Witness Name: Dr Gail Miflin
Statement No.: WITN0672006
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WITN0672141
Dated: 19.10.2021

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR GAIL MIFLIN

Statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 26 February 2021.

I, Gail Miflin will say as follows:

1. Before dealing with specific responses to the questions, I would like to make some observations and acknowledgements about the background to the Inquiry, and the role of National Health Service (NHS) Blood and Transplant **('NHSBT')** in it.

2. Firstly, I wish to say sorry to those who were infected and affected by the transmission of infected blood and blood products. On behalf of the historic transfusion services that we represent, the current organisation and our Board, we are so sorry that this happened, and we apologise for our part in the events that caused this.

3. I would also like to thank donors for the vital work they have done over the years, in giving their blood in the hope of saving or improving a life. Without them, very many life-saving treatments and procedures would not be available.

4. I acknowledge, on behalf of all at NHSBT, the enormous human tragedy that occurred through the events that have led to this Inquiry.

It has been called the biggest treatment disaster in NHS history, but it was much more than that; it was many personal tragedies. I know that all of those infected were much loved children, siblings, parents and partners and that many others had their lives changed by these events. We want to learn the lessons that we hope the Inquiry will bring at its conclusion. On a personal level, listening to and reading evidence and testimonies, I am in awe of the courage of those who are infected themselves, or have been in other ways affected, both in telling their stories and in fighting for so long to hear why things unfolded as they did to cause such harm. In my work, I am constantly reminded of our history, the importance of both maintaining the supply of blood components and also in ensuring as safe a supply as we can reasonably achieve in the context of the system we work within, the NHS; this is not something I personally take lightly. I know that the Board of NHSBT shares this view.

5. Given the magnitude of the scope and extent of this request, the Board could not possibly assimilate and review all the information or the content of this statement and I hope that can be accepted and understood. I am also necessarily having to speak on behalf of the current organisation and all its predecessors without any personal knowledge of the historic position and I hope it can be acknowledged that, to that extent, my response is limited. Despite this, I have tried to do my best to answer the questions in the fullest and most transparent way that I can, to set out a record of facts to try to help those wanting to understand what happened in the past. That said, it should be noted that I have not been able to see all the documents that are relevant as many of these have not yet been made available through the Inquiry, nor due to Inquiry rules have I yet seen the statements from my colleagues.

6. NHSBT is committed to helping the Inquiry. My approach to this document throughout has been to give the historical information in as detailed a form as I am able to, albeit I have had to rely on records. In

this regard I have had assistance from NHSBT's legal team, who have reviewed documents, provided relevant documents to me, and assisted me in drafting this statement. I have had to base much of what I say on the very large (and ever-increasing) amount of documentary evidence available, and on the knowledge of others, my colleagues, who I have worked closely with in preparing this. I would like to thank the many colleagues, past and present, who have worked so hard to try to help the Inquiry to get to the truth. This has been a very significant undertaking. What appears in the responses below and elsewhere on behalf of the organisation represents their work as well as mine.

7. This, together with the length of the request, has resulted in a long response, and inevitably also in some repetition within it, particularly where there is overlap between questions. I have tried to keep this repetition to a minimum by cross-referencing, etc.; but I also think that it is sometimes easier for those reading to see things repeated rather than to be referred to a different section within a long document. I have also included at the end of the statement a **Table of Acronyms**, which I hope will help.

8. I would like to comment also on the terminology used throughout this document, which at times has felt uncomfortable. I have used the terminology as it appears in the documents I reference. I acknowledge that some of these terms are not terms that are acceptable today. However, I didn't think it right to correct terms when referencing the content of documents. I apologise if this causes distress for anyone reading this statement.

9. Where I have thought it relevant, I have tried to make observations, and indeed sense, of all the documents presented in this statement. These are my personal observations made with the aim of trying to help the Inquiry and those reading this statement. However, given that I was not working for the blood services at the time and thus cannot possibly understand all of the context, and that I have the benefit of

hindsight, I am happy to accept that others may disagree or that my conclusions may not be correct.

10. Looking back on events, I believe, with the advantage of hindsight, that the organisational structures as set up before 1994 did not, at times, allow sufficiently effective coordination, decision making and policy setting. I also believe the medical culture at the time was significantly different from that of today. However, I, and the organisation, acknowledge that some changes, even with these structures in place, should have been achieved sooner, and some things should have been done differently. For these, I am truly sorry, both personally and on behalf of the organisation.

Section 1: Organisation history & structure

1. Please set out your name, address, date of birth and professional qualifications.

11. I am Dr Gail Miflin. My date of birth is GRO-C 1967 and my address is c/o NHS Blood and Transplant, 500 North Bristol Parkway, Filton, Bristol BS34 7QH. My GMC number is 3555785.

12. My professional qualifications are:

1988	BA Medical Sciences, University of Cambridge
1989	MA, University of Cambridge
1991	MB:BChir, University of Cambridge
1995	Member Royal College Physicians
2001	Fellow Royal College Pathologists
2015	Fellow Royal College Physicians

Current role at NHSBT and responsibilities in that role.

13. I am employed by NHS Blood and Transplant ('NHSBT') and I currently hold the position of Chief Medical Officer and Director of Clinical Services. I was appointed to the Chief Medical Officer role on 1 June 2016. My role has developed since my appointment, as described below.

14. I make this statement in response to a request for evidence by the Inquiry to the Chief Executive of NHSBT under Rule 9, dated 26 February 2021.

15. I joined NHSBT in 2010 as a Haematology Consultant alongside my role as a Haematology Consultant at UCLH Foundation Trust. My role was as a Donor Medicine Consultant leading a team of doctors and nurses addressing adverse reactions of donation and eligibility requirement for donation. I was involved in Clinical Governance of blood donation and advising on internal policy decisions.

16. From 2012, I was the Associate Medical Director for Blood Supply at NHS Blood and Transplant. In this role, I was responsible for a team of about 75 doctors and nurses who:

- advised on policy and safety of blood donation and its manufacture within NHSBT;
- managed serious adverse events in donors; and,
- were responsible for the implementation of safety policies and management of safety investigations for our blood components.

17. As a result of my role, I:
- was responsible for all aspects of Clinical Governance across the NHSBT Blood Supply Directorate, including managing any Serious Incident Investigations;
- was involved in policy setting and implementation, for in 2012 I was appointed Chair of the Joint UKBTS Professional Advisory Committee **('JPAC')** Care and Selection of Donors Specialist

Advisory Committee; and,

- worked closely with the University of Cambridge to establish the National Institute of Health Research Blood and Transplant Research Unit in Donor Health and Genomics.

18. From June 2016 I have been the Medical and Research Director or Chief Medical Officer (these two roles are synonymous). Initially I led the Clinical Directorate and was responsible for the medical and R&D teams in the organisation. Since my appointment, I have been responsible for the safety policy framework and clinical governance systems across NHSBT.

19. I also oversee research and development, acting as the interface with research bodies, including universities and Public Health England. In doing so it is my role to ensure evidence is provided to shape national and international healthcare policy in respect of transfusion and transplantation medicine and science. In the Medical Director / Chief Medical Officer role, I am a member of JPAC, Advisory Committee on the Safety of Blood, Tissues and Organs **('SaBTO')** and the UK Forum (all described in more detail below), and I also work closely with international colleagues.

20. In addition, I was responsible for information governance and the implementation of GDPR until this moved to our Digital, Data, and Technology Services Department in April 2020.

21. Since my appointment in 2016, I have been the Caldicott Guardian and, from April 2021, the Responsible Officer in NHSBT.

22. More recently, in 2020, I also took on the operational delivery of our services delivering Cellular, Apheresis and Gene Therapies, and our diagnostic or Pathology Laboratories. In this respect I am now additionally responsible for the operational delivery of these two services in addition to the original Medical and Research Director role.

Part of the rationale for this new role is to become an organisation that is closer to patients, understanding the outcomes of what we do, and striving to have the greatest impacts we can on these two things. In this respect, we have also brought R&D closer to our operations, closely aligning it to improving outcomes for patients by providing critical evidence to drive us to provide better, evidence-based services and outcomes.

23. With the unexpected pandemic NHSBT was asked to rapidly set up the ability to collect COVID-19 Convalescent Plasma in March 2020 by the Department of Health and Social Care **('DHSC')**. This programme of implementing the collection of plasma was initially to support the RECOVERY and REMAP-CAP trials of Covid-19 Convalescent Plasma. I was asked to lead this programme within NHSBT, working closely with others in the NHS.

24. Subsequently, following the outcomes of the trials of COVID-19 Convalescent Plasma where there was no overall demonstrated benefit, the DHSC instructed NHSBT to collect plasma for fractionation following a risk assessment of UK plasma by the Medicines and Healthcare Products Regulatory Agency **('MHRA')** and recommendations to Ministers. Currently, I remain the Director responsible for the collection and manufacture of Plasma.

25. My immediate predecessor as Medical and Research Director was Dr Lorna Williamson who was appointed in 2007. I understand that prior to this Dr Tim Wallington was interim Director for a few months in 2007 following the retirement of Dr Angela Robinson who was Medical Director between 1994 and 2007. Dr Harold Gunson was the first Medical Director of the National Blood Association **('NBA')**. He retired in 1994. He was also the National Director of the NBTS from 1988.

Career History

26. Immediately before joining NHSBT I worked as a Consultant Haematologist at University College London Hospitals NHS

Foundation Trust where I specialised in treating both adults and children with red cell disorders, both on the wards and in clinics with a multidisciplinary team. Alongside this I also worked in a specialist laboratory and gave general haematology advice as required.

27. Before this I was a Consultant Haematologist at the Royal Free Hospital between February 2002 and February 2005 where I covered general haematology duties, provided clinical leadership of therapeutic apheresis programmes, provided clinical input to laboratory aspects of the service and led the provision of services to people with red cell disorders.

28. During this time, and overlapping with both hospital roles, I also worked part-time for three years at South East London Strategic Health Authority as a Consultant, leading and working on clinical improvement programmes with other clinicians in South East London Trusts.

29. Prior to being appointed as a Consultant I trained in haematology in the Yorkshire Deanery and in Nottingham where I did research into the outcomes and recovery of those undergoing peripheral blood stem cell transplantation. Before this I did my junior doctor medical rotation in Nottingham with preceding roles in New Zealand and London. My initial 'house job' roles were in London.

3 Please outline the purpose, functions and responsibilities of NHSBT, both currently and historically.

30. Much of the information provided in this section is derived from *Fifty Years of Blood Transfusion* in Transfusion Medicine by Dr Gunson and Dr Dodsworth (1996, Volume 6, Supplement 1) [NHBT0000028]. In addition, I rely on the updated version of the *NHSBT Family Tree,* prepared for the purposes of the Inquiry [WITN0672007]. An earlier

version of this document was provided as an appendix to the response of Dr Robinson to the amended rule 9 request of 14 August 2020.

31. NHSBT is a Special Health Authority **('SHA')** in England and Wales that is classified as an executive non-departmental public body of the DHSC. It was established on 1 October 2005 and took over the responsibilities of UK Transplant and the National Blood Service. Its role is to provide a blood and transplantation service to the NHS, looking after blood donation services in England and solid organ transplant services across the UK. This response sets out the purpose, functions and responsibilities of NHSBT (and its predecessor bodies, many of which no longer exist) both currently and historically.

32. I understand from *Fifty Years of Blood Transfusion* [NHBT0000028] that in 1921 a civil voluntary blood donation service was set up in London by Percy Lane Oliver to *"solve the problem of blood donation by organising a transfusion service available at all hours, and able to send to any place a donor of guaranteed health, whose blood group has been duly verified"*.

33. From 1939, the Ministry of Health approved the establishment of a number of blood depots. Four civilian blood depots were established in London by the Medical Research Council **('MRC')**,[1] and an Army Blood Supply Depot was established in Bristol by the War Office.

34. From June 1940, a further eight regional centres were established (each a Regional Transfusion Centre **('RTC')**) to improve the blood service's ability to provide blood outside of London. Starting from September 1940, London was bombed uninterruptedly for three months and, together with most of the large provincial cities, intermittently until 1942. During this period, the transfusion service

[1] The Medical Research Council is responsible for co-coordinating and funding medical research in the United Kingdom. It was founded as the Medical Research Committee and Advisory Council in 1913, and then became the Medical Research Council under Royal Charter in 1920.

rapidly expanded, in order to meet the needs of injured civilians and to provide plasma for the armed forces.

35. In 1946, the RTCs were consolidated and formally constituted as a National Blood Transfusion Service **('NBTS')**. The NBTS was centrally managed and funded by the Ministry of Health. RTCs were responsible for the collection of blood from voluntary donors, the processing and testing of blood donations, and the supply of blood to hospitals within their area. On some occasions, RTCs also supplied blood to other hospitals and bodies outside their region (for example, to the Ministry of Defence). Teaching was also an important activity at RTCs – much 'in-service training' was provided for unqualified staff who needed to learn important work either in the laboratory or on blood collection sessions. Further, RTCs carried out extensive research into topics such as the results of transfusing products, the testing of donations and methods of blood collections.

36. For the next nearly 40 years, I understand that the RTCs remained as a loose group of institutions providing blood services. Further detail is provided in the *NHSBT Family Tree* [WITN0672007], and below in answer to question 18.

37. On 27 November 1992, the Department of Health announced its intention to establish a single body with executive authority, the NBA, on 1st April 1993, with responsibility for both the central laboratories in England and Wales and the RTCs. The aims of this SHA were stated as follows:

    a. to maintain and promote blood and blood-products supply based on the outstanding system of voluntary, unpaid donors;
    b. to implement a cost-effective strategy of ensuring an adequate supply of blood and blood products to meet national needs;
    c. to ensure that the high standards of safety and quality in the blood supply are maintained throughout the blood service;

d. to ensure that blood products meet a consistent standard of safety and quality;
e. to ensure the cost-efficient operations of the transfusion centres and the Bio Products Laboratory both individually and together as parts of the national service.

38. The NBA was established by the National Blood Authority (Establishment and Constitution) Order 1993 SI No 585 **('the NBA Order 1993')** as an SHA. Shortly after the NBA Order 1993 was made, it was significantly amended by the National Blood Authority (Establishment and Constitution) Amendment Order 1994 SI No 589 **('the NBA (Amendment) Order 1994')**.

39. Pursuant to article 2 of the NBA Order 1993, the NBA's functions were prescribed as follows:

"(aa) collecting, screening and processing blood and its constituents and supplying blood, plasma and other blood products for the purposes of the health service[2]
(a) the provision of laboratories for the manufacture of blood products and for other purposes;
(b) the preparation of plasma fractions and other products for therapeutic, diagnostic and other purposes;
(c) research and development in plasma protein fractionation and for other purposes;
(d) the manufacture of blood grouping re-agents and other related re-agents;
(e) the supply of products prepared or manufactured under sub-paragraph (b) or (d) above for the purposes of the health service;
(h) the promotion, by advertisement and otherwise, of the giving of blood and its constituents for the purposes of the health service, with a view in particular to maintaining an adequate number of persons who

[2] As inserted by National Blood Authority (Establishment and Constitution) Amendment Order 1994 SI No 589.

are willing to give blood or its constituents for those purposes;[3]
(i) the making of arrangements, on behalf of Regional Health Authorities, for the supply under NHS contracts of blood between those Authorities.[4]"

40. Pursuant to article 1 of the NBA Order 1993, 'the transfusion service' was defined as *"the arrangements made by Regional Health Authorities with respect to the collection and supply of blood in their respective regions for the purposes of the health service."* This definition was removed from the NBA Order 1993 by the NBA Amendment Order 1994.[5]

41. The Welsh RTC never became part of the NBA. In 1999, the Velindre National Health Service Trust (Establishment) Amendment Order 1999/826 provided that one of the functions of the Velindre NHS Trust was:

(b) *to own and manage Welsh Blood Service Headquarters, Ely Valley Road, Talbot Green, Pontyclun CF72 9WB and associated premises, and there to provide and manage services relating to the collection, screening and processing of blood and its constituents and to the preparation and supply of blood, plasma and other blood products.*

Further detail about the Welsh Blood Service and its relationship with NHSBT is provided in section 3 of this response below.

