis collection. The ratio of whole blood supply to apheresis supply differs between blood services across the world. As a result there is high variability of pricing of individual blood components between blood services, which makes international comparisons difficult.

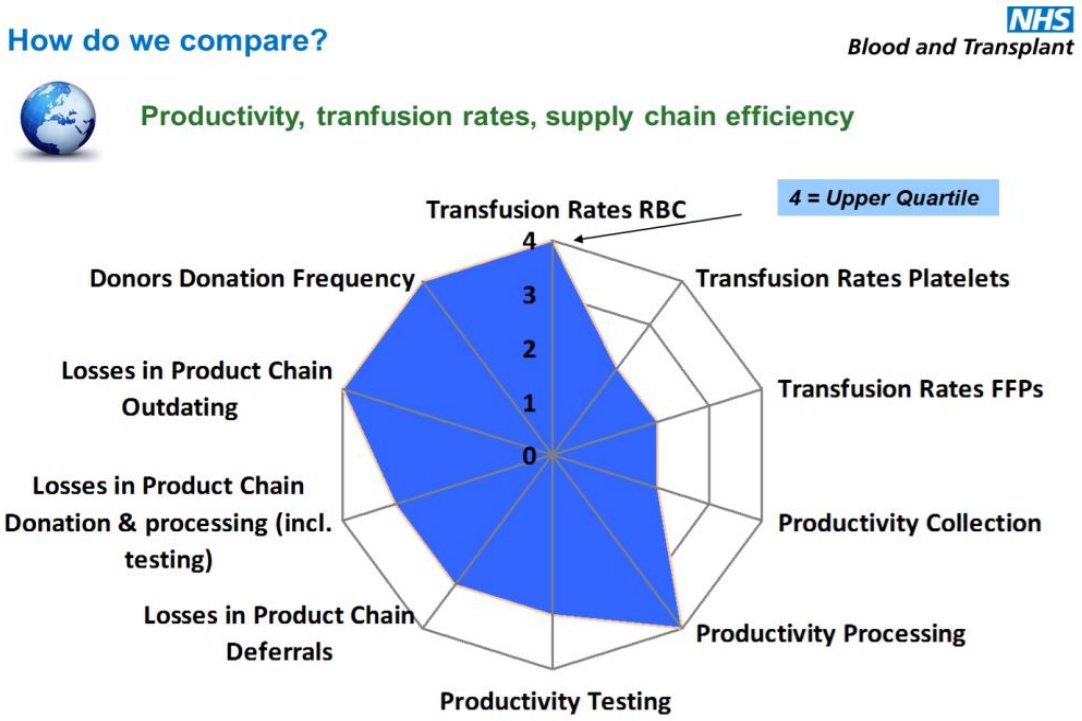
Figure 2



Source: Data based on NHSBT derived intelligence of the prices charged by other blood services, either provided directly to NHSBT or from publically available sources.

113. International benchmarking data is also helping NHSBT to decide how best to target future activity to improve further performance on blood collection and distribution. For example, NHSBT has identified the main area for future efficiencies is in terms of blood collection arrangements and transfusion rates, discussed in more detail in the 'Efficiency' section of this report. This is illustrated in Figure 3 below, which shows how NHSBT's current performance in those areas is only in the second quartile when compared with blood services in other countries.

Figure 3



Source: NHSBT, based on European Blood Alliance benchmarking data

114. Turning to Organ Donation and Transplantation, the call for evidence highlighted good performance in the five year period following the Organ Taskforce report *Organs for Transplant* (January 2008), with a 50% increase in the number of deceased donors and a 30.5% increase in transplants. The call for evidence also revealed the range of stakeholders across the UK, and international benchmarking data, used to help inform the nature and scale of the targets contained in NHSBT's Organ 2020 Strategy[19].

115. However, a number of respondents from the organ donation and transplantation community expressed concern about the fall in deceased donors in 2014-15. The fragmented nature of the ODT clinical pathway outlined in the Stage One report above was a common theme cited by many of them in terms of risks to sustaining improved performance by NHSBT on organ donation.

116. The review team noted that NHSBT has work in hand at the time of the review to help identify the key factors causing the fall in donors, and the action required to reverse that trend. This forms part of a wider series of initiatives to improve both the supply and management of organs up to the point of transplantation. Latest figures from NHSBT show that the targets contained in the Organ 2020 Strategy for 2015-16 were met in relation to deceased donors, and marginally below target but part of a significant year on year improvement in relation to deceased transplants – see table 6 below.

[19] Taking Organ Transplantation to 2020 – a detailed strategy. Copy available at: http://www.nhsbt.nhs.uk/to2020/get-the-strategy/

The review team notes the NHSBT Strategic Plan 2015-20 and the Taking Organ Donation to 2020 Detailed Strategy both flag there are further "technological developments, pilot initiatives and other programmes which are capable of bringing improvements"[20]. These would require a new business case for separate funding, and remain the subject of ongoing discussion and prioritisation between NHSBT and the four health departments.

Table 6: Deceased Donors and Deceased Transplants – Actual v Plan

Year	Deceased Donors		Deceased Transplants	
	Actual	**Plan**	**Actual**	**Plan**
2013-14	1320	1272	3508	3216
2014-15	1282	1439	3340	3756
2015-16*	1364	1365	3527	3694

* 15/16 figures for DBD and DCD donors as at 8 June 2016. Final figures will be published in the Annual Activity Report.

117. Although the five sub-business units of DTS (tissue services, diagnostic services, stem cell services/the cord blood bank, cellular and molecular therapies, and therapeutic apheresis services (TAS)), do not have a monopoly position in the respective markets within which they operate, and collectively comprise £50m (12%) of NHSBT annual turnover of £425m, they do represent significant players in those markets, and have done so over a number of years. For example, NHSBT diagnostic services has around 50% UK market share in H&I testing, and TAS has around 40% UK market share, with the balance of market share in both markets comprising individual hospitals. The specialised nature of the work associated with the DTS sub-business units, both in terms of laboratory infrastructure and personnel to support delivery, means that the nature and scale of the markets within which they operate change relatively slowly.

118. The review team noted from the evidence that there are ongoing risks associated with income generation across the DTS sub-business units, in particular in tissue services, and that the NHSBT Board has work in hand to monitor and manage those risks based on reports from the Executive Team.

Regulatory Landscape

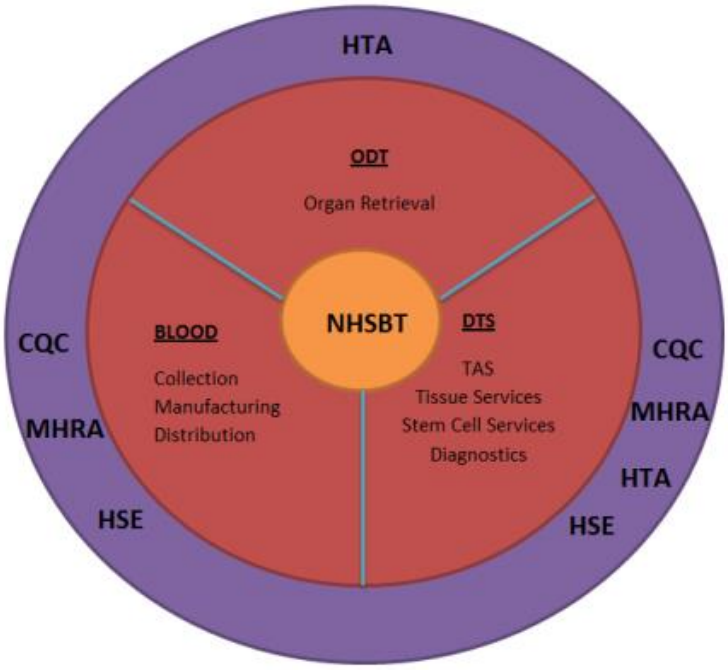
119. The nature and range of NHSBT's business activities, detailed in the diagram at Figure 4 below, mean that NHSBT needs to engage with a number of different regulators and licensing regimes, principally three other DH Arm's Length Bodies (ALB's) - the Care Quality Commission (CQC), the Human Tissue Authority (HTA), and the Medicines and Healthcare products Regulatory Agency (MHRA).

[20] Page 8, Taking Organ Donation to 2020

120. CQC is primarily concerned with NHSBT's engagement with patients (Therapeutic Apheresis Services) and blood donors (Blood Collection centres), whilst MHRA is focused on NHSBT's work activity associated with the collection, processing, testing and distribution of blood and blood components. MHRA also regulates NHSBT's manufacture and distribution of medicines (Specials and Investigational Medicinal Products as part of DTS Tissue Services and Stem Cell Services). HTA has a direct interest in NHSBT's organ donation/retrieval activity as well as the work of certain DTS sub-business units (most notably tissue services, stem cell donation and transplant, and the cord blood bank).