42. The NBA and UK Transplant were replaced by the establishment of NHSBT in 2005. The NHS Blood and Transplant (Establishment and

[3] As amended by the National Blood Authority (Establishment and Constitution) Amendment Order 1994 SI No 589.
[4] This was inserted by the NBA (Amendment) Order 1994.
[5] This list of functions is as amended by the NBA (Amendment) Order 1994. In particular, the following two functions were omitted and replaced with function (aa) above: *"(f) the monitoring of the operation by Regional Health Authorities of the transfusion service, and the provision of advice to the Secretary of State in connection with that service*" and *"(g) the provision of advice to Regional Health Authorities as to the co-ordination of their respective activities in connection with the transfusion service, with a view to securing and maintaining an adequate supply of blood and plasma for the purposes of the health service*".

Constitution) Order 2005 [RLIT0001544][6] is a joint England and Wales Order which provides NHSBT with a remit to:

a. collect, screen, analyse, process and supply blood, blood products, plasma, stem cells and other tissues to the health services;
b. prepare blood components and reagents;
c. facilitate, provide and secure the provision of services to assist tissue and organ transplantation;
d. carry out any other such functions as directed.

43. NHSBT is also directed by the NHS Blood and Transplant (England) Directions 2005 [RLIT0001545][7], and the NHS Blood and Transplant (Wales) Directions 2005 [RLIT0001546] and [RLIT0001547][8], as amended **('the Directions')**, which govern :

a. the arrangements relating to blood in England; and
b. the arrangements relating to tissue and organ donation and transplantation services in both England and Wales.

44. The Directions additionally direct NHSBT to:

a. conduct or commission research into the uses of, or development of, blood, stem cells and tissues;
b. 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;
c. 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);
d. conduct or commission research in connection with the field of organ donation and transplantation as NHSBT considers appropriate;

[6] Statutory Instrument 2005 No. 2529, reg.3 [RLIT0001544]
[7] These are made by the Secretary of State for Health, in exercise of the powers conferred by sections 16D(1), 17 and 126(4) of the National Health Service Act 1977(a) and can be found here: [RLIT0001545]
[8]These are made by the National Assembly for Wales, in exercise of the powers conferred by sections 16D(1), 17 and 126(4) of the National Health Service Act 1977can be found here: [RLIT0001546] see also NHS Blood and Transplant (Wales) Directions 2015 at RLIT0001547

e. 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.

45. There is some additional detail provided in my unsigned statement which has previously been provided to the Inquiry and is dated 5 September 2018 **('GM First Statement')** **[WITN0672001]** at [15]-[16]:

15. NHSBT['s]…role…includes managing the donation, storage and transplantation of blood, organs, tissues, bone marrow and stems cells, and researching new treatments and processes.

16. NHSBT's responsibilities are to:

…

- *Optimise the safety and supply of blood, organs, stem cells and tissue;*
- *Help raise the quality, effectiveness and clinical outcomes of blood and transplant services;*
- *Provide expert advice to other NHS organisations and the four UK Health Departments;*
- *Commission and conduct research and development to improve outcomes for patient; and*
- *Implement relevant EU statutory frameworks and guidance.*

46. As specialists, NHSBT clinicians and scientists also advise the policy making bodies in the UK (e.g. SaBTO and JPAC), in Europe and internationally on the safe use of all of our products and services [WITN0672009].[9] Where they hold these roles they are appointed to them on the basis of their expertise (and occasionally also on the basis of their job role) by the Chairs of the relevant committees according to their processes, not by the Blood Services themselves.

4. Please explain the current structure of NHSBT, including:

[9] NHSBT Annual Report 2019 – 2020, pg. 20 [WITN0672009]

a. **its staffing, in particular the roles and responsibilities of key decision-makers (for example the Director, the Medical Director, the Scientific Advisor etc.);**
b. **how, and by whom, key strategic decisions are made;**
c. **how it is funded;**
d. **the structure, composition and role of its various committees or working groups;**
e. **its remit, including the geographical area it covered and the transfusion centres within this area; and**
f. **the legislative and regulatory framework under which NHSBT operates.**

(a) Staffing

47. The roles and responsibilities of key decision-makers are set out in the NHSBT Standing Orders dated March 2019 **('the Standing Orders')** [WITN0672010]:

Chief Executive	The Chief Executive is responsible for the overall performance of the executive functions of NHSBT. S/he is the Accounting Officer for NHSBT and is responsible for ensuring the discharge of obligations under Financial Directions and in line with the requirements of the DHSC.
Finance Director	The Finance Director is responsible for the provision of financial advice to NHSBT and to its Members and for the supervision of financial control and accounting systems. He or she is responsible along with Chief Executive for ensuring the discharge of obligations under relevant Financial Directions.
Medical & Research	The Medical & Research Director is responsible for the provision of medical and research related

Director	advice to NHSBT and to its Members and for the supervision of medical and research staff and processes. He or she is responsible along with the Chief Executive for ensuring the discharge of directives from the DHSC relative to health matters.
Chair of the Board	The Chair is responsible for the operation of the Board and liaises with the DHSC, and the devolved UK Health Administrations, regarding the appointment of Non-Executive Directors and, once appointed, has responsibility either directly or indirectly for their induction, their portfolios of interests and assignments, and their performance. The Chair works with the Chief Executive and ensures that key and appropriate issues are discussed by the Board in a timely manner with all the necessary information and advice being made available to the Board to inform the debate and ultimate resolutions.

48. A full list of the Executive Team and the Board can be found at www.nhsbt.nhs.uk/who-we-are/our-board/.

(b) How, and by whom, key strategic decisions are made

49. NHSBT is led by a Board[10], which oversees the strategic direction and the delivery of objectives and ensures that the core purpose and values of the organisation are upheld. As detailed in the previous paragraph, the current Board members are detailed on our website.

50. The Board is comprised of [RLIT0001548][11]:

[10] The constitution of the Board is dictated by Statutory Instrument 2005 No. 2529 [RLIT0001548].
[11] Framework Agreement between the Department of Health and NHS Blood and Transplant 2014, para 3 [WITN0672011]

a. a non-executive chair, appointed [RLIT0001550][12] by the Secretary of State for Health and who is accountable for the governance of NHSBT;
b. not more than eight non-executive members, also appointed by the Secretary of State. One of these members shall include a person with particular experience suited to the interests of Wales;
c. a chief executive appointed by the non-executive chair and non-executive members; and
d. not more than eight executive board members, including the persons who hold the office of Chief Executive, Finance Director and Medical Director. The non-executive chair, non-executive members and the Chief Executive appoint the executive board members.

51. In addition, alongside the board member maintaining the relationship with Wales, we also have members who lead on relations with Scotland and Northern Ireland.

52. Under the Standing Orders relating to the Arrangements for the Exercise of Functions for Delegation (Standing Order 4) [WITN0672010, NHSBT is given powers to *'make arrangements for the exercise, on behalf of the Authority of any of their functions by a committee, sub-committee or joint committee appointed by virtue of Standing Order 5 or by an officer of the Authority, in each case subject to such restrictions and conditions as the Authority thinks fit or as the Secretary of State may direct.'* Delegated Powers are covered in the Scheme of Delegation **('SoD')** [WITN0672012] and has effect as if incorporated into the Standing Orders 2019.

53. Key decisions are made following papers being provided to the Board. Where a decision does not need to come to the Board, the Executive team will also make key decisions. These are detailed in the SoD. The

[12] The NHS Blood and Transplant Regulations 2005, Statutory Instrument 2005 No.2531, as amended, sets out the appointment and tenure of the board. The non-executive chair and non-executive members cannot hold office for longer than a total of eight years. [RLIT0001550]

Board may make decisions at the public and private Board meetings, or may delegate some decision making to Board subcommittees. Similarly, the Executive team meets weekly as a team but will also delegate decisions to Executive subcommittees as detailed below. Both of these subcommittees are detailed below in my answer to question 4(d).

54. Board papers fall into a number of categories and key strategic decisions will be made by the Board. The common kinds of paper that the Board will see are:

a. Information papers – a patient story and a CEO report are currently routinely presented at the Board.
b. Governance and assurance papers – the clinical governance and Management Quality Reviews as well as reports from the Board subcommittees including the Audit, Risk and Governance Committee and Finance Committee will be reported.
c. Performance report - a monthly Board performance report shows progress against the annual business plan and current strategic performance objectives. The report also includes trend data, progress on strategic projects and a summary of key issues for attention. The content of this report is reviewed periodically to ensure that it provides sufficient information and assurance to the Board.
d. Strategic papers - these detail strategic direction and the Board will make the decision on this.
e. Business cases and major change programmes - these detail new organisational projects and direction and are agreed by the Board unless they can be delegated according to the SoD.
f. Major procurement decisions – these will come to the Board according to their size as detailed in the SoD.

(c) How it is funded

55. NHSBT recovers its costs of producing blood products (based on full cost without profit). Hospital Trusts pay for the blood they use as per a cost per unit model. Pricing is negotiated annually with commissioners through the National Commissioning Group for Blood (WITN0672009) [13].

56. Commissioners agreed that during 2020/21, due to the significant demand changes as a result of COVID-19, Trusts would pay a fixed price based on their planned (pre-Covid) blood demand for that period (block contracting). In turn the hospitals' income was protected by block contract arrangements. In 2021/2022 a modified process was agreed with commissioners whereby Trusts fund NHSBT fixed costs based on planned (pre-Covid) demand plus a variable charge based on the variable cost of the actual units ordered. It is currently intended that a return to unit cost pricing would operate in 2022/2023.

(d) Structure, composition and role of various committees/working group

The Board[14]

57. The structure, composition and role of various committees on the Board are as follows:

The Board	Oversees the strategic direction and the delivery of objectives and ensures that the core purpose and values of the organisation are upheld. The Board is led by the Chair and comprises Non-Executive Directors (NEDs) and Executive Directors, including the Chief Executive, Chief Medical Officer and Director of Clinical Services and Finance Director

[13] NHSBT Annual Report 2019 – 2020, pg. 36 [WITN0672009]. This is true of all of the operating units except Organ Donation, CBB and BBMR which are funded by DHSC and the other UK Health Authorities.
[14] NHSBT Annual Report 2019 – 2020, pg. 54 – 55. [WITN0672009]

Remuneration & Nominations Committee	Consolidates the duties of both a Remuneration and Nominations Committee, fulfils the role of the Remuneration and Terms of Service Committee described in EL(94)40 of the Code of Conduct and Accountability 2004. The Committee determines remuneration, conditions of service and termination arrangements of those very senior managers currently paid under the terms of the Executive Senior Manager (ESM) Framework 2016 and any other management posts with a base salary in excess of £100,000 per annum. The Committee also oversees and advises the Board on termination and severance arrangements in relation to the Chief Executive and NHSBT Directors and determining which Executive Directors are members of the NHSBT Board
Trust Fund Committee	Oversees NHSBT's charitable funds which are used to support staff welfare and small research and development projects. NHSBT is the corporate trustee of the Trust Fund. The Board of NHSBT acts on behalf of the corporate trustee and Board members are not individual trustees
Finance & Performance Committee	Responsible for scrutinising NHSBT financial and planning reports, making recommendations to the NHSBT Board on financial performance, planning and pricing issues and providing assurance that these are being managed effectively
Audit Risk and	Formerly the Governance and Audit

Governance Committee (ARGC)	Committee (GAC). Provides the Board assurance that governance, risk management and internal control processes across all clinical and non-clinical activities are effective. The reports to ARGC are from Directors and Managers and Internal and External Auditors. The internal auditors are GIAA (the Government Internal Audit Agency). The ARGC also approves the Annual Report and Accounts on behalf of the Board and reviews the work and findings of the National Audit Office
Research and Development Committee	Provides strategic advice to the Board on the NHSBT research programme. It approves and allocates available funding for research projects within the delegated financial limits of NHSBT. It receives annual reports and monitors progress on funded projects and commissions research from external sources where appropriate. It also seeks assurance that appropriate arrangements are in place for staff development, research governance, agreements with academic and commercial collaborators, and protection of Intellectual Property. It further receives and considers the Annual Report of Research that is required by the DHSC

The Executive team

58. This group is the organisation's most senior leadership team. The Executive team has no specific delegated authority from the Board but acts as an advisory forum for all areas of the business and regularly reviews and contributes content to the Board and Sub-Committees. Proposals seeking approval from the Chief Executive are shared at

Executive team meetings for discussion and approval. The Executive team committee currently has several subcommittees that also report to it:

a. CARE - The Clinical Audit, Risk and Effectiveness **('CARE')** Committee's purpose is to provide the Executive Team, Audit and Research Governance Committee **('ARGC')** and Board with information on all elements of clinical effectiveness, and thus provide assurance on patient and donor clinical outcomes and safety, as well as management of clinical risk. Further details of this committee are provided in section 9.

b. Risk Management Committee **('RMC')** - This Committee is responsible for overseeing NHSBT's risk management framework ensuring it's the suitability, adequacy and effectiveness of NHSBT's risk management system. The Committee assists and makes recommendations to the NHSBT Board and Executive Team to fulfil their responsibilities regarding the risk appetite of NHSBT, its risk management and compliance framework, and the governance structure that supports it. Within its remit, the RMC also reviews the NHSBT Business Continuity Management System to ensure its continuing suitability, adequacy and effectiveness.

c. The Equality, Diversity and Inclusion Council – this body is responsible for overseeing NHSBT's commitment to develop a more diverse and inclusive organisation and to help establish and maintain a just culture. The Council provides oversight of the equality, diversity and inclusion programme and makes recommendations to the NHSBT Executive Team to fulfil NHSBT's responsibilities and ambition on equality, diversity and inclusion. It is also responsible for agreeing its objectives and monitoring progress to ensure delivery and impact of a programme of cultural change to generate improvements in employee morale and engagement.

d. Blood Operations Leadership Team **('BOLT')** - BOLT provides a focal point for the coordination of the blood supply chain strategic and operational delivery. It aims to improve overview and governance of the blood supply chain operational delivery, through effective decision-making, coordination and problem solving; and provide a holistic view and challenge of operational delivery performance across the blood supply chain. BOLT also provides effective challenge and scrutiny of relevant risks to the blood supply chain within the Corporate Risk Register and ensures the effective coordination of blood donor marketing activities and collection capacity, to ensure that the demand for blood is met. Lastly, BOLT reviews and approves the Blood Supply RACI (Responsible, Accountable, Consulted, Informed) document and the Terms of Reference for other meetings in the integrated supply planning process. The body is empowered to make decisions on all matters relating to the blood supply chain strategy and operational delivery.

Operating Units (WITN0672009)[15]

59. NHSBT is made up of the following operating units:

Donor Experience	Is responsible for recruiting the public to be donors for all aspects of NHSBT ie blood, platelet, plasma, stem cells (via the NHSBT British Bone Marrow Registry) and for marketing for the organ donor registry.
Blood Supply	Provides blood and blood components, primarily to NHS hospitals.
Clinical Services	This consists of two operational divisions described below as well as holding the responsibility for corporate clinical governance,

[15] NHSBT Annual Report 2019 – 2020, pg. 82; see also pg. 17 [WITN0672009]

	corporate R&D infrastructure and for R&D provision through the Medical Directors of each unit. Clinical Services also provides the majority of the interface with the NHS, largely through relationships with clinicians and hospital trusts. Pathology - provides specialist laboratory services (for example, Red Cell Immunohematology and Histocompatibility & Immunogenetics). Cellular Apheresis and Gene Therapies – These services provide stem cell transplantation services to some hospitals in the NHS, and includes Cellular and Molecular Therapies laboratories, the British Bone Marrow Registry (BBMR) and the Cord Blood Bank (CBB). Apheresis services provide a range of therapeutic apheresis services (e.g. plasma exchange, photopheresis) direct to patients in the NHS.
Organ and Tissue Donation and Transplantation	Funded by DHSC, with contributions from the Devolved Health Administrations, this Directorate has the remit to identify and facilitate the donation of organs, to manage the NHS Organ Donor Register and National Transplant Register, which lets us fairly match donors to people who are waiting for a transplant. The Directorate also retrieves, manufactures and provides human tissue products. The tissue and eye service, which processes tissues and eyes recovered from deceased donors (and some products such as serum eye drops), is funded on a cost per unit basis charged to trusts.
Plasma	Plasma collection has been run as a Transformation Programme during 2020 and to date.

60. These operating units are supported by Group Services which comprises the following directorates:

a. Quality Assurance
b. Finance
c. People
d. Digital, Data and Technology Services
e. Strategy and Transformation

(e) Remit, including geographical area and transfusion centres within this area

61. NHSBT's functions in relation to blood apply to England only (WITN0672007)[16]. However, NHSBT also has responsibilities across the United Kingdom with regard to organ donation and transplantation.

62. Much of the remit of the organisation is detailed in my answer to question 3 and question 4(f). The geographical areas and transfusion centres are detailed below.

63. NHSBT operates various permanent sites around England. These include blood centres, apheresis centres, and other administrative locations. The issue of what a "transfusion centre" is today is addressed in section 4 below. As is set out there, the apparent successor to the RTCs were the blood centres **('BC')**. NHSBT currently has 86 properties, of which 34 are donor centres. I have been provided the following details from our Head of Estates:

a. We have 36 stand-alone blood donation team bases. We have a further four blood donation team bases at main blood centres. A further two are co-located with donor centres. A final one is co-located with a warehouse.
b. We have 15 stand-alone donor centres at: Edgware, Luton, the West End (WEDC), Leicester, Bradford, Nottingham, Leeds,

[16] NHSBT initially provided a blood service to England and to North Wales but that changed to England alone in May 2016 when the All Wales Blood Service was formed. See [WITN0672007].

Manchester (Norfolk House), Birmingham, Liverpool, Stoke, Bristol, Gloucester, Poole and Shepherd's Bush. We have a further eight stand-alone donor centres in main blood centres: Manchester (Plymouth Grove), Oxford, Newcastle, Tooting, Cambridge, Lancaster, Southampton and Plymouth.

c. We have four primary centres which are involved in, among a range of other things, processing: Filton, Manchester, Colindale, and Speke.
d. We have 10 other main centres (including laboratories and stock holding units): Barnsley, Newcastle, Oxford, Basildon, Birmingham, Cambridge, Tooting, Southampton, Plymouth, and Lancaster.
e. We have three stand-alone warehouses: Borehamwood, Warrington, and Bristol.
f. We have an Organ Donation and Transplant office at Stoke Gifford.
g. We also have three stand-alone regional Organ Donation and Transplant offices at Cardiff, Falkirk and Belfast.
h. We have a further stand-alone office at Basildon.
i. We currently have a Clinical Biotechnology Centre at Langford. However, this is due to close in early 2022 and be relocated at Filton.
j. We have Therapeutic Apheresis Services embedded in five hospital trusts: Leeds, Liverpool, Manchester, Bristol, and Sheffield.
k. We have seven plasma collection centres at Croydon, Chelmsford, Stratford, Twickenham, Bolton, Stockton, and Reading. In addition, there are four other centres at NHSBT sites: Bristol DC, Manchester, Birmingham DC and Barnsley.

64. The large majority of blood donations take place at temporary locations, often in church halls or commercial sites. These temporary locations operate all around England.

(f) Legislative and Regulatory Framework

Legislative Framework

65. NHSBT is a statutory body which came into existence on 1 October 2005 under NHSBT (Establishment and Constitution) Order (SI 2005 No. 2529) **('the NHSBT Order 2005') [RLIT0001551]** and is regulated by the NHSBT (Establishment and Constitution) Regulations (SI 2005 No. 2531) **('the NHSBT Regulations 2005') [RLIT0001553]**. Further detail is provided above and in the *NHSBT Family Tree* document [WITN0672007]. It is constituted as an SHA in England and Wales with responsibilities across the United Kingdom for organ donation and transplantation.

66. Special health authorities are governed by the National Health Service Acts. The statutory functions conferred on NHSBT are set out in regulation 3 of the NHSBT Order 2005 [RLIT0001551].

67. The NHSBT Regulations 2005 [RLIT0001553] require NHSBT to adopt Standing Orders for the regulation of its proceedings and business.

68. NHSBT is also directed by the Directions (already commented upon above), which govern the arrangements relating to England for blood and relating to England and Wales for tissue and organ donation and transplantation services.

69. NHSBT also must comply with the duties of the Secretary of State in the Health and Social Care Act 2012 [WITN0672009][17].

70. NHSBT ensures that it has appropriate arrangements in place for the discharge of each of the statutory functions for which it is responsible and is clear about the legislative requirements associated with each of them, specifically any restrictions on the delegation of those functions. It ensures that it has the necessary capacity and capability to undertake those functions and ensures that it has the statutory power to take on a statutory function on behalf of another person or body

[17] NHSBT Annual Report 2019 – 2020, pg. 57 [WITN0672009]

before it does so. NHSBT will also ensure that there is a periodic audit of the discharge of its statutory functions in line with the Harris Review [WITN0672013].

71. There is no legislation directing NHSBT to provide organ donation and transplantation services to Scotland and Northern Ireland. In lieu of this, 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 [WITN0672011][18].

72. In addition to statutory requirements, the Secretary of State, through the DHSC, issues further requirements and guidance. These are normally issued under cover of a circular [WITN0672010][19].

Regulatory Framework

73. NHSBT is accountable to the four Health Departments in the UK for the delivery of organ donation and transplantation, and to the English Health Department for providing a blood service[20]. It is responsible for the delivery of policy objectives set for it by all of the four UK governments and works with them to facilitate effective delivery solutions in case of policy differences (Framework Agreement para 3.4 [WITN0672011]).

74. NHSBT is responsible for the safety of its donors, patients and its workforce and operates in a highly regulated environment (NHSBT Annual Report 2019-2020 p.20 [WITN0672009]).

    a. NHSBT is registered with the Care Quality Commission (**CQC**). The CQC monitors, inspects and regulates blood and plasma

[18] Framework Agreement between the Department of Health and NHS Blood and Transplant 2014, para 3.3 [WITN0672011]
[19] Standing Orders 2019 at 1.2 [WITN0672010]
[20] NHSBT Annual Report 2019 – 2020, pg. 20 [WITN0672009]

donation and the Therapeutic Apheresis Service to make sure they meet fundamental standards of quality and care.

b. The Medicines and Healthcare Products Regulation Agency **('MHRA')** is responsible for the regulation of medical devices and medicines used in healthcare and the regulation of blood establishments.
c. The Human Tissue Authority regulates the removal, storage and use of tissue and cells and organs for transplantation.

75. The Codes of Conduct and Accountability for NHS Boards [WITN0672014] were issued in April 1994 under EL(94)40 and last revised in July 2004. The Code of Conduct and Accountability requires that, inter alia, Boards draw up a schedule of decisions reserved to the Board, and also to ensure that management arrangements are in place to enable responsibility to be clearly delegated to senior executives (a scheme of delegation). The Code also requires the establishment of audit and remuneration committees with formally agreed terms of reference. The Code of Conduct makes various requirements concerning possible conflicts of interest of board members.

76. Framework Agreements exist between the DHSC and each of its Arm's Length Bodies **('ALBs')**. The purpose of the Framework Agreement is to define the critical elements of the relationship between the Department and its ALBs for functions carried out for the health system in England. The document is focused on:

a. How the Department and the ALB work in partnership to serve patients, the public and the taxpayer; and
b. How the ALB and the Department discharge their accountability responsibilities effectively.

77. The Framework Agreement between the Department and NHSBT was reviewed and jointly approved by the Department and the NHSBT Board in March 2014 [WITN0672012].

78. As has already been discussed, NHSBT has Standing Orders [WITN0672010] which constitute the composition of the board and the conduct of its meetings. It also has Standing Financial Instructions [WITN0672015] which describe the high level financial control procedures. There is also the SoD (Scheme of Delegation) [WITN0672012], which has already been referenced.

79. The SoD defines the overall accountability of the Board to the Secretary of State for Health. The SoD sets out the responsibility of the Board for setting policy, determining the strategic direction, setting strategic objectives for the Operating Divisions and Group Services, and monitoring performance against these objectives. Similarly, the SoD sets out the responsibilities of the Chief Executive, the Operating Division Directors and Group Directors to manage the activities of the NHSBT, to prepare business plans and report on performance to the Board.

80. The delegations, including financial limits, to achieve the strategic objectives and the business plans are detailed in the SoD. The SoD also sets out responsibilities of all NHSBT colleagues for receiving and holding funds on trust for the NHSBT.

81. As a statutory body, NHSBT has specified powers to act as a regulator, to contract in its own name and to act as a corporate trustee. In the latter role it is accountable to the Charity Commission for those funds deemed to be charitable as well as to the Secretary of State for Health & Social Care.

82. There is additional legislation and regulation related to organ donation and transportation services, however, that is less relevant for present purposes[21].

[21] Further information can be found here: odt.nhs.uk/odt-structures-and-standards/regulation/

5. Please explain how the structure of NHSBT has changed over time in light of questions 4(a) to (f).

General Commentary

83. The historic structure of NHSBT is something that I talk about in a number of my answers to this rule 9 request. Instead of repeating that detail, in this answer I have tried to give a headline summary of the structure and changes over time. Additional detail is provided in, for example, my answer to section 3 and my answer to question 18.

84. In essence the service has developed from a disparate group of semi-autonomous regional bodies who were managed, funded and governed very differently, with a line through Regional Health Authorities to DH. From 1988 there existed a body with a central coordinating committee function, but the management continued to report through the Regional Health Authorities. Subsequently in 1993 the National Blood Authority was formed with a professional management committee directly accountable to and funded by DH. The RTCs were incorporated into the NBA. Thereafter, in 2005, NHSBT was formed and now works as a national, coordinated body for blood across England, whilst maintaining its accountability to the (now) DHSC.

85. As Dr Gunson explained in his statement for the HCV (Hepatitis C virus) litigation, which has been made available to me [NHBT0000026_009], the position in Scotland, Northern Ireland and Wales was different. Scotland for example, retained throughout its own centrally-managed and independently funded service, established in 1940, comprising five RTCs.

86. The establishment as an SHA in 1993/1994 allowed the organisation to develop on a functional basis as a truly national body with effective funding, governance and lines of accountability. This allowed decisions, submissions about the need for change, research, and

improvements to be clearly understood and articulated and streamlined, it modernised and increased the efficiency of the service. It is no longer dependent on various standing or ad hoc committees to influence events and is able to speak with one voice when new challenges arise, such as vCJD (variant Creutzfeldt-Jakob disease), hepatitis E and Covid 19.

87. This was not the position for example in relation to screening for hepatitis B or C and the challenges of HIV / AIDS (human immunodeficiency virus / acquired immunodeficiency syndrome). It seems, reviewing the information retrospectively many years later, that Dr Gunson as Consultant Adviser to the Government and National Director, had to tread a delicate and diplomatic path between the demands of the Department and the different needs and idiosyncrasies of the RTCs and their Directors, the Regional Health Authorities **('RHAs')** who often had to be persuaded of the need for and costs of whatever was proposed and liaison with other UK blood services through joint committees, meetings and letters.

88. The blood service throughout various reviews over the years had essentially been keen to become an SHA as soon as that was considered appropriate. This model has now allowed the blood service to become fully national and coordinated, with effective avenues of communication in England and across the UK. This made it much easier to address the first challenges to arise after the blood service was given that status, in the HCV lookback, vCJD and the challenges since.

89. Further detail of how the structure of NHSBT has changed over time is provided in the NHSBT family tree [WITN0672007].

1921 – 1946

90. During this time, we are discussing a decentralised blood donation service. The nature of the RTCs prior to 1 April 1994 has already been

discussed above. Further information is provided in the response to question 18. This is also detailed in chapters 2, 3, and 11 of *Fifty Years of Blood Transfusion* [NHBT0000028].

91. The response to question 3 sets out:
    a. staffing, in particular the roles and responsibilities of key decision-makers within the decentralised blood donation service in existence at this time;
    b. the remit, including some detail around the geographical area covered by NHSBT's predecessors during this period.

92. There is limited information available on the legislative and regulatory framework during this time.

93. Between 1944 and 1946 I understand the service was briefly unified before the RTCs in existence at the time came into control of the regional health boards in 1946.

1946 – 1992

94. In 1946, the RTCs consolidated as the NBTS. I understand that from 1948 to 1993 there was no body which held authority over the individual transfusion centres. Each of the RTCs remained a separate entity led by a Regional Transfusion Director (**RTD**).

95. During this period, the lack of any central authority was a real issue. In understanding how, and by whom, key strategic decisions were made, assistance can be sought from the:
    a. response to question 18 - sets out the historical position;
    b. response to question 15 – describes the formation of the National Directorate of NBTS in July 1988 of which Dr Gunson was appointed the National Director in that same year.
    c. Additional detail about the role of the National Director and Directorate is also set out in the response to question 18, *The NHSBT Family Tree*, Dr Gunson's statement for the HCV litigation

[NHBT0000026_009] and *Fifty Years of Blood Transfusion* [NHBT0000028]. One point to note is that the work of the National Directorate was also done without any executive authority over the RTCs as they continued to be regionally managed by the RHAs.

96. In understanding how NBTS and the RTCs were funded during this time, the responses to questions 3 and 18 are of assistance, the latter of which describes the position following the devolution of budgets to districts.

97. The response to question 15 includes further information about NBTS in respect of the structure, composition and role of its various committees or working groups.

98. I understand that, by 1970, there were 14 quasi-independent regional centres and two central laboratories in England and Wales. All were attempting to provide a uniformly efficient service but without central coordination other than the RTD Committee which had no formal authority. Further detail can be found in the response to question 18.

99. I understand from an NBA half year review that, by April 1994, NBTS was made up of 13 RTCs across 16 sites [NHBT0015901_001]. From that date the regional health authorities no longer managed the RTCs. As a result, the name of the RTCs was changed to Blood Centres. Further information on the BCs and in particular the remit and geographical remit covered is set out in the response to question 18.

1992 – 2005

100. On 27 November 1992, DH announced its intention to establish a single body with executive authority, the National Blood Authority, on 1st April 1993, with responsibility for both the central laboratories in England and Wales and the RTCs. The NBA consisted of the Blood Products Laboratory **('BPL')** and the RTCs network making up the

NBTS. BPL was accountable to the Chief Executive and Accounting Officer via the BPL Committee and NBA Executive.

101. This consolidation was partly a response to the lack of central authority. Over the years following this consolidation, the BCs ceased to operate as distinct centres and increasingly were treated as parts of the whole institution.

102. I understand from an example of the minutes of the NBA that I have been provided with, from 23 September 1998 [NHBT0007687], that reports and the leadership at this time came from the Chief Executive, the Medical Director and the Director of Finance and Administration. Once the NBA was formed, the Chief Executive became the Accountable Officer for the performance of the organisation. The Medical Director's portfolio changed over the years, but included medical staffing, approval and delivery of clinical policies, and, from 2007 onwards, research. The Medical Director was also an Executive Director of the Board and thus shared responsibility for Board decisions.

103. From the half year review of the NBA that I have been provided with [NHBT0015901_001], it would appear that:

The overall philosophy has been to run a decentralised organisation with a "lean and mean" head office where direction can be given by functional specialists and a strong executive team and main board.

The philosophy means that the NBA must learn to use the considerable pool of talent which exists throughout the RTC's and BPL instead of appointing extra headquarters staff.

104. The NBA was an SHA. As I understand it, this was a complex organisation having multiple functions and belonging to a series of wider networks in both its commissioning and provider roles. This

complexity was reflected in the way it was organised. Although line management responsibility was discharged through a series of Operational and Support directorates, the philosophy behind the Service's management arrangements was that:

a. a corporate approach to the planning, development and delivery of services was essential;
b. the range of cross-directorate (corporate) objectives, organised around the service's three key business processes (relating to the patient, the donor and the organisation), impacted on all service areas and required leadership. Where a director or manager had such a role, they were accountable across the organisation and linked with managers in all directorates.