121. Figure 4 below also recognises that NHSBT interacts with the Health and Safety Executive (HSE) given its responsibilities as an employer under the Health and Safety and Work etc. Act 1974, and supporting regulations associated with the control of dangerous substances in the workplace.

Figure 4: The nature and range of NHSBT's business activities, and the associated regulators



122. The table on pages 41 and 42 (Table 7) summarises the main elements of the regulatory framework within which the different NHSBT business units operate, plus associated licensing regimes. The table also outlines the principal Accreditation Bodies of which NHSBT is a member.

Table 7: Current Regulatory Framework within which NHSBT operates				
NHSBT Functional Areas	**(1) Blood Distribution Blood Manufacturing**	**(2) Cord Blood Tissue Services Stem Cell Services Organ Retrieval**	**(3) Blood Collection Therapeutic Apheresis Services (TAS)**	**(4) All - workplace health & safety**
Regulators	Medicines and Healthcare products Regulatory Authority (MHRA)	Human Tissue Authority (HTA)	Care Quality Commission (CQC) MHRA (re: Blood Collection)	Health and Safety Executive (HSE)
Principal associated primary legislation		Human Tissue Act 2004 Human Tissue (Scotland) Act 2006	Health and Social Care Act 2008	Health and Safety at Work etc. Act 1974
Principal associated secondary legislation (Note: This list is not exhaustive)	Blood Safety and Quality Regulations 2005 as amended[21] The Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 and associated regulations[22] The Human Medicines Regulations 2012[23]	Human Tissue Quality and Safety Regulations 2007 as amended[24] The Quality and Safety of Organs Intended for Transplantation Regulations 2012 as amended[25] Advanced Therapy Medicinal Products (ATMP) Regulations[26]	H&SCA2008 (Regulated Activities) Regulations 2014[27] (Note: Blood Collection - see also regulations in column 1.	Control of Substances Hazardous to Health Regulations 2002[28] Health and Safety (Sharp Instruments in Healthcare) Regulations 2013[29]

[21] Further details at: http://www.transfusionguidelines.org/regulations

[22] Further details at: http://www.hra.nhs.uk/resources/before-you-apply/types-of-study/clinical-trials-of-investigational-medicinal-products/

[23] Further details at: http://www.legislation.gov.uk/uksi/2012/1916/contents/made

[24] Further details at: https://www.hta.gov.uk/faq/how-was-eu-tissues-and-cells-directive-eutcd-brought-uk-law

[25] Further details at: https://www.hta.gov.uk/policies/organ-donation-and-transplantation-regulations-and-framework

[26] Further details at: https://www.hta.gov.uk/policies/policy-advanced-therapy-medicinal-products-atmp-regulation-and-quality-and-safety

[27] Further details at: http://www.cqc.org.uk/content/regulations-service-providers-and-managers

Table 7: Regulatory Framework within which NHSBT operates (contd)				
NHSBT Functional Areas	**(1) Blood Distribution Blood Manufacturing**	**(2) Cord Blood Tissue Services Stem Cell Services Organ Retrieval**	**(3) Blood Collection Therapeutic Apheresis Services (TAS)**	**(4) All - workplace health & safety**
Licences	Blood Establishment Authorisation (BEA) Investigational Medicinal Products Licence (IMP) Specials Medicines Licence (SML) Wholesale Dealers Licence (WDL)	Research Licence for removal and storage of tissue under Human Tissue Act 2004 Human Application Licences for Tissues/Stem Cells/Cord Blood Procurement Licence for Human Organs	Site registrations	
Accreditation Bodies	European Federation for Immunogenetics (EFI) – H&I accreditation organisation Clinical Pathology Accreditation (CPA[30]) – diagnostic labs (RCI, NBL, NTMRL, H&I) Underwriters Laboratories (UL) – notified body for reagent manufacture	Joint Accreditation ICT Europe and EBMT (JACIE) – blood & bone marrow accreditation programme Foundation Accreditation for Cellular Therapy (FACT-NETCORD)–cord bloodbank World Marrow Donor Association (WMDA) – stem cell registry accreditation		
NHSBT compliance: Single Quality Management System, underpinned by Good Manufacturing Practice				

[28] Further details at: http://www.hse.gov.uk/coshh/

[29] Further details at: http://www.hse.gov.uk/pubns/hsis7.htm

[30] CPA is now part of United Kingdom Accreditation Service (UKAS)

123. Figure 4 and Table 7 illustrate the range and complexity of the regulatory framework. The review team found strong evidence of robust arrangements in NHSBT for ensuring compliance with relevant regulations and licensing arrangements, principally through a single quality management system managed by a dedicated Quality Assurance team in NHSBT and underpinned by good manufacturing practice in all relevant NHSBT sub-business units. The review team also noted NHSBT's recent performance in terms of non-compliance being limited to two items of major non-conformance in 2015-16, with evidence of a systematic approach to lesson learning from those incidents to manage the risk of repetition.

124. Despite NHSBT needing to engage regularly with four different statutory regulators, the review team found there was good common understanding of the respective roles and responsibilities of each of the regulators both within NHSBT and by each of the regulators. There was some evidence of collaboration and information sharing between regulators, although NHSBT cited examples of lack of coordination in terms of timing of inspection activity which had created burdens on the NHSBT Quality Inspection team at particular points in time. For example, NHSBT was subject to more than 16 different inspections by statutory regulators across its estate in any one calendar year, with seven taking place in one month alone.

125. From an analysis of the evidence gathered in the course of the review on the current regulatory landscape, the review team noted that NHSBT was being asked for the same background information by three of the statutory regulators (CQC, MHRA, and HTA) and by the CPA (Clinical Pathology Accreditation - in relation to the accreditation of NHSBT's diagnostic laboratories), within a short period of time, for example about the NHSBT single quality management system. This represents an unnecessary regulatory burden for NHSBT as a regulated organisation.

126. **The review team recommends that the Department of Health coordinates arrangements to support the Care Quality Commission (CQC), Medicines and Healthcare Products Regulatory Agency (MHRA), Human Tissue Authority (HTA) and other health and care system regulators, plus the United Kingdom Accreditation Service (UKAS), to provide an even more joined-up regulatory framework, including to identify ways to improve their current information sharing arrangements** and thereby reduce unnecessary repeated information requests being placed on NHSBT which is regulated/accredited by them. Such improved communications might also reduce the need or frequency of inspection activity by one or more of these statutory regulators, and help in terms of identifying mutually convenient timing for the inspections that still need to take place. **[Recommendation 12]**

6. Strategic Leadership

Strategic leadership and alignment with wider Government Strategy

127. The 'Function' section of this report briefly touches upon NHSBT's role in the wider strategic landscape. While many of NHSBT's functions have a very immediate necessity to them, which may change but will not stop in the medium or even long term, the following paragraphs consider the possible choices that NHSBT can make about the future trajectory of its business and potentially where NHSBT can make the greatest impact in coming years. In this context, this section of the report considers translational medicine and regenerative medicines.

128. To frame this discussion it is useful to bear in mind the wider context with respect to key government objectives. The Government has laid out its intention to: promote economic growth, especially through SMEs; bring innovative medical products to patients faster and more effectively through the Accelerated Access Review (AAR); and to meet a £22bn efficiency challenge in the NHS. There are a number of components to this work but the central cross-cutting strategies are the Five Year Forward View (FYFV) and the Carter Review. These strategies set the challenge of finding new ways for working, using standardisation to create contractual efficiency, and leveraging benefits from best practice. Efficiency and savings to the wider health and care system are discussed elsewhere in the review, so this section focuses on innovation through to delivery to patients.

129. NHSBT has a range of unique characteristics amongst the organisations in the UK health and care system. These characteristics point to opportunities to provide leadership in supporting others in the context of the wider government objectives, but also to drive forward changes and innovation in NHSBT's own actions.

130. The largely 'single supplier' status of NHSBT in relation to blood and organs means that it is uniquely placed in the UK to exploit integration of genomics, data, and assessment of patient outcomes. The NHSBT challenge group, which included clinical experts in these fields, believe that these same factors also open the door for NHSBT be a leader in the development of prognostic markers, personalised therapy and accelerated assessment of novel therapies on a global basis.

131. At the time of this report work on translation, regenerative and cellular medicine is a comparatively small aspect of NHSBT's overall portfolio, which NHSBT is required to prioritise within very real resource constraints. At a very practical level for example, NHSBT has a significant programme of IT development that is a priority in terms of improving not just efficiency but also capability and capacity to ensure a continued high quality of service for patients. The review team further recognises work in these fields is still embryonic in NHSBT. NHSBT also needs to act in a way which maintains and promotes altruistic donations. A key part of this has traditionally been using cost recovery pricing and not seeking any profit. Additionally, the review team notes that NHSBT has limited internal funding for research, and part of its uniqueness is access to a national size sample of materials and data, which is dependent on its SpHA status. These are real constraints in terms of the levels of funding NHSBT has to invest both in internal development work and in supporting partners.

132. The factors outlined above, however, did not preclude the review team from exploring the potential for the development of products and services that bring significant patient benefits and create growth and innovation in the wider UK economy.

133. NHSBT has a published Research and Development Strategy[31] taking the organisation from 2015 to 2020. The review team is confident that NHSBT has the capacity, capability, and associated governance, to produce and support high quality research. The question raised by the challenge group, and other stakeholders, is whether NHSBT should drive the agenda on translational and regenerative medicines far more than at present? The programme of work presented in the NHSBT R&D strategy selects a range of existing techniques to be translated for Blood and ODT, as well as containing some novel components. However, the strategy does not focus on using NHSBT's expertise to identify and promote innovative and novel research between now and 2020. In short, NHSBT is currently working as a facilitator, but could choose to assume a greater leadership role in relation to regenerative medicine.

134. While there are parameters within which NHSBT must operate, the review team believes there are possibilities for NHSBT to promote the various aspects of the wider strategic picture laid out above. Building on much existing work and relationships, this review believes that NHSBT could increase its leverage by:

- Using its position as a national Special Health Authority, and key partner for SMEs and universities, to lead debates on what transformative technologies should be pulled through, and define priorities
- Using its traction within the system to support the NHS as an excellent place to conduct clinical trials (e.g. access to big data, developing relationships between industry, academia and NHS organisations)
- Applying its unique infrastructure and capabilities to support the development of innovative and transformative therapies – both in its own products and services, and through working with others
- Supporting the collection of good quality data along each part of the pathway (e.g. marketing authorisation, NICE evaluation, local adoption). This would need to be co-ordinated with the action plan resulting from the Accelerated Access Review
- Raising awareness of novel trial design for example through existing networks of clinicians, or through early adoption in their own services offering (NHSBT has strong examples of improving their services through the use of innovation, for example genotype matching in compatibility testing)
- Advising how different players in the system can support uptake in relation to NHSBT's specific areas of expertise (e.g. work with their university partners and Cell Therapy Catapult)
- Using its position in the system to identify barriers to uptake of innovative products and ways of overcoming them, with particular reference to the clinical aspects of product development
- Using its logistics capability within the UK to support the effective delivery of products to patients in the UK

135. Most fundamentally, NHSBT needs to exploit all of these opportunities in a way that uses its own, and its partners', expertise and data to identify and drive forward key areas of innovation which will make the greatest difference to patients.

[31] http://www.nhsbt.nhs.uk/research-and-development/pdf/strategic_plan_june_2015.pdf

136. NHSBT has already built strong relationships with university partners in relation to R&D, but much of the research NHSBT is engaging in is early stage, so they also have limited experience of successfully bringing products to market. This creates a question about ownership of new products as they are brought to the point of marketability. As this is a theoretical question at present, the review team has not explored it in significant detail. But NHSBT will need to develop an approach to future ownership of these products. This may include a process that enables spin-off organisations to be created when appropriate, and appropriate Intellectual Property and profit sharing mechanisms to be put in place. In this work NHSBT should consider not only how best to deliver improvements to patients in the UK, but also how to internationalise products most effectively, generating growth for the UK and potentially income for NHSBT which can be re-invested in the business. This is an important point that should not be neglected as NHSBT continue to develop its role in translation and regenerative medicines.

137. At the heart of achieving NHSBT's full potential is the creation of a strategy that supports NHSBT to drive innovation rather than responding to a range of projects that are presented to them. This would complement NHSBT's existing research strategy, which is a strong foundation for future developments. As such, **the review team recommends that NHSBT should develop clear priorities for its role in the development of translation medicine, and gene and cell diagnostics and therapies in healthcare, and actively seek partnerships with relevant organisations to promote this work. [Recommendation 13].** In making this recommendation the review team understand NHSBT will already be delivering a number of important priorities in the near future, but they should use these opportunities to build in the direction of taking a greater leadership role in these new, developing, and potentially hugely significant areas of medicine.

7. Efficiency

Income and Expenditure

138. The extract below from the published NHS Blood and Transplant Report and Accounts provides a summary of revenue and expenditure for 2014-15.

Account of NHS Blood and Transplant at 31 March 2015

2. Segmental Reporting and Reconciliation of net operating expenditure to grant in aid

For the year 1 April 2014 to 31 March 2015	Total	Blood Components (incl R&D)	Diagnostics	Tissues	Stem Cells Unit	Therapeutic Apheresis Services	Organ Donation & Transplant
Revenue	**£000s**	**£000s**	**£000s**	**£000s**	**£000s**	**£000s**	**£000s**
Provision of Products and Services	343,222	289,413	25,047	8,063	11,690	6,097	2,912
Income from Scottish Parliament	5,670	-	-	-	-	-	5,670
Income from National Assembly for Wales	3,250	-	-	-	-	-	3,250
Income from Northern Ireland Assembly	1,941	-	-	-	-	-	1,941
Other Income	12,084	8,505	368	-	2,870	192	149
Revenue Grant In Aid	63,048	2,074	-	-	4,373	-	56,601
Total Revenue	**429,215**	**299,992**	**25,415**	**8,063**	**18,933**	**6,289**	**70,523**
Expenditure							
Variable Costs	(63,109)	(47,413)	(4,634)	(1,122)	(3,409)	(1,898)	(4,633)
Direct Costs	(215,134)	(124,007)	(13,720)	(4,798)	(10,396)	(2,240)	(59,973)
Direct Support Costs	(87,828)	(70,749)	(4,011)	(2,260)	(3,023)	(746)	(7,039)
Movement in value of stocks	(1,823)	(1,828)	-	5	-	-	-
Other Support Costs	(45,663)	(37,172)	(3,634)	(1,328)	(2,735)	(794)	-
Total Expenditure	**(413,557)**	**(281,169)**	**(25,999)**	**(9,503)**	**(19,563)**	**(5,678)**	**(71,645)**
Operating surplus for the financial period	**15,658**	**18,823**	**(584)**	**(1,440)**	**(630)**	**611**	**(1,122)**
Add : Notional cost of capital included in expenditure above	6,703						
Less : Revenue grant in aid	(63,048)						
Less : Capital charges paid to the Department of Health	(16,267)						
Net Expenditure	**(56,954)**						

Organisational and System wide efficiency

139. There are two aspects to efficiency which this report considers. These are: the operational efficiency of NHSBT itself, which looks at how efficiently the organisation is run; and system wide efficiency, which reviews whether NHSBT can create efficiencies for the NHS more widely. In many cases these two areas are interconnected, but the sub-division is useful to highlight that in a cost recovery pricing model for blood and DTS, internal efficiencies translate directly into savings for the NHS.

Blood

140. The largest part of NHSBT's cost base is the collection, manufacturing, and distribution of blood. NHSBT has already created significant efficiencies in blood production, which is reflected in the falling blood price. The current challenge for NHSBT in blood will be to maintain and reduce the comparatively low price for blood as demand continues to fall and it makes significant investments in

replacing out of date IT hardware and applications. Any additional reductions in blood prices will be realised in the NHS as the consumer, not by DH.

141. NHSBT is completing a programme of site consolidation for blood processing, which will create further efficiencies. The limiting factor on site consolidation is NHSBT's (and DH's) risk appetite in respect to the minimum geographical footprint required to ensure the continuity of supply – both in terms of how quickly hospitals can receive specific products and whether distribution can be maintained in case of severe weather or transport disruption. A small number of respondents in the call for evidence did express concern about the reduction in sites in terms of maintaining robust contingency planning arrangements, but the DH has received assurance from NHSBT that a full risk assessment has been conducted and this was integral in the Board's decision making. Importantly, the number of stock holding points are not being reduced, and NHSBT believe that this is a key determinant in the speed of supply.

142. As savings from site consolidation are limited NHSBT is considering other areas for efficiencies. NHSBT has already demonstrated that it is effective at using LEAN techniques to deliver efficiency savings in relation to blood processing, and these techniques will continue to be rolled out across the business. Anecdotally, NHSBT is significantly ahead of other ALBs and NHS bodies in its use of LEAN, but behind leaders in the private sector. This certainly correlates with the evidence from other triennial reviews and from the feedback from non-executives who work in processing industries. Furthermore, the NHSBT HR function has proved effective in supporting NHSBT business areas, including the management of business change associated with site consolidation. In the context of the efficiencies DH and its ALB need to find to meet the commitments of the 2015 Spending Review **the review team recommends, that DH should consider NHSBT's expertise in LEAN and HR as a potential shared services for other ALBs. [Recommendation 14]**The review team does recognise, that further potential benefits of LEAN could be achieved with additional investment to support NHSBT to achieve industry leading standards, which should be considered further if there is scope to deliver benefits more widely across the ALB landscape.