105. Capital funding was received from the Department of Health in order to purchase and replace fixed assets. The Authority primarily recovered its costs by charging NHS Trusts and other organisations for the supply of blood components and associated costs and services. These costs only reflected the handling charges, as all blood collected is freely donated by volunteer donors. I have been provided with the NBA Report and Accounts for April to September 2005 which set out some of the details of this [WITN0672016]. Further information on how the NBA was funded is set out in my response to question 18.

106. As I set out in more detail in the preceding answer, the NBA and now the NHSBT had/has a Board comprising Executive and Non-Executive Directors, which is the highest-level decision-making body within the organisation, being responsible for strategic direction and approval of major spending decisions. Executive Directors are responsible for the operational management of the organisation.

107. NHSBT is accountable to DHSC, and thus liable to instruction from Health Ministers, who in turn may receive advice from SaBTO and other advisory bodies. NHSBT may also receive advice from groups producing relevant guidelines or information, e.g. JPAC, the British

Society for Haematology, NICE (National Institute of Health and Care Evidence), and the NHS Central Alerting Service. Clinical governance arrangements ensure systematic review and implementation of such guidance.

108. On 1st April 1994, the 13 RTCs came under NBA control, which resulted in an organisation of around 4,500 people covering the same geographical areas as NBTS [NHBT0015901_001]. The legal rights and obligations of the RHAs in respect of the RTCs were transferred to the NBA on 1 April 1994. This legal position has continued since 1 October 2005 and the establishment of NHSBT. Thus, from a legal perspective, there has been no distinction between the NBA (and, later NHSBT) and the 'transfusion centres' since 1 April 1994.

109. Further information about the NBA's legislative and regulatory framework is set out in the responses to question 3 and 18.

2005 - Present

110. The NBA and UK Transplant were replaced by the establishment of NHSBT in 2005. That information has already been discussed in questions 3-4 above and will continue to be provided as I give a picture of the current position at NHSBT in my other answers.

6. Please provide a list of individuals who held decision-making roles in NHSBT from 1970 to today.

111. I have provided part of my answer to this question as [WITN0672017] with details of the Chief Executives and Medical Directors in the table below.

112. As I have already noted in my answers above, NHSBT only came into existence in 2005. I assume that this question is referring to the RTCs making up the NBTS prior to the establishment of the NBA in 1993.

113. I only joined NHSBT in 2010, and therefore have no knowledge of the staff of the institution prior to that time. I also have limited knowledge of specific roles and tenure of staff even in recent years. I have been provided details given in the exhibit by other staff at NHSBT, and by those advising me who have collected information while reviewing documents. More detail is available on mid-level decision makers from recent years and this is reflected in the tables. Save for reading the provided and exhibited tables, I have very little first-hand knowledge of any of the matters set out therein.

114. It is not entirely clear what a "decision-maker" is for the purposes of this question. This answer tries its best to identify relevant senior people. This represents the best attempt that we could make in the time available using proportionate resources. While it tries to provide as much information as possible it is not a complete record. Nor does the table reflect all roles held by a particular individual, the records therefore prioritise the most senior position that they held.

115. I understand from those who provided these tables for me that a question mark next to any piece of information indicates something which is unclear.

116. Some of the information in this answer has been obtained by reviewing the NBA annual reports. I provide them as exhibits to assist the Inquiry. For example 1995 WITN0672018], 1996 [WITN0672019], 1997 [WITN0672020], 1998 [WITN0672021], 1999 [WITN0672022], 2000 [WITN0672023], 2001 [WITN0672024], 2002 [WITN0672025] and 2005 [WITN0672026].

117. I provide details of medical and chief executives to NHSBT and precursor bodies here. The remainder of the information is set out in [WITN0672017].

Title	First Name	Surname	Tenure Start	Tenure End
Chair NBA/NHSBT				

Sir	Colin	Walker	1993	1998
Mr	Mike	Fogden	1998	2005
Mr	Bill	Fullagar	2005	2013
Mr	John	Pattullo	2013	2017
Ms	Millie	Banerjee	2017	2021
Mr	John	Pattullo	2021	present
Chief Executive NBA/NHSBT				
Mr	John	Adey	1993	1997
Mr	Barry	Savery*	1997	1998
Mr	Martin	Gorham	1998	2007
Ms	Lynda	Hamlyn	2008	2014
Mr	Ian	Trenholm	2014	2018
Ms	Sally	Johnson*	2018	2019
Ms	Betsy	Bassis	2019	present
National Director of NBTS				
Dr	Harold	Gunson	1988	1993
Medical Director of the NBA				
Dr	Harold	Gunson	1993	1994
Medical Director of the NBA/NHSBT				
Dr	Angela	Robinson	1994	2007
Medical Director of NHSBT				
Dr	Tim	Wallington*	2007	2007
Dr	Lorna	Williamson	2007	2016
Dr	Gail	Miflin	2016	present
Consultant Advisor to DHSS				
Dr	William	Maycock	1946	1978
Dr	Geoffrey	Tovey	1978	1981
Dr	Harold	Gunson	1981	1994

*Denotes interim appointment

7. Please describe NHSBT's involvement in any other inquiries, investigations or criminal/civil litigation in relation to the human immunodeficiency virus ("HIV") and/or hepatitis B virus ("HBV") and/or hepatitis C virus ("HCV") infections and/or variant Creutzfeldt-Jakob disease ("vCJD") in blood and/or blood products.

118. I deal separately with inquiries, investigations and criminal/civil litigation. For the reasons I have already explained in respect of historic events, my knowledge of these matters is very limited.

Lookback Inquiries and Investigations

119. We have submitted detailed responses to the lookback Rule 9 request setting out the origin of jaundice inquiries from the Second World War,

lookback exercises following the introduction of screening for Hepatitis B, HIV and Hepatitis C and the involvement with the Transfusion Medicine Epidemiology Review **('TMER')** in relation to cases of possible transfusion transmitted vCJD.

120. We have described in this and other responses submitted to the Inquiry how cases of infection possibly caused by transfusion, where they were identified and notified to the blood services, are and were investigated by NHSBT and our predecessor organisations. This was by way of traceback or reverse lookback. It included the first HIV transmission in England after screening was introduced, which occurred in 1996.

Other Inquiries

121. I am aware of previous relevant inquiries including the Archer Inquiry and Penrose. In an earlier response dated 6 September 2018, we have noted that we provided documents in response to a request by the Penrose Inquiry. This included a number of sets of minutes which are also available to this Inquiry. How NHSBT considered the findings by Lord Penrose is addressed by Dr Williamson in her response to the amended rule 9 request of 14 August 2020 (the lookback request).

Civil Litigation

122. In terms of litigation, individual claims are received, and since we joined the Clinical Negligence Scheme for Trusts have been dealt with, on our behalf by the NHS Litigation Authority, now known as NHS Resolution, which was established in 1995, as is the case with all claims for clinical negligence against the NHS in England. NHS Resolution also deals with non-clinical claims, covered by the Risk Pooling Scheme for Trusts (RPST), on behalf of NHSBT.

123. Prior to that, the blood service in England was assisted in dealing with civil litigation by solicitors Le Brasseur J Tickle. An example is document [NHBT0004800], a letter I have been shown, dated 15 May

1991, from Dr Hewitt to Dr S. Adam, North West Thames Regional Health Authority, regarding an allegation of transfusion transmitted HIV infection from a transfusion in 1984, before screening was available.

124. I have been provided document [NHBT0005963_001], which is a letter dated 28 December 1994 from Dr Robinson to John Lovell, Yorkshire Health Legal Services, regarding the number of legal cases pending against the 13 RTCs at that time, and regarding National Blood Authority policy that all HIV and Hepatitis C cases should be centrally managed due to the potential national impact. The *NHSBT Family Tree* document sets out how the national blood service changed its status and responsibilities over time, including moving from Regional Health Authorities to the National Blood Authority.

125. I understand that document [NHBT0010128] is a summary for the NBA Board Meeting on 20 March 1997 of current claims at that time, broken down between the three Zones. Out of a total of 83 claims, 73 were current and 40 had arisen from the HCV lookback exercise, of which 35 were live at that time. The third graph shows the basis of the claim and that 52 of the 73 live cases were HCV transfusion claims.

126. The National Blood Authority was the defendant in the group claim brought under the Consumer Protection Act 1987 – *A and others v National Blood Authority* [2001] EWHC QB 446 (26th March 2001), the papers relating to which have been provided to the Inquiry. Dr Gunson's statement in that litigation, referred to several times in this response, has been a useful resource for us in responding to the Inquiry's requests, and I expect to others, in understanding the structure and working of the English blood service at the relevant time.

127. There was also some blood service involvement in the HIV litigation in relation to which papers are available on Relativity, including for example [CBLA0000006_037] which is the Defence of North West Thames Regional Health Authority to the Re-Amended Main

Statement of Claim. As I understand it, the involvement of the blood services would have been via the Regional Health Authorities who were responsible for RTCs at the time. The Defence referred to above of North West Thames RHA is in relation to their role at the material time in hosting the Central Blood Laboratories and does not relate to the work of the transfusion centre. In 1994 (by the time of the HIV litigation) responsibility for both the central laboratories and the RTCs had transferred to the National Blood Authority. However, as I understand it, the Central Blood Laboratory Authority **('CBLA')** was funded by DH, who underwrote the costs and any liabilities in that litigation. The role of the blood services in that litigation was limited I think to providing information to the RHA defendants.

128. As I understand it, Dr Gunson provided draft expert evidence in the HIV litigation: [DHSC0000142].

Current Group Litigation

129. I am aware that there is a Group Litigation Order covering at least several hundred claimants brought by Collins Solicitors, which is stayed pending the outcome of the Inquiry. As I understand it, the Secretary of State for Health is the defendant, but I am told that there are other potential group claims in relation to which NHSBT is on notice.

Criminal Proceedings

130. I am not personally aware of any criminal investigations or proceedings that have involved NHSBT but have been advised of the following

131. Professor Allain of the Cambridge RTC was convicted in France on charges relating to the safety of blood products there in respect of HIV. I know nothing about this but note that document [MDIA0000064] is a Guardian report dated 23 June 1992 of the trial in France.

132. For completeness, I also understand that Dr Marcela Contreras (as she then was) was involved in giving evidence in the 1980s at the Old Bailey[22] [RLIT0001555] and [RLIT0001556] in the prosecution of individuals involved in the theft of plasma from North London RTC at Edgware, although I know no more than that. I have also seen reference to criminal proceedings relating to plasma theft from the Army Blood Supply Depot, which I refer to in my answer to Q40 arising out of minutes I was provided for that section.

Inquests

133. I understand that from time to time we are or have been involved in inquests the nature of which would fall within the Inquiry's Terms of Reference. Some of these have included core participants to the Inquiry. I understand that a separate response has been submitted in relation to a Rule 9 request dealing specifically with inquests.

Section 2: Record keeping arrangements

134. I should begin by noting that the vast majority of the information set out in my answers to this section has been provided by others working within NHSBT. The storage of information and record keeping arrangements are, save for at a high level, not in my knowledge. Insofar as I deal with the historic position in this section, the position is the same as elsewhere. I am limited to referring to the available documents that have been provided to me by those advising me as I have no first-hand knowledge.

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22 [RLIT0001556]

[RLIT0001555]

8. Please describe the record keeping system in place for donor information at NHSBT, both currently and historically.

135. I have previously provided a draft witness statement to the Inquiry which provides an account of the NHSBT archiving system [WITN0672001]. That account reflects the position as was understood to be the case by NHSBT as it was at 5 September 2018, the date of the draft. That account of the archive system includes, but is not limited to, a description of the record keeping system in place for donor information at NHSBT as it was at 5 September 2018. That account was prepared with help from colleagues and much of the detail is provided by others. I will therefore repeat here the relevant paragraphs from that witness statement:

26. NHSBT is obliged to maintain substantial cohorts of records to support its quality system and for operational and medico-legal purposes. Many of these records either pre-date, or are supplementary to, computer-held electronic records and so are held on paper.

27. NHSBT has an off-site paper archiving agreement with Iron Mountain ('IM'). IM is currently the sole provider of such services to NHSBT. As I understand the position, prior to the agreement with IM, TDG[23] provided our archiving services. Procurement services have stated that the first record of a contract with TDG is from 1 November 1999. We believe that TDG was taken over by IM in 2002 and then a new contract appears to have been entered into with IM in 2005.

…

29. IM store the vast majority of NHSBT's paper records across four different sites in the UK. In order to ensure that regulatory requirements of the Medicines and Healthcare Products Regulatory

[23] Transport Development Group.

Agency (who are the appointed competent authority under the Blood Safety and Quality Regulations) are met, NHSBT sites retain paper records for at least two years…

…

35. Paper archive storage at NHSBT is managed via a suite of documents and are controlled under NHSBT's 'Quality Management System' ('QMS'). This system is established to meet regulatory traceability requirements.

36. The following QMS documents are utilised by trained staff to send department's records off-site to IM. The primary documents linked with the archive process include a storage specification (SPN) and a number of 'work instructions' (termed 'Standard Operating Procedures' - SOPs).

- *Specification (SPN189) 'NHSBT Record Storage' applies retention periods to defined document types linked primarily to the requirements of the Records Management NHS Code of Practice and the Blood Safety and Quality Regulations.*

- *Work instruction (SOP492) 'Preparation, Transfer and Retrieval of Archive Records' using 'IM Connect' is the procedure used to manage the addition of new boxes into storage and the retrieval of boxes from the archive utilising an on-line access tool.*

- *Work instruction (SOP14) 'Issue of Archive Storage Box Labels & Barcode Reader' is the procedure used to manage the issuing of barcoded archive box labels and a barcode reader to a Department.*

- *Work instruction (SOP13) 'Review/Destruction of Paper Records Placed In Offsite Storage' – is the procedure concerning the*

destruction of paper records that have been placed into off-site storage at the end of their defined retention period. Although we have this SOP there was an embargo on the destruction of records relating to blood product traceability i.e. from the donor to the patient, that was put in place by the then Medical Director, Dr Angela Robinson. I attach marked 'GM 2' [WITN0672003] *an early (now obsolete) version of SPN189 'NBS Record Storage' which at page 10 includes a reference to "NBA Policy decision (1) by Dr Angela Robinson (NBA Medical Director & Caldicott Guardian) February 2001" and relates specifically in this document to the Donor's Donation History ('Donor 101 card or equivalent log'). I have also corroborated this with a colleague present at that time.*

- *In 2015 this decision was revisited when the Blood Supply CARE group recommended to NHSBT CARE (NHSBT National Clinical Governance, Audit, Risk and Effectiveness group) that the 30-year minimum retention requirement for donor to patient and patient to donor traceability should be formally extended to indefinite retention since 1980 on the basis of vCJD traceability requirements, while the 15 year minimum retention requirement for associated information is set at 15 years for Blood Supply records. This was approved at CARE with Dr Williamson as Chair.*

37. *Prior to 2015 NHSBT used a paper form (FRM23) to log archive boxes. Since 2015 the paper format for archiving was made obsolete and replaced by the electronic link to IM (Connect on-line portal) so electronic only logging of archive boxes has been in place since May 2015.*

38. *In relation to the archiving of the key donor health records 'Donor Health Checks' ('DHC'), NHSBT currently has a contract for the electronic storage of these forms with a third party supplier. Since 2014 all DHCs are stored electronically on a 'Visions System' at*

Restore. This is a secure system viewer accessed using individual usernames and passwords.

39. I attach marked 'GM 3' [WITN0672004] a description of electronic and heritage electronic systems in relation to Blood Donors and Blood Donations. The systems covered in the paper are Pulse – NHSBT Core Blood System covering both production and archive, Hematos - NHSBT Patient system, other NHSBT IT systems integrated to Pulse, heritage data stored both at the donor and donation level, physical data stored on Optical disk. The paper was prepared by NHSBT's Information Communications and Technology services.