143. Looking across the blood related benchmarks, the largest efficiency that NHSBT could gain in terms of its operations would be to increase its productivity in blood collection. Improvements in this area require a number of initiatives including a greater focus on using fixed blood donation centres and operating a small number of larger mobile collection venues. While direct comparisons are difficult with other countries, there is a maximum efficiency of approximately £18m. NHSBT have been moving in this direction in England, but the context is important and should be understood. A theme did emerge in the evidence that some stakeholders perceive there to be a 'right to donate', which is very likely to be challenged if NHSBT operates less frequently in remote parts of the country. On the basis that donations are altruistic, any action that alienated donors could be damaging to the blood supply. While some stakeholders did express this opinion, NHSBT is facing the challenge of reducing demand for blood, so to maintain the current price per unit NHSBT has to continue to find efficiencies. Although there are risks **the review team recommends that NHSBT's blood collection modernisation strategy be accelerated, but monitored through a phased plan, with key decision points reflecting analysis of the impact on donor behaviours. [Recommendation 15]**

144. The second area where the international benchmarks suggest there are significant efficiencies is demand management, where NHSBT support clinicians to minimise their use of blood. This is currently in line with worldwide trends, so in fact is linked to better patient care. If NHSBT were to reach the level of red cells issued per 1,000 of population in the most advanced western nation the maximum saving would be approximately £13m. As discussed, demand reductions do need to be balanced with a sustainable business model so the price of blood does not increase. However, the review team believes that there is an opportunity through the Carter Review to work with the pilot hospitals to actively reduce blood usage. **The review team recommends that work to actively reduce blood use is included in the implementation of the Model Hospital proposed by Lord Carter's review of operational efficiency [Recommendations 16].** Even if this results in the price of blood remaining static, there are clinical benefits to patients.

145. The other tool that NHSBT could use to drive down demand for certain blood products is differential pricing, based on analysis of how effectively key blood products are used. Using pricing to alter behaviours would help to drive down demand. The National Commissioning Group on Blood has already agreed in principle to a variable price for blood, to drive behaviours, in particular to drive down the use of O negative blood where other products might be more appropriate. **The review team recommends that NHSBT and DH undertakes analysis to establish whether there is scope to drive behavioural change through alternative pricing structures for blood** [**Recommendation 17].** The review team proposes that this initial analysis is targeted at establishing whether there is scope to create benefits through blood pricing, looking at whether hospitals are using appropriate levels of O negative blood. If this work suggests there are potential benefits, consideration should be given to a more in-depth study of the elasticity of blood pricing. This work should support NHSBT in deciding whether to include the capability for differential pricing in its programme of IT changes.

ODT

146. Due to the infrequent and unpredictable nature of organ donation activity, NHSBT uses a call off contract with a third party supply to arrange road transport of specialist nurses and/or the donated organ from donating hospitals to transplant centres. In certain circumstances, for example if the location of the donating hospital and/or transplant centre make road transport impractical or too time consuming, NHSBT arranges air transport, again using a third party supplier. NHSBT's own transport fleet is generally not used for ODT activity, as it is primarily committed to delivering transport services in support of regular, high volume transport of blood and DTS products. The recent NORS review made a recommendation about current NHSBT arrangements for using third party suppliers in relation to ODT transport, and the review team has not revisited that recommendation.

DTS

147. DTS is comparatively small, so even large proportional savings will not be significant financial sums. Like blood, DTS services are sold on a cost recovery basis so that the NHS would benefit from efficiencies rather than DH. In this context efficiencies would be created if DTS was able to deliver economies of scale

148. NHSBT believe that there are potential system savings, should their market share increase across DTS services. However, comparisons are difficult as the cost of DTS services provided by hospitals in house are often rolled into the wider costs of, for example, pathology labs. The Carter Review would provide an opportunity for NHSBT to demonstrate there is a strong business case for using their services on financial grounds, or understand the difference in costs based on service levels on a more solid data base. **The review team recommends that the Productivity and Efficiency Programme supports NHSBT to access appropriate data from providers to build a more effective business case, with specific case studies, to understand the levels of efficiency that hospitals could achieve,** if their services were provided by NHSBT's DTS sub-business units. **[Recommendation 18]** This will, in effect, help NHSBT and hospitals to identify the opportunity costs related to DTS services.

Stage Two Conclusions

149. Stage two of this report paints a positive picture of an organisation that takes seriously both the needs of donors and patients, plus efficiency for the tax payer. NHSBT is able to point to a range of successes in relation to all of these areas. NHSBT also recognises the challenges that it faces and areas for potential improvements.

150. The stage one review considered a range of challenges that NHSBT is managing through its current functions and delivery model. In the stage two report, the Strategic Leadership section considers what additional opportunities there are for NHSBT to play an even more crucial role in the heath and care system through creating a stronger leadership role in relation to translational and regenerative medicines. The review team strongly encourages NHSBT and DH to consider how best to prepare for these roles in the future when making investment and setting priority decisions in the short term.

151. The other sections of the stage two report make a short series of recommendations that are intended to support NHSBT develop further its interactions across the health and care system, and support the ongoing delivery of efficiencies.

152. A summary of recommendations from the stage two report can be found on pages eight and nine.

Annexes

Annex A: core review team, project board, and challenge group membership, and review costs

Review team

Role	Name
Senior Review Sponsor	Sir Keith Pearson
Lead Reviewer	Adam McMordie
Assistant Reviewer	Paul McCormack

Project Board

Role	Name
Chair	Sir Keith Pearson
Member: NHSBT Director of Finance	Rob Bradburn
Member: DH Sponsor Team for NHSBT	Ted Webb
Member: Welsh Government representative	Caroline Lewis
Member: TR review team	Adam McMordie
Secretary	Paul McCormack

Challenge Group*

Organisation	Name
Chair	Adam McMordie
Consultant Anaesthetist, Royal Stoke University Hospital, University Hospitals of North Midlands NHS Trust	Dr Charles Baker
Centre for Clinical Haematology, University Hospitals Birmingham NHS Foundation Trust	Professor Charles Craddock
Professor of Diversity in Public Health & Director, Institute for Health Research, University of Bedfordshire	Professor Gurch Randhawa

*The Challenge Group comprised people with the necessary skills and experience to provide constructive challenge on the work of the review team, but was not a representative cross section of all those individuals/organisations with an interest in the work of NHSBT.

Review Costs

The direct cost of the review is estimated to be £60,000. This comprises the DH resources (total salary costs for review team members), and travel and subsistence for the review team.

No additional fees were paid to members of the NHSBT, the Welsh Government, the SRS, or the challenge group.

The indirect costs of the time of the SRS, NHSBT Chair and other non-Executives, the NHSBT Executive Team, Cabinet Office officials, Welsh Government officials, and officials in the other Devolved Administrations, in engaging with the review team are not included in this calculation.

Annex B: Initial Written Ministerial Statement of 25 June 2015

HEALTH

Arm's Length Bodies (Triennial Reviews)

The Parliamentary Under-Secretary of State for Health (Jane Ellison): I am today announcing the start of the triennial reviews of the Committee on Mutagenicity of Chemicals in Food, Consumer Products and the Environment, the Human Fertilisation and Embryology Authority, the Human Tissue Authority, and NHS Blood and Transplant.

The triennial review programme ensures that all Government Departments review their non-departmental public bodies on a regular basis. In order to ensure that the Department of Health is operating as an effective system steward and can be assured of all the bodies it is responsible for, it has extended the programme of reviews over the period 2014-17 to include all of its arm's length bodies.

The reviews are conducted in two stages. The first stage will examine the continuing need for the function and whether the organisation's form, including operating at arm's length from Government, remains appropriate. If the outcome of this stage is that delivery should continue, the second stage of the review will assess whether the bodies are operating efficiently and in line with the recognised principles of good corporate governance.

[HCWS57]

Annex C: Organisations given advance written notification of the Call for Evidence

Advisory Committee on the Safety of Blood (SaBTO)	Kidney Kids Scotland
Afro Caribbean Leukaemia Trust	Kids Kidney Research
Anthony Nolan	Kidney Research UK
Brake	Leukaemia Care
British Blood Transfusion Society	Leukaemia and Lymphoma Research
British Kidney Patient's Association (BKPA)	Lifeblood
British Heart Foundation	Live Life then Give Life
British Transplantation Society	Local Government Association
British Society of Haematology	Macmillan Cancer Support
British Association for Tissue Banking	Marie Curie
British Liver Trust	Medical Research Council (MRC)
British Lung Foundation	Myeloma UK
British Society for Gene and Cell Therapy	National Kidney Federation
British Society for Genetic Medicine	NHS Clinical Commissioners (NHSCC)
Cardiff and Vale Health Board Renal Transplant Unit	National BAME Transplant Alliance (NBTA)
Cell Therapy Catapult	National Blood Transfusion Committee
Children's Liver Disease Foundation	National Commissioning Group for Blood members (NCGB)
Cystic Fibrosis Trust	NHS Confederation
Cure Leukaemia	RNIB
Delete Blood Cancer UK	Rugby League Foundation
Innovate UK	Royal College of Pathologists
Diabetes UK	Sarcoma
Donor Family Network	Sickle Cell Society
Flesh and Blood.org (KORE)	Steve Prescott Foundation
Foundation Trusts Network	Teenage Cancer Trust
Genomics UK	Transplant Sport UK
Give a Kidney	UK Stem Cell Strategic Oversight Committee
Gift of Living Donation	UK Thalassemia Society
Guide Dogs	UKTPP Network
Healthcare UK	Welsh Health Specialised Services Committee/Welsh Renal Clinical Network
Intensive Care Society	Welsh Blood Service
Keratoconus Self Help and Support Group	

British Medical Association Royal College of Nursing Unison Unite the union Alliance of Blood Operators European Blood Alliance Human Tissue Authority NHS Business Services Authority Public Health England Care Quality Commission Health and Safety Executive National Institute of Health and Care Excellence Medicines and Healthcare products Regulatory Authority Health Research Authority NHS England Office of Life Sciences Department of Health, Social Services and Public Safety, Northern Ireland Scottish Government Welsh Government	

Annex D: Public Call for Evidence Questions

Function

This section seeks to assess whether there is a continuing need for the functions of NHSBT and, if this need exists, to assess whether the current form is the most effective and efficient way of delivering these functions.

Question 1: Is there an ongoing need for the current function of NHSBT?

Yes/No/Don't know [please delete as appropriate]

Please give reasons for your answer

Question 2: Which NHSBT functions, if any, could be stopped? What would be the consequences of doing so?

Please give reasons for your answer

Question 3: Is there an overlap with the functions performed by any other UK body?

Yes/No/Don't know [please delete as appropriate]

Please give reasons for your answer

Question 4: Does the current composition of the NHSBT Board membership best support NHSBT's functions?

Yes/No/Don't know [please delete as appropriate]

Please give reasons for your answer

Question 5: Are there any functions delivered elsewhere in the health and care system that could be more efficiently delivered by NHSBT?

Yes/No/Don't know [please delete as appropriate]

Please give reasons for your answer

Form

This section seeks to assess the appropriate organisational form of NHSBT.

Question 6: Are there barriers to the delivery of NHSBT's objectives related to its status as a Special Health Authority?

Yes/No/Don't know [please delete as appropriate]

Please give reasons for your answer

Question 7: Is the current funding model the best way to ensure the efficient provision of NHSBT's services?

Yes/No/Don't know [please delete as appropriate]

Please give reasons for your answer

Performance and Efficiency

This section seeks views on how well NHSBT performs in delivering its services.

Question 8: Are there other organisations which could be used as a benchmark for the performance of NHSBT?

Yes/No/Don't know [please delete as appropriate]

Please give reasons for your answer

Question 9: Are there ways in which NHSBT's assets and expertise could be exploited to improve system wide efficiency, deliver greater innovation in the health and care sector or to drive economic growth? For example, in the development of digital diagnostics, regenerative medicine, cell therapy, genomics, and stratified medicine in the UK?

Yes/No [please delete as appropriate]

Please give reasons for your answer

Question 10: Are there barriers to improved collaboration between NHSBT and others in the health and care system? For example, in terms of diagnostic and therapeutic services, and integrated transfusion services.

Yes/No/Don't know [please delete as appropriate]

Please give reasons for your answer

Question 11: Does the current regulatory framework governing NHSBT operations conform to better regulation principles (proportionate; accountable; consistent; transparent; and, targeted on the greatest risks), or are there potential improvements/efficiencies that can be made?

Yes/No/Don't know [please delete as appropriate]

Please give reasons for your answer

Question 12: Does NHSBT have the necessary capability and capacity in terms of horizon scanning and strategic planning to respond effectively to changing demands, a changing regulatory/policy environment, and/or emerging innovative medicines and medical technologies?

Yes/No/Don't know [please delete as appropriate]

Please give reasons for your answer

Question 13: How well does NHSBT drive innovation and what more could be done? Examples might include developing innovative types of product, exploiting stratified medicine, new diagnostics, and digital health technologies, and facilitating use of such products in the wider health and care system.

Please give reasons for your answer

Question 14: How easy is it for donors and service users to engage with NHSBT about the products and services that NHSBT offers?

Very easy/Easy/Average/Difficult/Very difficult [please delete as appropriate]

Please give reasons for your answer

Governance

This section explores the governance of NHSBT and whether there is good governance and effective accountability structures in place.

Question 15: Is there an appropriate level of transparency in the NHSBT's end to end processes and decision making?

Yes/No/Don't know [please delete as appropriate]

Please give reasons for your answer

Other Comments:

Are there any other issues or evidence you think the review team should take into account?

Annex E: List of Respondents to the Call for Evidence

No.	Organisation/Individual
1	Individual
2	Technidata Medical Software
3	The Queen Elizabeth Hospital King's Lynn NHS Foundation Trust
4	Individual
5	Individual
6	Individual
7	Sandwell & West Birmingham NHS trust
8	Individual
9	British Cardiovascular Society
10	Individual
11	Western Sussex NHS Hospitals Foundation Trust
12	Spire Pathology
13	Royal Brompton & Harefield NHS Foundation Trust
14	Derby Teaching Hospitals NHS Foundation Trust
15	Chesterfield Royal Hospital
16	Individual
17	Barts Health NHS Trust/British Cardiac Society
18	Royal College of Pathologists
19	Roche Diagnostics
20	UK Donation Ethics Committee

No.	Organisation/Individual
21	British Heart Foundation
22	Great Ormond Street Hospital for Children NHS Foundation Trust
23	British Blood Transfusion Society
24	Individual
25	National LGB&T Partnership
26	Freedom to Donate
27	Professional Standards Authority

Annex F: List of Review Team bilaterals with key stakeholders

(NB. Face to face meetings or teleconferences unless otherwise stated)

No.	Date	Name	Organisation
1	3 July 2015	David Brown	Biological Agents Unit, HSE
2	23 July & 3 Aug 2015	Ted Webb Triona Norman Kay Ellis	DH Sponsor Team for NHSBT
3	23 July 2015	Dr Rowena Jecock	Head of Infectious Diseases Policy, DH
4	27 July 2015	Colin Pavelin	Head of Genetics and Rare Disease Policy, DH
5	27 July 2015	Gareth Brown Pamela Niven Kathy Collins	Scottish Executive Scottish Executive National Commissioning Services Scotland
6	28 July 2015	Wayne Lawley Heather O'Shea Ian Trenholm Stuart Penny Ben Hume Dr Andrew Hadley John Kirkwood Dr Lorna Williamson	NHSBT (Site visit to Filton)
7	29 July	Ian Hudson	Chief Executive, MHRA
8	29 July 2015	Alastair Campbell	Deputy Director, Secondary Care Services, DHSSPSNI (Northern Ireland)
9	30 July & 1 Sept 2015	John Pattullo	NHSBT Chair

No.	Date	Name	Organisation
10	30 July 2015	Keith Rigg	NHSBT NED
11	31 July 2015	Dr Ian McKay	Infectious Diseases Policy, DH
12	4 Aug 2015	Andrew Blakeman	NHSBT NED (& Chair of Governance & Audit Committee)
13	6 Aug 2015	Gilles Follea	Former Executive Director, European Blood Alliance
14	6 Aug 2015 (NB. Via correspondence)	Dr Felicity Harvey	DH Senior Departmental Sponsor for NHSBT
15	12 Aug & 7 Sept 2015	Caroline Lewis Jenny Thorne Pat Vernon Dr Chris Jones	Welsh Government
16	14 Aug 2015	Roy Griffins	NHSBT NED (& Chair of Trust Fund Committee)
17	19 Aug 2015	Kari Aranko	Executive Director, European Blood Alliance
18	24 Aug 2015	Prof John Forsythe	Chair, Safety Advisory Committee on Blood, Tissues and Organs (SaBTO)
19	24 Aug 2015	Dr Jonathan Wallis	Chair, National Blood Transfusion Committee (NBTC)
20	25 Aug 2015	Rob Bradburn	NHSBT Finance Director
21	25 Aug 2015	Ian Trenholm	NHSBT CEO
22	25 Aug 2015	Clive Ronaldson	NHSBT Blood Supply Director
23	25 Aug 2015	Huw Williams	NHSBT Diagnostic & Therapeutic Services Director
24	25 Aug 2015	Sally Johnson	NHSBT Organ Donation & Transplantation Director