136. It will be seen from my previous account above that NHSBT's current record keeping system for donor information comprises a variety of sources. This is a result of both developments in archival technology and the centralisation of blood services initially in 1993 with the establishment of the NBA and thereafter the foundation of NHSBT in 2005.

137. Historically, by 1970, there were thirteen RTCs managed by twelve (later fourteen) Regional Hospital Boards and then Regional Health Authorities following the National Health Service Reorganisation Act 1973. These RTCs were led by RTDs and effectively operated independently, including in relation to record keeping systems. Historically, therefore, record keeping systems in place across the RTCs was neither standardised nor consistent. There was site by site variation in the type of records created in local systems and then archived; the volume of records archived; the date ranges of records archived (and required retention periods); and the approach to the sorting and filing of paper records.

138. Greater consistency in record keeping has, however, been achieved since the implementation of a national computer system, Pulse,

between 1996 and 1998; coupled with the placing of a national paper archiving contract, initially with the Transport Development Group **('TDG')** in 1999 and then with Iron Mountain ('IM') from 2003, and national operating procedures.

139. Attached, NHSBT provides SPN1042/2 [WITN0672027] explains the history to date of donor information record keeping systems and archived data linked to blood supply and the processes in place for the retrieval of such data depending on the relevant storage medium, which in turn is determined by the date on which the data was entered into the archives. The document moreover provides timelines for individual site records which show the format in which records have been kept as they relate to a specific time period at a specific site. In summary, the records are found in the following formats:

    a. Paper records held off site (currently Iron Mountain – the management of such records is currently addressed in SOP4292 [WITN0672028]);

    b. Microfilm/microfiche records held on site in Manchester and off-site (currently Restore);

    c. Electronic heritage system records since 2019 held as a searchable 'national heritage database' backed up on the NHSBT network;

    d. Pulse archive system records; and

    e. Pulse live system records.

140. NHSBT SPN1042/2 [WITN0672027] should be read in conjunction with NHSBT GM/3 [WITN0672029]. NHSBT GM/3 (and its attached Pulse Specification PSPEC004 [WITN0672030]) is a paper prepared by NHSBT's Information Communications and Technology services

providing details of the ICT systems used by NHSBT in which information is stored electronically in relation to blood donors and blood donations. The original GM/3 [WITN0672004] is attached to my draft statement, but I have been provided an updated version of this document to be attached to my response to this rule 9 request.

141. Records were held primarily on paper from the 1940s up until the late 1980s using 'Donor 101 cards' or equivalent systems, for example 'Kardex' cards in the South West. Paper records are primarily held in commercial record storage facilities under the national NHSBT contract described above, currently with IM. The paper records typically contain the following information: donor demographic information, donation volume, venepuncturist's name, blood group information, record of donation history, and any clinical comments. In 2001, the National Blood Authority adopted a policy of indefinite storage of Donor 101 cards and their equivalents from 1980 onwards.

142. In the mid-1980s, some sites adopted microfilm and / or microfiche records alongside paper. Key donor health records 'Donor Health Checks' **('DHC')** archiving for NHSBT was initially undertaken by Advanced Microfilm Imaging from 1997 who had the contract for over 10 years. The work was then done by Electronic Document Management before TNT/Restore took over in 2014. This was done through microfilming under a national contract. A microfilm copy of the DHC is retained by the company to assist it in providing a DHC image retrieval service to NHSBT. The original DHC is destroyed after satisfactory quality control checks on the master film by NHSBT. Since 2014, NHSBT has had a contract with a third-party supplier, currently Restore Digital, for the electronic imaging and storage of DHCs on a secure system viewer accessed using individual usernames and password – the Vision system.

143. Between around 1990 and the implementation of Pulse between 1996 and 1998, all RTCs used in-house computer systems – now heritage

computer systems. These heritage systems were diverse, as was the format in which records were archived, and they were installed at different times at different centres. In 2011, Heritage database 1 was created, which was a single searchable heritage database covering most sites. It contained various data including testing, stock, donation and donor information of varying degrees. The process of moving information across to Heritage database 1 was difficult because it would depend on how the in-house computer systems at each RTC were set up. Not every historic record from these in-house computer systems was transferred to Heritage database 1. Insofar as there was a need to trace back information into the old records that were not transferred across, this was addressed in SPN1042/2 [WITN0672027] and MPD1407 [WITN0672031].

144. In 2019, a new national electronic heritage database covering all sites was created to replace Heritage database 1. Internally this is called the All_Heritage_Database. Heritage data requests are managed via MPD1407 [WITN0672031] '*Heritage Archive Request Management*' where data engineering search the virtual 'pre-Pulse heritage database' records. There was, until recently, heritage information from Tooting, Brentwood and Lancaster stored physically on optical disks and retained in a firesafe within Savant (the supplier of Pulse). This database has now been copied off the disks and is stored in the All_Heritage_Database.

145. As I have indicated above, since between 1996 and 1998, the heritage computer systems have been replaced by a national Pulse computer system which is the current core electronic system for donor record retention in NHSBT. During the period between 1996 and 1998, data was migrated from NHSBT heritage ICT systems in the various centres to the Pulse system. Within that migration, the Donation ID numbers of donations which were previously bled up to three years prior to the implementation of Pulse were copied into the new system but without component details. The historic data transferred would,

depending on the timing of the migration and the in-house system being migrated from, range between 1 and 3 years of information. In respect of the older Mithras computer system, which was used by some centres, there are migrated data records back to around 1990. A limiting factor with some of the information transferred across to Pulse was that some centres did not have full laboratory information management systems at the time of the migration: e.g. Lancaster, Leeds, and Cambridge.

146. Initially, Pulse was operated as three separate donor bases from three servers which covered three different regions until a single Pulse database was created in July 2008. The Pulse computer system consists of two elements: Pulse Live and Pulse Archive. A donor record will be sent from Pulse Live to Pulse Archive where the relevant donor has not attended an NHSBT site for five years. Pulse continues to be NHSBT's core electronic record keeping system for donor information, used in conjunction with the earlier archival technologies I have identified above where it is necessary to access a historic donor record.

147. There is also in operation a separate database called Hematos which has some links with Pulse. This is explained further in GM/3 [WITN0672029], but Pulse is the single integrated software package used within NHSBT. Hematos is used in the provision of services by NHSBT and is a single patient/donor record reference point. Donor information is retained and tracked in the Pulse system, albeit accessible through Hematos.

148. Aside from SPN189 [WITN0672032], NHSBT also has a number of policies that it uses for the backup of data, although there is no overarching backup policy to cover all systems (backup of Pulse is addressed below). These are MPD287 [WITN0672033] '*Pulse Backup Procedures*' v1.1 (22 November 2011), POL202 '*Infrastructure Backup*

Policy' v.1 (17 March 2015) and POL237 '*Stoke Gifford Backup and Recovery Policy*' v.1 (7 December 2014).

149. The earliest version of our current record storage specification, SPN189 [WITN0672032], dates back to 2009. I am told that this specification was based on an earlier policy SPN/PTI/QU/017. That policy was formulated from a policy group report from 1997 titled *Document Image Storage: Policy Group Report*. I understand that the various sources listed internally for the versions of SPN/PTI/QU/017 are:

a. BCSH Guidelines on product liability for the Hospital Blood Bank in (1990) 12 Clin. Lab. Haemat. 329-344.

b. Control of Substances Hazardous to Health Regulations.

c. The Document Image Storage: Policy Group Report 1997.

d. HC(89)20 Health Services Management: Preservation, Retention and Destruction of Records: responsibilities of Health Authorities Under the Public Records Act.

e. The Retention and Storage of Pathological Records and Archives: Bulletin of the Royal College of Pathologists January 1995.

f. NBA Policy Decision (1) by Dr Angela Robinson (NBA Medical Director & Caldicott Guardian) February 2001.

g. Blood Safety and Quality Regulations SI 2005/50.

150. The historic position in respect of record keeping is addressed in section 4. In short, because the control of the RTCs was devolved and not in a central body as it is today, the NBTS in its various forms had far less control of the record keeping arrangements at each centre.

There was no central location from which the blood service was run so, unlike today, there was no central place to retain documents.

9. Does NHSBT maintain a central database of blood donors? If so:

a. How long has this database been in operation?

b. What donor details does it record?

c. How is the information stored?

d. Who is able to access this information?

e. Is NHSBT required to report to other organisations in respect of any of the donor information it stores?

f. How long does NHSBT store this information for?

g. What is NHSBT's policy in relation to the destruction of these records?

151. The answers to these questions below, in line with the questions above, have required much input from colleagues in the NHSBT IT department and Quality Assurance departments. The complex nature of these systems means that much of how they are set up and work is not known to me. I do not have access to Pulse computer system in my current role and therefore do not use this on a day-to-day basis.

152. I have referred to the Pulse computer system above but for ease of reference NHSBT SPN1042/2 [WITN0672027] provides an overview of what data Pulse keeps and how this maps to the predecessor databases and record keeping systems. I have given an account of the Pulse computer system above in response to request 8, but I am happy to provide any further explanation that might assist.

153. For the avoidance of doubt, the Pulse computer system has since its full implementation in 1998 been the central system for blood donor information required for the collection, storage, testing, manufacture and distribution of blood and blood components. The data is held in a Mimer SQL database. It consists of two databases, being Pulse Live and Pulse Archive, both of which I have referred to above and which NHSBT maintains as its central database of blood donors.

154. Any donor records which are not captured on the Pulse computer system are kept in accordance with the historic record keeping systems identified above, namely: a) on heritage systems which since 2019 have been searchable across all sites on the All_Heritage_Database; b) on the Vision system; or, c) for any other donor records, the 'Donor 101 cards' or their equivalents, on paper or microfilm.

155. The Vision system is a record of individual donations and retains (among other things) the paper copies, in a scanned format, of the donor health checks and consent forms. The system exists to take in the bit of the donation process which is not digitised. Some of this information is stored within Pulse, as Pulse is designed to store the outcome information of a given donation. However, Vision is an independent database of information. If one wishes to search from Pulse into Vision, the information is cross-checkable using the donation identifier (for a given donation), the donor identifier (for a given donor) or aspects of the personal data.

a) – How long has this database been in operation?

156. The Pulse computer system has been fully operational for all blood donor information within NHSBT since February 1998, the point at which the Donation ID numbers of donations which were previously bled up to three years prior to the implementation of Pulse were

migrated from heritage systems to Pulse, which took place between 1996 and 1998.

157. The earlier myriad databases identified above, however, pre-exist the Pulse computer system and NHSBT SPN1042/2 [WITN0672027] provides an archive overview timeline, in addition to details of how to retrieve records where possible from earlier systems.

b) – What donor details does it record?

161. The donor details recorded by the Pulse computer system may be split between inputs and outputs. Inputs are the data which are recorded in order to facilitate future searches of a donor's details. Outputs are the data available to a user on completion of a search using the relevant inputs. Again, NHSBT SPN1042/2 [WITN0672027] provides a helpful summary of the relevant inputs and outputs for Pulse, in addition to earlier record keeping systems.

162. Regarding the Pulse computer system, the inputs and outputs are the same irrespective of whether the database being searched is Pulse Live or Pulse Archive.

163. In respect of inputs, the following data is recorded: Donor Number, consisting of nine characters including a check digit; Donation ID number, which since 1 April 2001 have been only in Code 128 format consisting of 14 characters including a check digit (all beginning with the letter 'G') – prior to then, some Donation ID numbers were in ABC Codabar format; forename and surname; and, date of birth.

164. In respect of outputs, the following data is recorded: donation information; address information; issuing information; medical history; laboratory history; manufacturing information; award information; audit

information; discretionary testing information; communications; deferral information; blood group information; and testing information.

165. Pulse holds data within a relational database where many data tables store the data. These matters are far outside my area of knowledge. There are over 90 tables in the system that hold donor data and NHSBT is happy to arrange for the appropriate members of staff to go through the detail associated with these tables on a call with the IBI if required. NHSBT does have a full breakdown of all the table structures that can be used as part of the discussion.

c) – How is the information stored?

166. Currently, the information is stored in the Mimer SQL relational database containing both Pulse Live and Pulse Archive, which is located in two data centres owned and operated by SCC in Birmingham. The database is backed up every night with a 13-month retention on the backed-up data. NHSBT has contracted with SCC since 2016, following NHSBT's exit from an NHSBT owned data centre in Elstree and migration of IT services from Colindale. MPD287, which is provided as an [WITN0672033], details the back-up information for PULSE further. While stored in a third-party centre, the hardware for the databases is that of NHSBT. A complete refresh of the Pulse hardware housing for the database was carried out and completed in August 2020.

d) – Who is able to access this information?

167. The Pulse computer system is accessible only to those NHSBT authorised users who have been trained in its proper use and duly authorised by NHSBT to access donor information. That will include the National Contact Centre, our call centre which is run by a third-party organisation (currently Teleperformance) and other contracting third parties, for example those who we contract to send out Donor

Health checks, emails and other forms of communication. However, to do so there will be training and monitoring of use. Moreover, a user's access to data within Pulse is limited on a role and action approved basis. Authorised users therefore will only see data available to their specific access levels and where appropriate training has been carried out for them to gain access to Pulse.

168. Currently, certain individuals, primarily Savant who design and run the system for NHSBT, have "non-captive accounts" which are not confined to the graphical user interface used by most users to access the database. Instead, Savant have back-end access to the database itself. Savant will, applying SOP1381 [WITN0672034] be able to make database amendments. The NHSBT data team also have non-captive accounts.

169. The database maintains audit trails of the documents that have been accessed by individuals, whether they are using a captive or non-captive account. This means that the information that is being accessed by individuals using the system can be monitored. In addition, NHSBT has since 2019 undertaken an annual review of privileged access on the system.

e) – Is NHSBT required to report to other organisations in respect of any of the donor information it stores?

170. Since May 2018 NHSBT has had a duty under the General Data Protection Regulations (GDPR) to report serious breaches of personal data to the Information Commissioner's Office. The thresholds for reporting can be found within the Data Security Protection Incident Reporting Guidance (DSP IR September 2018) [WITN0672035].

f) – How long does NHSBT store this information for?

171. NHSBT SPN189/5.1 *NHSBT Record Storage* [WITN0672032] governs NHSBT's policy on record storage, including the periods for which different records must be retained. The policy covers all records held by NHSBT, but I understand that the Inquiry's request relates only to that information which pertains to donors.

172. On 8 November 2005, the EU Blood Directive (Directive 2002/98/EC) came into force in the United Kingdom and was transposed into the Blood Safety and Quality Regulations (SI 2005-50) **('BSQR')** after a nine-month derogation period. For present purposes, the BSQR required that a) there must be a system to ensure blood components can be traced from donor to recipient for a period of at least 30 years; and b) donor records must be kept for at least 15 years.

173. On 9 February 2015, at a meeting of the BS Clinical Audit, Risk and Effectiveness Committee, it was agreed that NHSBT would set the 30-year minimum retention requirement for donor to patient and patient to donor traceability mandated by the BSQR to indefinite, while the 15-year minimum requirement for associated information would remain set at 15 years. I provide the minutes of the Clinical Audit, Risk and Effectiveness (CARE) Committee for 3 March 2015, where this decision was reported [WITN0672036]: "*A recommendation that the 30-year minimum retention requirement for donor-patient traceability is formally extended to indefinite retention since 1980 on the basis of vCJD traceability requirements has been approved. The 15-year minimum retention requirement for associated information was adopted. More work will be done to look at implementation*".

174. To my knowledge, currently, no key donor/donation data has been deleted from Pulse under these data retention policies (save for what follows). The issue is being reviewed at a national level. There have been deletions in specific cases where that has been requested by a donor. A snapshot of Pulse was also taken for the purposes of the IBI.