No.	Date	Name	Organisation
25	27 Aug 2015	Jeremy Monroe	NHSBT NED (& Chair of Transplant Policy Review Committee)
26	27 Aug 2015	Leonie Austin	NHSBT Communications Director
27	27 Aug 2015	Ian Bateman	NHSBT Assoc Director of Quality
28	1 Sept 2015	Prof Mark Bellamy	Professor of Critical Care, University of Leeds, and Past President of the Intensive Care Society
29	1 Sept 2015	Aaron Powell	NHSBT Chief Digital Officer
30	7 Sept 2015	David Evans	NHSBT Workforce Director
31	8 Sept 2015	Simon Butler	Anthony Nolan
32	22 Sept 2015 (NB. In addition, via correspondence in Aug/Sept 2015)	Dr Lorna Williamson	NHSBT Medical & Research Director

Annex G: Call for Evidence Responses – Quantitative Analysis

Call for Evidence Question **(Majority response shown in bold)**	**Yes**	**No**	**Don't know**	**Not Answered**	**Total**
1. Is there an ongoing need for the current functions of NHSBT? Please give reasons for your answer	**26** **(96%)**	0 (0%)	0 (0%)	1 (4%)	27 (100%)
2. Which NHSBT functions, if any, could be stopped? What would be the consequences of doing so?	n/a (free text box only) [**17** responses received to this question.]			10 (37%)	27 (100%)
3. Is there an overlap with the functions performed by any other UK body?	6 (22%)	**9 (33%)**	6 (22%)	6 (22%)	27 (100%)
4. Are there barriers to the delivery of NHSBT's objectives related to its status as a Special Health Authority?	5 (18.5%)	5 (18.5%)	**9** **(33%)**	8 (30%)	27 (100%)
5. Is the current funding model the best way to ensure the efficient provision of NHSBT's services? Please give reasons for your answer.	3 (11%)	4 (15%)	**12** **(44%)**	8 (30%)	27 (100%)
6. Does the current composition of the NHSBT Board best support NHSBT's functions?	4 (15%)	2 (7%)	**14** **(52%)**	7 (26%)	27 (100%)

Annex G (contd)

Call for Evidence Question **(Majority response shown in bold)**	**Yes**	**No**	**Don't know**	**Not Answered**	**Total**
7. Are there any functions delivered elsewhere in the health and care system that could be more efficiently delivered by NHSBT? Please give reasons for your answer.	**9 (33%)**	4 (15%)	6 (22%)	8 (30%)	27 (100%)
8. Are there other organisations which could be used as a benchmark for the performance of NHSBT?	7 (26%)	5 (18%)	**8 (30%)**	7 (26%)	27 (100%)
9. Are there ways in which NHSBT's assets and expertise could be exploited to improve system wide efficiency, deliver greater innovation in the health and care sector or to drive economic growth? For example, in the development of digital diagnostics, regenerative medicine, cell therapy, genomics and stratified medicine. Please give reasons for your answer.	**16 (60%)**	4 (15%)	n/a	7 (25%)	27 (100%)
10. Are there barriers to improved collaboration between NHSBT and others in the health and care system? For example, in terms of diagnostic and therapeutic services, and integrated transfusion services. Please give reasons for your answer.	**13 (48%)**	0 (0%)	7 (26%)	7 (26%)	27 (100%)

Annex G (contd)

Call for Evidence Question **(Majority response shown in bold)**	**Yes**	**No**	**Don't know**	**Not Answered**	**Total**
11. Does the current regulatory framework governing NHSBT's operations conform to better regulation principles (proportionate; accountable; consistent; transparent; and, targeted), or are there potential improvements/efficiencies that can be made? Please give reasons for your answer.	7 (26%)	3 (11%)	**12** **(45%)**	5 (18%)	27 (100%)
12. Does NHSBT have the necessary capability and capacity in terms of horizon scanning and strategic planning to respond effectively to changing demands, a changing regulatory/policy environment, and/or emerging innovative medicines and medical technologies? Please give reasons for your answer.	6 (22%)	**8 (30%)**	7 (26%)	6 (22%)	27 (100%)
13. How well does NHSBT drive innovation and what more could be done? Examples might include developing innovative types of product, exploiting stratified medicine, new diagnostics and digital health technologies, and facilitating use of such products in the wider health and care system. Please give reasons for your answer.	n/a (free text box only) [**22** responses received to this question.]			5 (18%)	27 (100%)

Annex G (contd)

Call for Evidence Question **(Majority response shown in bold)**	**Yes**	**No**	**Don't know**	**Not Answered**	**Total**
14. How easy it is for donors and service uses to engage with NHSBT about the products and services that NHSBT offers.	Very Easy – 5 (18%) Easy – 5 (18%) Average – 5 (18%) Difficult – 1 (4%) Very difficult – 0 (0%)			**11 (41%)**	27 (100%)
15. Is there an appropriate level of transparency in the NHSBT's end to end processes and decision making? Please give reasons for your answer.	**10 (37%)**	4 (15%)	5 (18%)	8 (30%)	27 (100%)
Any other comments?	n/a (free text box only) [**20** responses received to this question.]			7 (26%)	27 (100%)

Source: Citizen Space summary report

Annex H: NHSBT Compliance with the Principles of Good Corporate Governance

The areas of partial or non-compliance with the principles of good corporate governance which need to be addressed are discussed in more detail in the section “Governance of NHSBT”.

PRINCIPLES OF GOOD CORPORATE GOVERNANCE Accountability			
Statutory Accountability		**Compliant (Yes/No)**	**Review Findings**
Principle	***The public body complies with all applicable statutes and regulations, and other relevant statements of best practice.***		
Supporting Provisions	The public body must comply with all statutory and administrative requirements on the use of public funds. This includes the principles and policies set out in the HMT publication “Managing Public Money” and Cabinet Office/HM Treasury spending controls.	Yes	The majority (85%) of NHSBT’s current income derives from sales of blood and specialist products and services to NHS hospitals in England and north Wales. Volumes and prices are agreed in advance of the budget year via the National Commissioning Group for Blood, chaired by a representative of the Senior Departmental Sponsor. Prices are set to recover costs and should be set in line with HM Treasury guidance in respect of fees and charges. The associated expenditure is considered front-line and is therefore classified as Programme Expenditure. The remainder of NHSBT s income is provided by way of direct funding from the Department of Health in respect of organ and stem cell transplantation. Contributions (on a population basis) are additionally provided by the other UK Health Departments in support of NHSBT s UK wide responsibilities for organ donation and transplantation. As NHSBT is a Public Corporation, the associated expenditure is considered to be a subsidy and classified as Programme Expenditure.

	The public body must operate within the limits of its statutory authority and in accordance with any delegated authorities agreed with the sponsoring department.	Yes	
	The public body should operate in line with the statutory requirements and spirit of the Freedom of Information Act 2000. It should have a comprehensive Publication Scheme. It should proactively release information that is of legitimate public interest where this is consistent with the provisions of the Act.	Yes	
	The public body must be compliant with Data Protection legislation.	Yes	
	The public body should be subject to the Public Records Acts 1958 and 1967.	Yes	

Accountability for public money		**Compliant (Yes/No)**	**Detail**
Principle	***The Accounting Officer of the public body is personally responsible and accountable to Parliament for the use of public money by the body and for the stewardship of assets***		
Supporting Provisions	There should be a formally designated Accounting Officer for the public body. This is usually the most senior official (normally the Chief Executive).	Yes	
	The role, responsibilities and accountability of the Accounting Officer should be clearly defined and understood. The Accounting Officer should have received appropriate training and induction. The public body should be compliant with the requirements set out in "Managing Public Money", relevant Dear Accounting Officer letters and other directions. In particular, the Accounting Officer of the public body has a responsibility to provide evidence-based assurances required by the Principal Accounting Officer (PAO). The PAO requires these to satisfy him or herself that the Accounting Office responsibilities are being appropriately discharged. This includes, without reservation, appropriate access of the PAO's internal audit service into the public body.	Yes	
	The public body should establish appropriate arrangements to ensure that public funds: • are properly safeguarded; • are used economically, efficiently and effectively; • are used in accordance with the statutory or other authorities that govern their use; • deliver value for money for the Exchequer as a whole.	Yes	