175. The position now, so far as is relevant, is as follows (it should be noted that for rules related to BSQR the time runs from the date of donation if appropriate):

a. Any record that supports traceability of blood and blood products from donor to issue is stored indefinitely. Relevant records include, but are not limited to, Donor 101 cards; donor, donation and product records held on current or legacy database systems; records of product traceability through manufacture e.g. batch records; and, issue records.

b. Where the records do not fall under the indefinite rule, records which are relevant to donor or donation safety, for example post-donation information, are stored for 30 years in line with BSQR traceability requirements;

c. Records relating to donation quality held by NHSBT's Component Processing/Production department are stored for 30 years in line with BSQR traceability requirements;

d. Records held by NHSBT's Donor Testing (Grouping and Microbiology) department relating to additional (non-mandatory) test worksheets and results, confirmatory testing worksheets and results, and grouping and testing summary results and statistics are stored for 30 years in line with BSQR and the Royal College of Pathologists' Guidelines **('RCPath Guidelines')**;

e. Records held by NHSBT's Donor Testing (Grouping and Microbiology) department relating to blood grouping result printouts, phenotyping records, manual grouping results, additional (mandatory) test results, microbiology result printouts, and QC Records including National External Quality Assessment Service **('NEQAS')** are stored for 15 years in line with BSQR and the British Society of Haematology Guidelines **('BSH Guidelines')**;

f. Records held by NHSBT's Hospital Services/Issues department relating to product issue records and product disposal records are stored for 30 years in line with BSQR traceability requirements;

g. Records held by NHSBT's Hospital Services/Issues department relating to donation quality, including temperature control charts, are stored for 15 years in line with BSH Guidelines;

h. Records held by NHSBT's Quality Assurance department relating to product recalls and issue concessions are stored for 30 years in line with BSQR traceability requirements and BSH Guidelines;

i. Records held by NHSBT's Quality Assurance department relating to non-conformance quality incidents are stored for 15 years;

j. Records held by NHSBT's Reference / Special Services department relating to detailed request forms and those containing clinical information; worksheets, laboratory books and other raw data containing test results for named patients; results of transfusion related tests; correspondence on patients; patient investigation reports; results of group and antibody screen; blood banking records; and, patient investigation reports are stored for 30 years in line with RCPath Guidelines and, in the case of blood banking records, also in line with BSQR traceability requirements;

k. Records held by NHSBT's Reference / Special Services department relating to records of any serious adverse events which may affect the quality or safety of blood or blood components, temperature records for refrigerators / freezers, and batch manufacturing records (reagents) are stored for 15 years in line with RCPath Guidelines and BSH Guidelines; and,

l. Records held by NHSBT's Transport department relating to temperature monitoring during the transport of products are stored for 15 years in line with BSH Guidelines.

g) – What is NHSBT's policy in relation to the destruction of these records?

176. The general position on the length of time for which documents are stored is dealt with in SPN189/5.1 [WITN0672032] already discussed above. That policy has been previously amended to emphasise that it applies to both physical and electronic documents. Therefore, what appears below in the rest of this answer should be treated as covering both physical and electronic documents, unless detailed otherwise.

177. Currently NHSBT does not have a standard operating procedure (**'SOP'**) that deals with the destruction of electronic records. Once IBI has concluded, and taking account of the findings of the Inquiry, we will be reconsidering our document destruction SOPs.

178. NHSBT Standard Operating Procedure SOP13/2 *Review/Destructions of Paper Records Placed in Offsite Storage* [WITN0672037] is NHSBT's SOP in relation to the review and destruction of paper records placed in offsite storage. In order for a record to be destroyed at the end of its retention period, a multi-layered review process must be undertaken with responsibility shared between a number of persons.

179. There has been an embargo on destroying records related to blood product traceability since 2001 as a result of a direction of Dr Angela Robinson when she was medical director of the NBA. This decision was made in light of vCJD and the knowledge that timelines for this disease could be substantially longer than the requirements of record traceability. It was felt that the need for full traceability in the

knowledge of vCJD was more important than meeting the time requirements for the destruction of records.

180. In summary, each of the following persons has various responsibilities in relation to the review and destruction of stored documents at the end of their retention period:

a. The Storage Agency who, in summary, is required to notify the Records Manager of any records which have reached retention review and, if approval is given to destroy those records, arrange for and subsequently confirm their confidential destruction;

b. The Records Manager who, in summary, requests and receives notification of records which have reached retention review from the Storage Agency; notifies the Information Asset Owner (IAO); conveys the authorisation to destroy, if so made, to the Storage Agency; and, upon destruction of a record, ensures that records of approval and confirmation that records have been sent for destruction/destruction certificate are maintained;

c. The IAO or Appointed Deputy who, in summary, reviews any notifications sent to them by the Records Manager; ensures that records required to be retained are kept for as long as needed or otherwise identifies and authorises destruction of records which have reached or exceeded their retention date; and returns the completed list of any such records to the Records Manager; and

d. Departmental Managers/Operators, who are required to update Iron Mountain Connect (IM's online portal) with new retention dates.

181. The SOP outlines the various steps that must be taken in order for a record to be destroyed. First, the NHSBT Records Manager will

request a preliminary notification list from the Storage Agency – these notifications will be provided at a minimum of every six months.

182. Second, the Storage Agency will send the Records Manager a Preliminary Destruction listing, which will include a certain amount of minimum information as mandated by the SOP.

183. Third, on receipt of the Preliminary Destruction listing, sent electronically in spreadsheet format, the Records Manager will update the spreadsheet with an additional 'FATE DECISION' column from which the following options may be selected: 'Destroy', 'Retain', or 'Not my box', which is then sent with a covering email to the relevant IAO.

184. Fourth, on receipt of the updated Preliminary Destruction listing, the IAO or their Appointed Deputy must review the 'FATE DECISION' options and agree with Information Governance on the appropriate course of action, whether to destroy the records or extend the retention date. If a record's retention date is to be extended, it will be sent back to the Records Manager and the IAO must inform the Departmental Manager/Operator who will then update IM Connect with extended retention dates.

185. In the event that an IAO decides that a record should be destroyed, they will return the Preliminary Destruction listing to the Records Manager who will add a further column to the spreadsheet titled 'Approved Destruction Decision' for the boxes to be destroyed, which will then be sent to the Storage Agency. Any boxes which need to be reattributed will be updated on IM Connect.

186. On receipt of the updated Preliminary Destruction Listing from the Records Manager, the Storage Agency will then review the same and send it back to the Records Manager for signature to authorise destruction of the records. Once the Records Manager has so authorised the destruction, having conducted final checks against the

notification previously sent to the IAO, the Storage Agency will conduct a further verification that the list if approved and signed by authorised personnel before destroying records on the approved list in a secure and confidential manner.

187. The Storage Agency will then update IM Connect, highlighting the boxes which have been destroyed on the system and send the destruction certificate along with a list of the records destroyed to the Records Manager, who will mark the destruction certificate as a vital record and retain the original destruction certificate within the Information Governance section.

10. Does NHSBT contribute donor information to databases maintained by other organisations? If so, please provide details.

188. We share information for a number of reasons with a number of organisations. This will be for different reasons
    a. The best interests of the donor
    b. Maintaining blood safety
    c. Business reasons
    d. Public health reasons

Interests of the donor

189. We share clinical information with GPs for example donors with a positive test result or where we need more information to determine their eligibility to donate. We consent donors before contacting their GP. I have provided further detail of this below in section 9.

190. Similarly, donors with a positive result may be referred to consultants in secondary care with their consent for treatment

To promote and ensure blood safety

191. We share information for the purposes of safety in blood donations and transfusions:

a. We provide anonymised data annually to Public Health England **('PHE')** so that the Safer Supplies joint report between NHSBT and PHE can be produced.

b. As appropriate, we provide information required by the regulator: the MHRA.

c. We provide information to Serious Hazards of Transfusion **('SHOT')** for the recording of serious hazards of transfusion including transfusion-transmitted infections, and since 2015 donor adverse effects. That information is stored in an anonymised format so that no personal donor, donation, staff or recipient information is available. For further details about SHOT (and Serious Adverse Blood Reactions and Events database **('SABRE')**) see the SHOT Rule 9 response dated 23 January 2019.

Business reasons

192. In order to promote and maintain levels of blood donation, NHSBT shares donor information with at least three separate organisations:

a. Teleperformance for SMS and Telephone contacts. Such sharing is limited to donor ID number and telephone number which is stored on their external system. Further information access from our system is only granted with consent once a person answers the phone and confirms such access. Such information is provided to Teleperformance to pursue donor recruitment and retention activities;

b. Since the introduction of the Pulse computer system, NHSBT has used mailing houses for donor call up processes, originally Stralfors in Redruth between 1998 – 2017 (acquired by Paragon Customer Communications in 2012), and latterly since 2018 APS in Manchester. The NHSBT Board approved the change of mailing

service provider to HH Global after they won the CCS (Crown Commercial Services) Lot 1 contract in December 2020; the transition from APS (the current provider) to HH Global is at the time of writing ongoing.

c. NHS Digital for transmission of NHS numbers and blood donor number details. The HSCIC transmission related to the GMS1 form used to register with a GP whereby a person can indicate an interest in becoming a blood donor.

193. In order to do R&D with partner organisations we may share information after consent with academic partners, for example we provide information to the STRIDES and INTERVAL studies being run at the Universities of Cambridge and Oxford. NHSBT does research with other such institutions. Such sharing of information for research is done with consent, and there are full data protection impact assessments. As an example, I provide as an exhibit the Data Protection Impact Assessment **('DPIA')** for the STRIDES project [WITN0672038].

194. As the company operating PULSE, Savant internally maintain databases related to ensuring that our systems operate properly. They will, among other relevant data, have a copy of the live PULSE data as part of this. This is subject to their being a contractor for us working to provide PULSE and is subject to a non-disclosure agreement.

Public Health reasons

195. We are required to notify certain diseases to Public Health England, this is a statutory duty, and we will do this when a notifiable infection is detected in a donor.

196. Equally as described in my answer to question 42 we provide donor details to the PHE registers on HCV and HTLV (human t-cell lymphotropic virus). For the HTLV register where donor identifiable details are included, this is done following the donor's consent. For the

HCV register, ethics approval does not require consent. Data on the register is pseudo-anonymised. The information sheet for patients/donors includes the following detail:

This study has been approved by the North Thames Multi-Centre Research Ethics Committee (MREC/98/2/47). Approval has also been given to process HCV National Register information without consent under Section 251 of the National Health Service Act 2006 and under Regulation 3 of the associated Health Service (Control of Patient Information) Regulations 2002. The law on protecting personal information, known as the General Data Protection Regulation (GDPR) and the Data Protection Act 2018, allows us to use the personal information collected and held in the HCV National Register

197. The TMER was set up to share data between donor/recipient and CJD Research centre across the 4 nations (see for example the commentary in the progress report to 31 January 1999 at [NHBT0004117]). This is a collaborative public health surveillance project and was a DHSC funded initiative. We share information between the UK National CJD Research & Surveillance Unit **('NCJDRSU')**, NHS Digital and the other UK Blood Services. The main aim is to investigate evidence that CJD and vCJD may be transmitted via blood and help prevent that.

198. The TMER receives the minimum amount of personally identifiable information on reported CJD cases and uses that information to identify any individuals who have received or donated blood components from/to cases of CJD. This information is then shared with NCJDRSU, and further with NHS Digital services in order to get further information on recipients and donors with respect to details on the date, location and cause of death when a recipient or donor dies.

199. The TMER has special permission to do this under Section 251 of the NHS Act 2006 and Health Service (Control of Patient Information)

Regulations 2002 for England and Wales, and from the Public Benefit and Privacy Panel (PBPP) for Health and Social Care for Scotland.

11. What are the retention policies of NHSBT regarding medical records of individuals? Have these policies changed since the 1960s? If so, please provide details.

200. I have provided an account of NHSBT's current retention policy regarding record storage, including relevant retention periods for different types of records, in response to request 9f above.

201. For convenience, NHSBT SPN189/5.1 0 NHSBT Record Storage [WITN0672032] is the relevant policy in force, covering all records including those medical records of individuals which are in the possession of NHSBT – principally donors rather than patients.

202. As has already been discussed above, because of the fragmented nature of the service prior to the 1990s it is difficult to identify a unified policy, and I have not seen policies for independent RTCs on this point. Insofar as might be relevant, I can point to the discussion of historic policies on data already included above.

12. Is NHSBT subject to any legislative or regulatory requirements in respect of record keeping? If so, please provide details.

203. NHSBT is required to comply with several legislative and regulatory requirements. NHSBT SPN189/5.1 0 *NHSBT Record Storage* [WITN0672032], in addition to providing details of NHSBT's record storage and retention policy, cites the relevant legislative or regulatory requirement that informs the decision on how long to retain NHSBT records as a minimum storage period. As part of my response to request 9f, I have given details of the relevant legislative or regulatory instrument which governs the retention period of the records described above.

204. NHSBT's legislative and regulatory obligations in respect of record keeping, which is not limited to donor information, emanate from various instruments, as documented in NHSBT SPN189/5.1 0 NHSBT Record Storage [WITN0672032]:

a. Blood Safety and Quality Regulations SI 2005/50 (as amended), in conjunction with the Good Practice Guidelines for Blood Establishments[RLIT0001543] and [RLIT0001549];[24]

b. In respect of human tissue, The Quality and Safety of Human Organs Intended for Transplantation Regulations SI 2012/1501 (as amended) [RLIT0001552];[25]

c. The NHS Records Management Code of Practice for Health and Social Care 2016 [RLIT0001554];[26]

d. The retention and storage of pathological records and specimens (5th edition) – Guidance from The Royal College of Pathologists and the Institute of Biomedical Science April 2015 (The Royal College of Pathologists Guidelines); [RLIT0001474][27]

e. Control of Substances Hazardous to Health Regulations 2002, Regulation 11 (as amended);[28]

f. The British Society for Haematology Guidelines;[29]

g. Directive 2001/83/EC, Article 80, Directive on the Community code relating to medicinal products for human use;[30]

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[24] [RLIT0001543]; [RLIT0001549]
[25] [RLIT0001552]
[26] [RLIT0001554]
[27] [RLIT0001474]
[28] https://www.legislation.gov.uk/uksi/2002/2677/contents/made
[29] http://www.b-s-h.org.uk/about-us/committees/guidelines/
[30] http://ec.europa.eu/health/documents/eudralex/vol-1/index_en.htm

h. Directive 2003/94/EC, Article 9, Directive on the principles and guidelines of Good Manufacturing Practice in respect of medicinal products for human use and investigational medicinal products for human use;[31]

i. The International Standards Organisation, 'Medical laboratories – Requirements for quality and competence (ISO 15189:2012) 4.13';[32] and

j. The Human Medicines Regulations 2012 SI 2012/1916 (as amended).[33]

13. Does NHSBT have a policy on recording information on death certificates when a patient has been infected with blood borne infections relevant to the Inquiry's terms of reference? Has this policy changed since the 1960s? If so, please provide details.

205. My understanding is that neither NHSBT nor its predecessor organisations has ever been involved in recording information on death certificates and therefore there is no such policy, current or historic.

Section 3: Relationship of NHSBT to other UK blood services

14. Please explain NHSBT's relationship to the other three blood services in the UK and how this has changed over time, particularly from the 1970s to date.

[31] DHSC0041165_067
[32] https://www.iso.org/obp/ui/#iso:std:iso:15189:ed-3:v2:en [NB. behind a paywall]
[33] http://www.legislation.gov.uk/uksi/2012/1916/contents/made

206. In the current day we have many and diverse relationships with other blood services: speaking to, or emailing, our colleagues across organisations on, what I would guess is, an almost daily basis. We have the advantage of email, on-line connectivity and personal phones that mean we can, and do, frequently contact each other on both a formal and informal basis outside the more formal meetings. Also, nowadays, there are relationships at many levels between our organisations from the CEOs and Medical Directors, to our colleagues planning the collection and distribution of blood. Collaboration will mainly occur whilst formulating safety policy, for example when on working groups of JPAC or SaBTO, or other working groups such as SHOT, British Blood Transfusion Society **('BBTS')**, EBA or ISBT, at conferences and meetings, when requesting specialist components between organisations, when sharing information, and when reaching out to specialists for advice. Some of these more formal interactions are detailed below in my answer to question 15.

207. The history of NHSBT and its predecessors is explored elsewhere in this response. Since its inception as individual centres in the Second World War, NHSBT has been an independent service from the Scottish National Blood Transfusion Service **('SNBTS')** and Northern Ireland Blood Transfusion Service **('NIBTS')**. As is discussed below, while independent, it has cooperated with the other UK blood services.

208. It would appear from the documents I have seen in providing this answer (which are detailed below), that the predecessors of the Welsh Blood Service have had a closer relationship with the predecessors of NHSBT. It has had various names over the years and has been at various locations. For ease of reference, I will describe the predecessors to the Welsh Blood Service as NBTS (Wales).

209. The centre at Cardiff began as one of the RTCs created in the Second World War. In 1946 it became part of the National Blood Transfusion Service. In 1948, following the NHS being established, NBTS (Wales)

became managed by the Welsh Regional Health Board. Then, in 1974, responsibility was handed over to the Welsh Office, which retained overall control of NBTS (Wales) until 1999. In 1982 immediate responsibility for NBTS (Wales) moved to the South Glamorgan District Health Authority and in 1991 to the Welsh Health Common Services Authority. In 1993 the NBA was established as an SHA (with executive control of the RTCs being transferred to it in 1994). NBTS (Wales) was not transferred to the NBA. Instead, it remained separate. In 1997 the Welsh service moved to its current premises at Talbot Green. Then, in 1999 it became a division of the Velindre NHS Trust.

210. North Wales remained with the Mersey RTC (together making up the Mersey and North Wales RTC) until 2016. From that point control for the North Wales region was handed over to what is now the Welsh Blood Service. I provide as an exhibit the project report dated 8 December 2016 for the *All Wales Blood Service Project* which explains this transfer in more detail [WITN0672039].

211. Further detail of the relationship between the Welsh and English services is provided in *Fifty Years of Blood Transfusion* in Transfusion Medicine by Dr Gunson and Dr Dodsworth (1996, Volume 6, Supplement 1) [NHBT0000028], the report of Dr Gunson in the HIV litigation [DHSC0000142], and the statement of Dr Gunson in the HCV litigation [NHBT0000026_009]. I have relied on these heavily in this section, along with the *NHSBT Family Tree* [WITN0672007] paper.

15. Please outline the arrangements in place to enable cooperation between the four blood services, including any forums or reporting lines established to aid this cooperation.

212. I have already addressed the current and historic relationship between NHSBT and the Welsh Blood Service in my answer to Q14. Some examples of how that relationship worked in practice are provided in the section "*The Welsh Blood Service*" below. I then note the informal

arrangements that were in place between the different blood services of the UK and have set some examples of this out under "*Informal cooperation*". Evidence of the more formal cooperation which has existed from the beginning of the RTD meetings in the 1940s to today is then set out in "*Formal cooperation*". I have divided this section into "*historic*" and "*recent*", although this is for ease of understanding rather than a strict dividing line. At the end of my answer to this question I have also flagged some other avenues of cooperation between staff of each blood service, either through professional organisations or organisations external to the UK. That information is at "*Other avenues of cooperation*" and demonstrates the current focus on the importance of international collaboration with other Blood Services today.

213. The position remains that, save for the most recent information provided here, I have been provided documents and been made aware by other staff at NHSBT of the historic relationship with the other blood services.

The Welsh Blood Service

214. At the outset it should be noted that until 1994 NBTS (Wales) was a constituent centre of the English NBTS, and the North Wales area was covered by NHSBT until 2016. The cooperation between the Welsh RTC and the remainder of the English service was in the style of a centre as part of that service. For example, this meant that the Director of NBTS (Wales) (as the director of the Welsh RTC) attended the meetings of the Regional Transfusion Directors from 1948 onwards (see [BPLL0004826] at pp.27-28).

215. I have been shown various documents which appear to show the relationship between Cardiff and the other RTCs prior to the Welsh Blood Service being established:

a. [NHBT0094250_004]: a memorandum from Dr Napier to directors of centres who supplied blood to Cardiff in September 1989 to respond to a shortage.
b. [NHBT0092855_004]: minutes of a Western Division NBTS meeting on 12 May 1983 where Dr Napier attended and proposed a red cell clearing house.
c. [NHBT0006284]: a Medicines Inspectorate report from 20 November 1990 discussing a computer system developed at Cardiff that had been adopted at Leeds, Cambridge and Liverpool RTCs.

Informal cooperation

216. I understand that informal cooperation has been a feature of the relationship between the blood services of the UK since their inception. It is difficult now to comment on the informal interactions of staff of the different services because of the passage of time. However, it seems each of the services did not operate in a vacuum, and the staff that made up the services will have regularly interacted on an informal basis. The disclosure available to the Inquiry, including extensive letters between different directors, indicates this informal correspondence and cooperation. Some examples I have been provided with for illustration include:

a. [PRSE0003435]: correspondence between Dr Hewitt of the English Service and Dr DBL McClelland of the Scottish service concerning explanatory notes to the donor leaflet at the North London Blood Transfusion Centre.
b. [NHBT0003691] and [NHBT0003698]: I understand Dr Gunson would sometimes copy in Dr Cash (and other senior members of the Scottish service) to letters to the RTDs. These two documents concern anti-HIV-2 testing.
c. [JPAC0000001_155]: correspondence between Dr George Galea of SNBTS to Dr Virge James at the Trent RTC dated 10 February 1995 enclosing a letter from Dr Chitcha Bharucha, Deputy Director

of NIBTS discussing evidence of sexual transmission of HCV. This letter was copied to Prof Cash of SNBTS.

d. [JPAC0000056_003]: correspondence between Dr Elizabeth Love of NBTS and Dr Bharucha of NIBTS from 25 November 1999 regarding a special UK Standing Advisory Committee on Transfusion Transmitted Infection **('SACTTI')** meeting on NAT testing.

e. [NHBT0094549_007]: a letter dated 30 April 1984 from Dr W M McClelland, Director of the Northern Ireland Blood Transfusion Service, to Dr H Gunson, regarding transfusion associated hepatitis reports for 1983.

217. There also seem to have been some occasions when the RTDs would come together to agree a form of words for a letter to a journal. In this respect I have been shown [PRSE0004824], from The Lancet for March 1985, which includes directors from Scotland, Wales, England and Plasma Fractionation Laboratory **('PFL')** in Edinburgh.

Formal cooperation – historic

218. Moving to formal methods of interaction, I understand that from 1948 the Consultant Advisor in Blood Transfusions to the Department of Health and Social Security **('DHSS')** chaired ten meetings each year of the Directors of the RTCs. There are extensive records of these meetings available to the Inquiry. I understand from the documents I have been provided with that Scottish and Northern Irish representatives attended some of these meetings: [DHSC0100059] and [NHBT0017071]. A membership list appears to have been collated in [BPLL0004826] at p.28. I understand the nature of these meetings became mainly scientific when the National Directorate of the NBTS was formed [NHBT0018188].

219. Over the years I understand that various working parties were created by the RTDs. These included the UK Working Party on Transfusion-Associated Hepatitis ([BPLL0004826] at p.31), and the UK AIDS

Working Group ([BPLL0004826] at p.32). In respect of the former, it would appear that the Scottish service was involved through the inclusion of DBL McClelland as one of the members ([NHBT0000023_002] and [NHBT0000023_003). Also, there was the anti-HTLV-III screening group established by the RTDs at the request of the Expert Advisory Group on Aids **('EAGA')**, which included Dr DBL McClelland [DHSC0000406].

220. Looking to Scotland, it would appear that members of the English service would attend some SNBTS meetings. For example, see Dr Gunson and Dr Wagstaff attended the SNBTS meeting in June 1983 to discuss AIDS [MACK0001960_001]. There is also correspondence between Dr DBL McClelland and Dr Wagstaff discussing the donor leaflet from shortly after in 1984 [PRSE0000249] and [PRSE0000351].

221. Official liaison between the English and Scottish Services came with the constitution of the Advisory Committee on the NBTS. As established in December 1980, the terms of reference of the Advisory Committee were the following:

To advise DHSS and the Welsh Office on the co-ordination of:-
(1) The development and work of the Regional Transfusion Centres and the Central Blood Laboratories in England and Wales.
(2) As necessary, the English and Welsh Blood Transfusion Service and that of Scotland.

222. However, at the first meeting the terms of reference were amended as follows:

To advise the Department of Health and Social Security and the Welsh Office on the co-ordination of the development and work of Regional Transfusion Centres and the Central Blood Laboratories in England and Wales, and the English and Welsh Blood Transfusion Service with those of Scotland and Northern Ireland.

223. In his statement for the hepatitis litigation [NHBT0000026_009] Dr Gunson records of the original terms of reference that "*[t]his was the first occasion that there was an official liaison between the English and Scottish Services*" (see paragraph 11). The members and observers of the Advisory Committee on the NBTS are available at [BPLL0004826] (pp.10-12) and include members from the Welsh Office, Scottish Home and Health Department, the Northern Ireland DHSS, and Dr JD Cash (as National Medical Director of the SNBTS). I understand that the committee met on 14 occasions between 1 December 1980 and 8 February 1988.

224. The Advisory Committee established committees including the Working Group on AIDS. The membership was broadly from the English service but included Dr DBL McClelland as an observer [CBLA0001934_002].

225. Existing alongside the Advisory Committee was the CBLA. I understand this replaced the old Joint Management Committee (managed by NW Thames RA with the DHSS). Details about the CBLA are at chapter 8 of [NHBT0000028]. The CBLA had a Central Committee for Research and Development in Blood Transfusion which first met on 21 June 1983 [PRSE0002741]. The body included attendance by Dr Gunson and Dr DBL McClelland. The body set up an ad hoc committee including Dr Gunson and Dr McClelland on AIDS. The first meeting of that group was on 14 October 1983 [CBLA0001755].

226. A number of members of the different national blood services were members of the EAGA. At the first meeting there was attendance from Dr Cash, Dr Gunson, Dr Contreras and Dr DBL McClelland [PRSE0002734]. One of the sub-committees of EAGA was a screening test sub-group which included Dr Gunson and Dr McClelland [DHSC0000425]. At least in respect of work on this sub-

group, Dr Gunson and Dr McClelland worked closely as they produced a paper on the field trial for testing [DHSC0000421].

227. On 28 July 1988 the National Directorate of the NBTS was formed with Dr Gunson as the National Director. The committee included a coordinating committee. I understand it was this which took over the role of the Advisory Committee on the NBTS. As he notes in his statement for the HCV litigation, in this role Dr Gunson had no executive authority and had to work through persuasion ([NHBT0000026_009] para 14). While this was a role as head of the NBTS, the work done by Dr Gunson extended to working with the other blood services of the UK in achieving a common approach to certain matters. This role sat alongside the various working groups and committees discussed above which continued to exist over the period. The Inquiry has available to it the significant amounts of correspondence produced by Dr Gunson (over this period, and more generally).

228. Around the early 1990s a specific SNBTS/NBTS liaison committee was established. The minutes from 30 April 1991 are available at [PRSE0004478] and show that a range of issues was discussed including the commencement date for anti-HCV testing and HCV PCR (polymerase chain reaction) confirmatory testing. Dr Gunson and Dr Moore attended for NBTS, Dr McIntosh, Prof Cash and Mrs Porterfield attended for SNBTS.

229. As is discussed in more detail in answer to the question below, in 1989 the first edition of the 'Red Book' was printed by Her Majesty's Stationary Office **('HMSO')**. This was compiled by experts from the then RTCs and the National Institute for Biological Standards and Control (the UKBTS/NIBSC Executive Committee). The first meeting of this committee was on 12 July 1993 [NHBT0000126_001]. The organisation itself had existed since 1987. In the mid-1990s that organisation itself became JPAC, which (among a range of other

things) continues to produce the 'Red Book' guidelines for the blood transfusion services. Further information about JPAC is set out in the Rule 9 Response provided on 31 January 2019. Hard copies of the JPAC and Standing Advisory Committee minutes and papers from 1993 to date exist and electronic copies from 2004 are available.

Formal cooperation – recent

230. This section of my answer primarily addresses bodies which, while they may have been set up many years ago, remain in operation today. I have some familiarity with the most recent incarnations of most of the bodies addressed here.

231. JPAC is the Joint United Kingdom Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee. It has two distinct functions, namely; to prepare detailed service guidelines for the United Kingdom Blood Transfusion Service and to be an Advisory Committee to the United Kingdom Blood Transfusion Services. The 2019 UK Forum constitution [WITN0672041] provides for quarterly reporting to it from JPAC.

232. The organisation itself convenes seven standing advisory committees, the executive working group and JPAC itself. The details of JPAC and its committees and membership is available on its website[34]. I am a member of the committee as the medical director of NHSBT. I provide more detail about JPAC in my answer to Q42.

233. One standing committee of JPAC is the UK Advisory Committee on Transfusion Transmitted Diseases, and its successor the UK Standing Advisory Committee on Transfusion Transmitted Infection (SACTTI), now had and have significant involvement in cooperation across the UK. As to its terms of reference, there is a discussion between Dr Ala and Dr Robinson from April 1995 of the committee's purpose at [NHBT0008002]. In that Dr Robinson says that the body "*must act as*

[34] https://www.transfusionguidelines.org/about

an expert professional advisory body to the UK Transfusion Services constantly reviewing the scientific information available such that it can recommend appropriate policies in a timely manner to prevent transfusion transmitted infections".

234. For examples of SACTTI work, see the minutes from November 1996 which included various members of the English and Scottish services [NHBT0010921]. There was a special meeting on testing in 1999 which was attended by the Scottish, English, Northern Irish services. Also in attendance were members of the Irish blood service [NHBT0004108_001].

235. JPAC is one of the committees which reports to the UK Forum (the United Kingdom Blood Transfusion Services' Forum). I provide the current constitution March 2018 as an exhibit to this document [WITN0672042]. This body was established in 1999 with the objective of providing for communication and cooperation between the blood services of the UK. While the UK Forum provides for communication and collaboration, each of the blood services is still responsible for their own territories and accountable to their own Chief Executive and Director.

236. The UK forum meets at least four times a year. Its core membership is the four Chief Executives/Directors and the four Medical Directors of the UK Blood Services. There is an elected chair and meetings can be held at any venue. The primary processes through which the UK Forum discharges its responsibilities are listed in the constitution as: JPAC, SHOT and the Blood Stock Management Scheme. Annual reports are also provided by the Systematic Review Group, BBTS, Quality Group, and Emerging Planning/Business Continuity. Two members of the core UK Forum Membership also attend the European Blood Alliance board meetings (to which, see further below).

237. Also, in 1996 SHOT was formed as an independent, professionally led haemovigilance scheme. SHOT is described in more detail in the rule 9 response provided on 23 January 2019. That document particularly includes references to the annual SHOT reports from 1996 to date. This is a UK body funded through the UK Forum with proportional cross-charging so that all blood services contribute. I have been shown a document which shows that Scotland provided a portion of the funding from SHOT's inception: [NHBT0007371].

238. The need for liaison between jurisdictions was important in relation to vCJD in the late 1990s. [NHBT0009032] is a letter dated 28 October 1997 from Dr Napier to Dr Robinson regarding vCJD Look back. Dr Napier referred to '*our aspirations to maintaining patient (donor) confidentiality*', and to the need to agree '*the right and proper procedures for handling this information*'. He appreciated that within the NBA we may have agreed to transfer such data freely, subject to proper patient confidentiality controls, but was not entirely happy about conveying personal details of this nature direct to BPL. They would have to pass these back to centres within the National Blood Service anyway. The principle he had agreed to with regard to their own patient confidentiality policies was that "*data custodians*" e.g. himself as Medical Director, would be prepared to pass across any such information where it seems necessary to other data custodians who also accept the same patient confidentiality responsibilities.

239. The sharing of information on those potentially affected by vCJD was a very difficult issue on which there was liaison between the UK services. See for example [NHBT0000611_001] and [NHBT0004047_001], the latter a letter from Dr Robinson, then Medical Director to Dr Williams, Medical Director of the Welsh Service on sharing the details of all vCJD cases between the UK Blood Transfusion Services, saying that she was advised by DH that they should take advice from Dr Ailsa White, who had DH responsibility for the CJD Surveillance Unit, as to how we should proceed.