	The public body's annual accounts should be laid before Parliament. The Comptroller and Auditor General should be the external auditor for the body.	Yes	NHSBT annual report and accounts are presented to the Westminster Parliament (pursuant to Paragraph 6(3), Section 232, Schedule 15 of the National Health Service Act 2006), and laid before the Scottish Parliament by Scottish Ministers (in pursuance of Section 88 of the Scotland Act 1998)

Ministerial Accountability		**Compliant (Yes/No)**	**Detail**
Principle	***The Minister is ultimately accountable to Parliament and the public for the overall performance of the public body.***		
Supporting Provisions	The Minister and sponsoring department should exercise appropriate scrutiny and oversight of the public body.	Yes	
	Appointments to the board should be made in line with any statutory requirements and, where appropriate, with the Code of Practice issued by the Commissioner for Public Appointments.	Yes	
	The Minister appoints the Chair and all non-executive board members of the public body and is able to remove individuals by suspension or termination of employment if the criteria set out in legislation are met.	Yes	
	The Minister should be consulted on the appointment of the Chief Executive and will normally approve the terms and conditions of employment.	No	The Chair and Board members appoint the Chief Executive who is employed under NHS terms and conditions including the Very Senior Manager pay scale.
	The Minister should meet the Chair and/or Chief Executive on a regular basis.	Yes	NHSBT Chair meets the DH Public Health Minister and Health Ministers in the Devolved Administrations periodically, principally when a new Minister takes up post. The regular accountability mechanism is through the NHSBT-DH official level reporting arrangements (see row below).

	A range of appropriate controls and safeguards should be in place to ensure that the Minister is consulted on key issues and can be properly held to account. These will normally include: • a requirement for the public body to consult the Minister on the corporate and/or operational business plan; • a requirement for the exercise of particular functions to be subject to guidance or approval from the Minister; • a general or specific power of Ministerial direction over the public body; • a requirement for the Minister to be consulted by the public body on key financial decisions. This should include proposals by the public body to: (i) acquire or dispose of land, property or other assets; (ii) form subsidiary companies or bodies corporate; and (iii) borrow money; • a power to require the production of information from the public body which is needed to answer satisfactorily for the body's affairs.	Yes	NHSBT as a Special Health Authority in England and Wales is directed by Ministers via the NHS Blood and Transplant (England) Directions 2005, and the NHS Blood and Transplant (Wales) Directions 2005, as amended. These directions govern the arrangements relating to England and Wales for blood, stem cell, tissue and organ donation and transplantation services. NHSBT s accountabilities to the Scottish Government and the Department of Health, Social Services and Public Safety in Northern Ireland are governed via its Board arrangements and through Income Generation Agreements. The Senior Departmental Sponsor in DH for NHSBT signs off the NHSBT business plan on behalf of the Minister. NHSBT, DH and the Devolved Administrations work closely in the development of new operational policies.
	There should be a requirement to inform Parliament of the activities of the public body through publication of an annual report.	Yes	

PRINCIPLES OF GOOD CORPORATE GOVERNANCE Roles and responsibilities			
Role of the Sponsor Department		**Compliant (Yes/No)**	**Detail**
Principle	***The departmental board ensures that there are robust governance arrangements with the board of each arm's length body. These arrangements set out the terms of their relationship and explain how they will be put in place to promote high performance and safeguard propriety and regularity.*** ***There is a sponsor team within the department that provides appropriate oversight and scrutiny of, and support and assistance to, the public body.***		
Supporting Provisions	The departmental board's regular agenda should include scrutiny of the performance of the public body. The departmental board should establish appropriate systems and processes to ensure that there are effective arrangements in place for governance, risk management and internal control in the public body.	No	The Senior Departmental Sponsor in DH for NHSBT is a member of the departmental board, and escalates NHSBT – related issues to that board as necessary.
	There should be a Framework Document in place which sets out clearly the aims, objectives and functions of the public body and the respective roles and responsibilities of the Minister, the sponsoring department and the public body. This should follow relevant Cabinet Office and HM Treasury guidance. The Framework Document should be published. It should be accessible and understood by the sponsoring department, all board members and by the senior management team in the public body. It should be regularly reviewed and updated.	Yes	There is an existing framework agreement in place between NHSBT and DH which outlines their respective roles, responsibilities, governance and accountability arrangements. That document also touches upon the relationship between the other UK Health Departments and NHSBT for functions carried out in the rest of the UK. NHSBT's accountabilities to the Scottish Government and the Department of Health, Social Services and Public Safety in Northern Ireland are governed via NHSBT's Board arrangements and through Income Generation Agreements.
	There should be a dedicated sponsor team within the parent department. The role of the sponsor team should be clearly defined.	Yes	

	There should be regular and ongoing dialogue between the sponsoring department and the public body. Senior officials from the sponsoring department may as appropriate attend board and/or committee meetings. There might also be regular meetings between relevant professionals in the sponsoring department and the public body.	Yes	

Role of the Board		**Compliant (Yes/No)**	**Detail**
Principle	***The public body is led by an effective board which has collective responsibility for the overall performance and success of the body. The board provides strategic leadership, direction, support and guidance.*** ***The board – and its committees – have an appropriate balance of skills, experience, independence and knowledge.*** ***There is a clear division of roles and responsibilities between non-executive and executives. No one individual has unchallenged decision-making powers.***		
Supporting Provisions	The board of the public body should: • meet regularly; • retain effective control over the body; • effectively monitor the senior management team.	Yes	
	The size of the board should be appropriate.	Yes	
	Board members should be drawn from a wide range of diverse backgrounds.	Partial	The NHSBT Board has a wide range of skills and experience appropriate to NHSBT's work activity. However, Board diversity requires further consideration as there is currently no BAME representation on the Board.
	The board should establish a framework of strategic control (or scheme of delegated or reserved powers). This should specify which matters are specifically reserved for the collective decision of the board. This framework must be understood by all board members and by the senior management team. It should be regularly reviewed and refreshed.	Yes	
	The Board should establish formal procedural and financial regulations to govern the conduct of its business.	Yes	

	The Board should establish appropriate arrangements to ensure that it has access to all such relevant information, advice and resources as is necessary to enable it to carry out its role effectively.	Yes	
	The Board should make a senior executive responsible for ensuring that Board procedures are followed and that all applicable statutes and regulations and other relevant statements of best practice are complied with.	Yes	
	The Board should make a senior executive responsible for ensuring that appropriate advice is given to it on all financial matters.	Yes	
	The Board should establish a remuneration committee to make recommendations on the remuneration of top executives. Information on senior salaries should be published. The board should ensure that the body's rules for recruitment and management of staff provide for appointment and advancement on merit.	Yes	
	The Chief Executive should be accountable to the Board for the ultimate performance of the public body and for the implementation of the Board's policies. He or she should be responsible for the day-to-day management of the public body and should have line responsibility for all aspects of executive management.	Yes	
	There should be an annual evaluation of the performance of the board and its committees – and of the Chair and individual board members.	Yes	

Role of the Chair		**Compliant (Yes/No)**	**Detail**
Principle	***The Chair is responsible for leadership of the board and for ensuring its overall effectiveness.***		
Supporting Provisions	The board should be led by a non-executive Chair.	Yes	
	There should be a formal, rigorous and transparent process for the appointment of the Chair. This should be compliant with the Code of Practice issued by the Commissioner for Public Appointments. The Chair should have a clearly defined role in the appointment of non-executive board members.	Yes	

	The duties, role and responsibilities, terms of office and remuneration of the Chair should be set out clearly and formally defined in writing. Terms and conditions must be in line with Cabinet Office guidance and with any statutory requirements. The responsibilities of the Chair will normally include: • representing the public body in discussions with Ministers; • advising the sponsoring Department and Ministers about board appointments and the performance of individual non-executive board members; • ensuring that non-executive board members have a proper knowledge and understanding of their corporate role and responsibilities. The Chair should ensure that new members undergo a proper induction process and is normally responsible for undertaking an annual assessment of non-executive board members' performance; • ensuring that the board, in reaching decisions, takes proper account of guidance provided by the sponsoring department or Ministers; • ensuring that the board carries out its business efficiently and effectively; • representing the views of the board to the general public; • developing an effective working relationship with the Chief Executive and other senior staff.	Yes	
	The roles of Chair and Chief Executive should be held by different individuals.	Yes	

Role of Non-Executive Board Members		Met (Yes/No)	Detail
Principle	***As part of their role, non-executive board members provide independent and constructive challenge.***		
Supporting Provisions	There should be a majority of non-executive members on the board.	Yes	The NHSBT Board currently consists of an independent Chair plus seven non-executive directors, and a CEO and six NHSBT executive directors. The other five NHSBT executive directors attend Board meetings as observers. One non-executive director has specific responsibilities for Wales in accordance with the NHSBT (Wales) Directions 2005
	There should be a formal, rigorous and transparent process for the appointment of non-executive members of the board. This should be compliant with the Code of Practice issued by the Commissioner for Public Appointments.	Yes	
	The duties, role and responsibilities, terms of office and remuneration of non-executive board members should be set out clearly and formally defined in writing. Terms and conditions must be in line with Cabinet Office guidance and with any statutory requirements. The corporate responsibilities of non-executive board members (including the Chair) will normally include: • establishing the strategic direction of the public body (within a policy and resources framework agreed with Ministers); • overseeing the development and implementation of strategies, plans and priorities; • overseeing the development and review of key performance targets, including financial targets; • ensuring that the public body complies with all statutory and administrative requirements on the use of public funds;	Yes	

	• ensuring that the board operates within the limits of its statutory authority and any delegated authority agreed with the sponsoring department; • ensuring that high standards of corporate governance are observed at all times. This should include ensuring that the public body operates in an open, accountable and responsive way; • representing the board at meetings and events as required.		
	All non-executive Board members must be properly independent of management.	Yes	
	All non-executive board members must allocate sufficient time to the board to discharge their responsibilities effectively. Details of board attendance should be published (with an accompanying narrative as appropriate).	Yes	
	There should be a proper induction process for new board members. This should be led by the Chair. There should be regular reviews by the Chair of individual members' training and development needs.	Yes	

PRINCIPLES OF GOOD CORPORATE GOVERNANCE Effective Financial Management			
Effective Financial Management		**Compliant (Yes/No)**	**Detail**
Principle	***The public body has taken appropriate steps to ensure that effective systems of financial management and internal control are in place.***		
Supporting Provisions	The body must publish on a timely basis an objective, balanced and understandable annual report. The report must comply with HM Treasury guidance.	Yes	
	The public body must have taken steps to ensure that effective systems of risk management are established as part of the systems of internal control.	Yes	
	The public body must have taken steps to ensure that an effective internal audit function is established as part of the systems of internal control. This should operate to Government Internal Audit Standards and in accordance with Cabinet Office guidance.	Yes	
	There must be appropriate financial delegations in place. These should be understood by the sponsoring department, by board members, by the senior management team and by relevant staff across the public body. Effective systems should be in place to ensure compliance with these delegations. These should be regularly reviewed.	Yes	

	There must be effective anti-fraud and anti-corruption measures in place.	Yes	NHS Blood and Transplant is registered with the CQC as a service provider. As a result, additional checks are in place for all new appointments to the NHSBT Board to satisfy the requirements of the Fit & Proper Person Test under the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.
	There must be clear rules in place governing the claiming of expenses. These should be published. Effective systems should be in place to ensure compliance with these rules. The public body should proactively publish information on expenses claimed by board members and senior staff.	Yes	
	The annual report should include a statement on the effectiveness of the body's systems of internal control.	Yes	
	The board should establish an audit (or audit and risk) committee with responsibility for the independent review of the systems of internal control and of the external audit process.	Yes	
	The body should have taken steps to ensure that an objective and professional relationship is maintained with the external auditors.	Yes	

PRINCIPLES OF GOOD CORPORATE GOVERNANCE Communications			
Communications		**Compliant (Yes/No)**	**Detail**
Principle	***The Public Body is open, transparent, accountable and responsive.***		
Supporting Provisions	The public body should have identified its key stakeholders. It should establish clear and effective channels of communication with these stakeholders.	Yes	
	The public body should make an explicit commitment to openness in all its activities. It should engage and consult with the public on issues of real public interest or concern. This might be via new media. It should publish details of senior staff and boards members together with appropriate contact details.	Yes	
	The public body should consider holding open board meetings or an annual open meeting.	Yes	NHSBT holds an annual stakeholder event, and open Board meetings.
	The public body should proactively publish agendas and minutes of board meetings.	Yes	Published agendas and minutes have elements redacted where necessary.
	The public body should proactively publish performance data.	Yes	NHSBT Annual Report and Accounts contain comprehensive data and commentary on NHSBT performance.

	In accordance with transparency best practice, public bodies should consider publishing their spend data over £500. By regularly publishing such data and by opening their books for public scrutiny, public bodies can demonstrate their commitment to openness and transparency and to making themselves more accountable to the public.	Yes	
	The public body should establish effective correspondence handling and complaint procedures. These should make it simple for members of the public to contact the public body and to make complaints. Complaints should be taken seriously. Where appropriate, complaints should be subject to investigation by the Parliamentary Ombudsman. The public body should monitor and report on its performance in handling correspondence.	Yes	As a Special Health Authority, NHSBT is required to follow the legislative framework laid down in the Local Authority Social Services and the National Health Service Complaints (England) Regulations 2009.
	The public body must comply with the Government's conventions on publicity and advertising, and digital communications. These conventions must be understood by board members, senior managers and all staff in press, communication and marketing teams.	Yes	
	Appropriate rules and restrictions must be in place limiting the use of marketing and PR consultants.	Yes	
	The public body should put robust and effective systems in place to ensure that the public body is not, and is not perceived to be, engaging in political lobbying. This includes restrictions on board members and staff attending political conferences in a professional capacity.	Yes	

PRINCIPLES OF GOOD CORPORATE GOVERNANCE Conduct and behaviour			
Conduct and behaviour		**Compliant (Yes/No)**	**Detail**
Principle	***The board and staff of the public body work to the highest personal and professional standards. They promote the values of the public body and of good governance through their conduct and behaviour.***		
Supporting Provisions	A Code of Conduct must be in place setting out the standards of personal and professional behaviour expected of all board members. This should follow the Cabinet Office Code. All members should be aware of the Code. The Code should form part of the terms and conditions of appointment.	Yes	NHS Blood and Transplant is registered with the CQC as a service provider. As a result, additional checks are in place for all new appointments to the NHSBT Board to satisfy the requirements of the Fit & Proper Person Test under the Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.
	The public body has adopted a Code of Conduct for staff. This is based on the Cabinet Office model Code. All staff should be aware of the provisions of the Code. The Code should form part of the terms and conditions of employment.	Yes	
	There are clear rules and procedures in place for managing conflicts of interest. There is a publicly available Register of Interests for board members and senior staff. This is regularly updated.	Yes	
	There are clear rules and guidelines in place on political activity for board members and staff. There are effective systems in place to ensure compliance with any restrictions.	Yes	

	There are rules in place for board members and senior staff on the acceptance of appointments or employment after resignation or retirement. These are effectively enforced.	Yes	
	Board members and senior staff should show leadership by conducting themselves in accordance with the highest standards of personal and professional behaviour and in line with the principles set out in respective Codes of Conduct.	Yes	

Annex I: NHSBT National Administrations Committee – Terms of Reference

NHS Blood and Transplant

NATIONAL ADMINISTRATIONS COMMITTEE

TERMS OF REFERENCE (JULY 2012 (V3))

1. Constitution

The Board hereby resolves to establish a Committee of the Board to be known as the National Administrations Committee (the Committee). The Committee is a non-executive committee of the Board and has no executive powers, other than those specifically delegated in these Terms of Reference.

2. Membership

The Committee is appointed by the Board and consists of three Non-Executive Directors, one of whom chairs the meetings, and two Executive Team Directors[32], the Director of Organ Donation and Transplantation and the Director of Communications. A quorum at a meeting is 3 members, two of whom must be a Non-Executive Director.

3 Attendance

Other Executive Team Directors or senior managers may attend by invitation of the Committee. External representatives of the other UK Health Departments may also be invited.

The Secretary to the Committee is the Director of Communications, who may delegate this task.

4 Frequency

The Committee meets as frequently as it may determine to be necessary to complete its tasks. It typically meets three / four times each year and this may be by teleconference.

5 Authority

The Committee has full executive powers, on behalf of the Board, to oversee the ongoing review and development of arrangements in place to represent the interests of all four Health Departments in the United Kingdom.

6 Duties

The Objectives of the National Administrations Committee are:

- Review the adequacy of current arrangements for the Board to be able to represent the interests of all four Health Departments with regard to organ donation at the NHSBT Board
- Provide high-level support and direction to the development of future management arrangements for working with UK health Departments.

7. Reporting

The minutes of the Committee meetings shall be formally recorded and submitted to the Board. The Chair of the Committee shall draw to the attention of the Board any issues that require disclosure to the full Board, or require executive action.

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[32] 'Executive Team Director' means an officer that is a member of the NHSBT Executive Team, as determined by the Chief Executive. They may or may not be 'Executive Directors' ie officer members of the NHSBT Board.