240. I have been shown [NHBT0000088_020], which is the minutes of a SACTTI meeting on 21 January 1998 at which it was agreed that the TMER could be used to collate all information on vCJD notification within the UK. It is noted that this had already been agreed by Dr Williams of the Welsh Transfusion Service and a reply was awaited from Dr McClelland of the Northern Irish Service. It was agreed that, for the sake of consistency, all names notified to the NBA should be checked with all English Centres. At that time there was no facility for exchange of information between the 4 countries, and Dr Will of TMER had insisted that he would only notify the relevant Medical Director, based on residence of the case. Concern was expressed that cases may have donated blood outside their locality, for instance on holiday and it would be sensible for all cases to be checked throughout the UK. The agreed action was to ensure that all names notified in England were checked with all English Centres. Dr Robinson was to write to Dr Jeremy Metters at the Department of Health.

241. DH and other ministries across the UK are advised by SaBTO, established in 2008. Minutes for around the last 10 years are available through the Government website and the National Archives. Various members of NHSBT staff have sat on SaBTO over the years that it has existed. I am currently a member of SaBTO as the UK Blood Services Medical Director representative. SaBTO is discussed further in my answer to section 9.

Other avenues of cooperation

242. External to the UK, the Council of Europe has for many years convened the Committee of Experts on Blood Transfusion and Immunohaematology as part of securing a Europe-wide approach to (among other things) blood transfusion issues. Detail of the Council of Europe meetings, particularly in the context of AIDS, is given in the answers provided to the amended rule 9 request dated 14 August 2020 (the 'lookback' response). I have been provided various relevant

documents from this body. See, for example [CBLA0001710] which is a report from Dr Gunson of his attendance of such a meeting in May 1983. It would also appear that specific symposiums on quality in blood transfusion were established in 1986 [NHBT0000030_020]. There were similarly meetings of the World Health Organisation **('WHO')** on AIDS. At the end of 1983 Dr DBL McClelland appears to have attended such a meeting. See a draft report at [CBLA0001775] and a discussion of his attendance at [CBLA0001799].

243. Aside from these specific institutions, a number of institutions have been relevant to cooperation in the dissemination of knowledge. These include the British Society for Haematology (from 1960), the Royal College of Pathologists (from 1962), the British Blood Transfusion Society (from 1982), the Institute of Biomedical Science (from 1912), the International Society for Blood Transfusion (from 1935), the BEST Collaborative (Biomedical Excellence for Safer Transfusion, an international collaborative of blood providers, industry and academic experts from 1991), the European Blood Alliance (from 1998), the National Blood Transfusion Committee (2001) and the Alliance of Blood Operators (from 2002). NHSBT Consultants sit or have sat, on working groups of all of the organisations mentioned above.

244. Of particular note, we were and are involved in writing transfusion guidelines for the British Society for Haematology and the Blood Transfusion guideline for the National Institute of Health and Care Excellence (NICE) in November 2015. We are pivotal to the provision of transfusion education and examining doctors for the Fellowship exams of the Royal College of Pathology (FRCPath) through roles with the RCPath. We hold leading roles in many professional societies and bodies. For example, NHSBT Consultants are or have been recent Presidents or Directors of the British Blood Transfusion Society, The American Association of Blood Banks, The International Society for Blood Transfusion [WITN0672043] and the BEST Collaborative. An NHSBT Consultant also currently holds the Chair of the Steering

Committee of the Council of Europe, European Committee on Blood Transfusion (CD-P-TS). The NHSBT CEO is currently the Chair of the Alliance of Blood Operators. NHSBT funds and provides the secretariat for the National Blood Transfusion Committee. More details of all these bodies can be found on their websites. This paragraph serves to demonstrate the current approach NHSBT takes to collaborating internationally, learning from others and sharing information widely, ensuring NHSBT is always aware of best practice internationally, where there is one, and what other services are doing where there are differences.

245. In addition, where best practice is not clear NHSBT collaborates internationally in R&D, with four external invited expert (internationally recognised leaders in their field) members of our NHSBT Board R&D Committee. I am a member of the Canadian Blood Services Scientific and Research Advisory Committee and other NHSBT Consultants collaborate in international R&D through the BEST Collaborative and on an ad hoc basis for individual studies with peers internationally. Our recent involvement and co-leadership of the multi-national COVID-19 Convalescent Plasma arm of the REMAP-CAP trial is a good example of this.

16. Is there a UK-wide approach to policy development and implementation in respect of blood and/or transfusion safety, or is an approach agreed on a case by case basis? Has this changed over time? If so, please provide details.

246. Much of the answer to the previous question is also applicable here in the understanding of UK-wide approaches to policy and implementation; JPAC, SaBTO and SHOT are UK wide. The National Blood Transfusion Committee **('NBTC')** in England has representatives from the other UK Blood Services. There is collaboration in education across the services. Following instructions on safety policy from Ministers, UK Blood Services will discuss

implementation largely looking to implement across the UK at a similar time and learning from each other's approaches.

247. As I have noted in question 15, particularly prior to the establishment of the NBA, the approach between the UK blood services appears to have been one of informal cooperation. This cooperation was secured through the committees and processes identified as part of the answer to the previous question. These appear to have usually had no executive authority over any blood service in the UK, or any formal legislative standing. As such, at least historically, there has been no UK-wide approach to policy development and implementation overall. There has been some work, secured through informal cooperation, to adopt some comparative approaches in specific cases. As has been discussed above, Dr Gunson in his role as National Director was influential in this respect.

248. The relationships between the blood services in adopting the same policy was clear in the context of the HCV lookback. This is something addressed in the evidence of Dr Robinson to the amended rule 9 request dated 14 August 2020. While the Scottish service was in a position to proceed with HCV lookback ahead of England (and therefore Wales), SNBTS's positioning facilitated a speeding up of the process south of the border: see for example the minutes of the SACTTI meeting of 18 January 1994 [NHBT0000088_006]. The work done by Dr Gillon of SNBTS on donor counselling in relation to HCV positivity was also largely adopted for the purposes of the HCV lookback – see for example the Advisory Committee for Transfusion Transmitted Diseases **('ACCTD')** minutes for 10 June 1991 [NHBT0000044_003].

249. Over the years there has been significant direction and guidance from the Council of Europe through recommendations. For example, in respect of AIDS the Committee of Ministers issued recommendation R(83)8 concerning AIDS in blood and blood products

[NHBT0010651_004]. Dr Gunson discussed such meetings and recommendations in a number of documents, including [CBLA0001710].

250. As was noted above, in 1989 the first edition of the Red Book was provided to give guidelines for the blood transfusion services. Various editions have been published subsequently (2nd in 1993, 3rd in 1994, amendments to 3rd in 1999, 4th in 2000, 5th in 2001, 6th in 2002, 7th in 2005 and 8th in 2013). These guidelines were produced to secure a unified approach across the UK to blood transfusion.

251. The Red Book itself has in part been a product of the unified approach sought by the European Union. The first edition closely followed the introduction of the Product Liability Directive. Following the introduction of various EU directives in 2004 and 2005, and the corollary BSQR, the Red Book has come to contain the various requirements and recommendations for guidelines for the blood transfusion services. This has been a pan-UK approach, and is not specific to any one nation. In addition, JPAC produces alongside the British Committee for Standards in Haematology (now British Society for Haematology) the Handbook of Transfusion Medicine (last updated in February 2014).

252. The SHOT scheme is a UK wide body introduced in the 1990s. From 2005 it sat alongside the SABRE reporting scheme operated by MHRA in compliance with the BSQR. Further details about both schemes, and particularly SHOT, are set out in the Rule 9 response provided on 23 January 2019. SHOT also provides recommendations to improve safety to the UK blood services.

253. The functions of JPAC were explained in the previous answer. It produces policy and guidelines that aim for consistency in approach across the UK. It should be noted that whilst it is an advisory committee, and decisions on policy implementation are vested in the

individual chief executives and service boards of the blood services, it is in my experience uncommon for individual services to deviate from these guidelines and certainly not without a risk assessment.

17. Does NHSBT share information with other UK blood services about excluded donors, donors that pose a risk to the safety of the blood supply, or infected blood donations? If yes, is this on a formal or informal basis? Please describe the mechanisms in place to share information (if any) including how these have changed over time.

254. With regard to excluded donors, the consistent approach of NHSBT has been to advise the donor that they fall into an excluded category and should not donate. There has not been, and continues not to be, any formal mechanism by which NHSBT shares information about excluded donors with other blood services in the UK in general. I have discussed above the specific situation in relation to vCJD (SACTTI meeting on 21 January 1998 [NHBT0004640_001]).

255. Blood Services have to trust donors to a large extent throughout the whole of the collection process: from them telling us their history and lifestyle risks truthfully, to behaving in a trustworthy way when we tell them they are not able to donate blood, we trust them to provide proper information and follow our instructions. Once they have been advised that they have been excluded in one area it would be a very rare donor who would seek to donate in a different jurisdiction in the knowledge that they might be putting the safety of blood supply at risk. In any event, if they had been detected by available screening in one region as ineligible to donate, then they would be similarly detected if they sought to donate elsewhere. In an on-line, unlinked and anonymous survey in 2013/4, with over 65,000 donors responding, we calculated the compliance with answering our donor health check questions accurately [WITN0672137]. Over 99.2% of donors complied with deferrals concerning infectious disease risks that included travel and sexual behaviours [WITN0672138]. For deferrals specifically

regarding MSM this was estimated to be as high as 99.7%. [WITN0672139]

256. As mentioned in my answer to section 9, donor honesty and compliance with the donor health check is only one of a number of systems resulting in the safe supply of blood. Others are donor selection, cleaning of donors' arms, and screening of donations. Thus, even with donor compliance above 99% we still have other 'lines of defence' for the very few donors who, either deliberately or mistakenly, fail to comply with our processes.

257. When a donor is excluded, which we describe as 'deferred', in England this will be on their records held on the national computer system PULSE, which has been in effect since 1997. Scotland and Northern Ireland have, and I believe have had for many years, their own systems. Donors who have current or past infection that is identified on blood donation screening will be contacted by NHSBT and informed of their results, given information about what this means and as appropriate onward referral arrangements. At this post-test discussion we would generally ask donors about risks relating to their infection and for first time donors we would sometimes press them about possible previous donations particularly if they have lived in a different region or jurisdiction, perhaps many years before. Where other donors are very clear that they have donated previously, but we are unable to find any evidence of this, we would ask about whether they donated in another country. If they think that they have donated in another UK blood service or sometimes overseas we would follow up with the appropriate agency. We would have a duty under public health regulations to inform other blood services if appropriate. This is an informal arrangement. We do not routinely share information about excluded donors with anyone but Public Health England as part of our statutory duty to inform PHE of notifiable infections in our donors.

258. There is the potential to inform other UK blood services about potential risks to blood supply in the case of lookback investigations if the donor has previously donated elsewhere in the UK. Such investigations would apply to infections even where an infection may not be identified until many years later. We would normally inform the affected donor if we were intending to share this information. Information would be shared with our colleagues in the donor clinical team. Potentially we would also contact other blood services if we were investigating a post-transfusion infection and an implicated donor had moved area into another country of the UK. If potential transfusion transmitted infections **('TTIs')** are reported many years after transfusion and archives are not available in some cases we will try and locate donors via the NHS spine. In those rare cases where a donor's health was at risk, we would use all available means to track them down.

259. As to "*donors that pose a risk to the safety of the blood supply*", this may mean donors that are temporarily (rather than permanently) deferred from donation. This would cover individuals who have recently travelled abroad to certain locations (e.g. hotspots for West Nile Virus), or people who have received procedures like a tattoo or piercing. The position for such individuals is essentially the same as is set out above, save that the deferral will be time limited.

260. In respect of infected blood donations, these are immediately removed from the blood supply. If a test is positive the Pulse computer system prevents their issue and there is a mandatory discard of all related components. In the event of a potential transfusion reaction being reported from a hospital all other components related to those implicated in the transfusion are discarded. Similarly, if a donor gives more information subsequent to donating that suggests that their donation could be at a higher risk of infection then, again, all components related to the donor will be discarded, or recalled from a hospital if they have been issued, and if they are transfused there is a formal mechanism for letting the hospital know about the potential risk.

261. Data on the numbers of infected donations are compiled annually in the Safe Supplies joint NHSBT/PHE Epidemiology report detailed in section 9. In the case of actual transmissions, these are reported to SHOT, collated across the UK and detailed in the annual SHOT report. This has already been commented upon in the SHOT rule 9 Answer dated 23 January 2019.

262. I am aware of at least one case where the Welsh Blood Service and NHSBT shared information as the donor had transferred from one service to the other as part of the reconfiguration of the Welsh Blood Service. I refer to the *All-Wales Blood Service Project* report which I cited at the beginning of my answer to Question 14.

263. The process for transferring to the Welsh Blood Service after it went live in May 2016 was as follows. If a donor wished to transfer, we would stop their record and place a deferral code on their record, requesting that the donor be transferred to Wales. However, donors would themselves have to contact the Welsh Blood Service to register there. I understand that a number of donors' records were sent across to the WBS, but am unable to quantify that number more precisely.

264. It is worth noting that there is mutual aid across the blood services so if we had issued units to Wales/Scotland which were part of a lookback or post-transfusion investigation, then we would contact them at the earliest opportunity. In all cases and scenarios we would adhere to the NHS Caldicott principles when making decisions on information sharing of donors.

265. It is also worth mentioning the regular UK/Ireland wide meeting that the clinical teams dealing with microbiology results hold about 3 times year. We discuss cases and share anything of relevance.

266. As detailed in my answer to question 10 information is shared on donors with Public Health England for notifiable diseases, with PHE disease registries and with the TMER where relevant

267. There is further detail in my answer to section 4 about the sharing of information between RTCs.

Section 4: Relationship of NHSBT to transfusion centres

18. Please explain the relationship between NHSBT and the transfusion centres within its remit, including but not limited to the following issues:

a. the authority NHSBT has over the day to day activities of transfusion centres;

268. The relationship between NHSBT and the transfusion centres has already been dealt with at quite a high level in the *NHSBT Family Tree* paper [WITN0672007]. I have also been shown the following documents which deal with the matter in some detail:

a. *Fifty Years of Blood Transfusion* in (1996) 6 Transfusion Medicine by Dr Gunson and Dr Dodsworth [NHBT0000028].
b. Dr Gunson's report for the HIV litigation [DHSC0001967].
c. Dr Gunson's statement for the HCV litigation [NHBT0000026_009].

269. NHSBT does not have RTCs. Those were historic bodies that existed before NHSBT was established. As a result of this, I have no first-hand knowledge which directly answers this question.

270. The nature of RTCs prior to 1 April 1994 is detailed elsewhere. For the period prior to 1 April 1994, I understand "transfusion centres" in this question to be referring to those bodies.

271. My understanding of the documents I have been shown is that the term "transfusion centre" in RTC is a bit of a misnomer. First, the RTCs were rarely involved in giving transfusions. They were instead involved in the collection and supply of blood and blood components to hospital and other laboratories that were then used by those bodies. Second, while the RTCs were centres, collections of blood have been and are usually from temporary locations such as church halls and commercial sites. The RTCs were, among other things, the management hub of such collection.

272. On 1 April 1993 the National Blood Authority ('NBA'), the predecessor to NHSBT, was established as an SHA. At that time the NBA was responsible for BPL and the International Blood Group Reference Laboratory **('IBGRL')**. On 1 April 1994 the NBA then became responsible for the RTCs. I understand that from that date the regional health authorities no longer managed the RTCs. The name of the RTCs was changed to blood centres (BCs). Notwithstanding this, from 1 April 1994 I will treat "transfusion centres" in this question to be referring also to the BCs.

273. Referring to the documents I have been provided, it would appear that the BCs and their functions became assimilated into the NBA as a single national service. The centres increasingly were treated as parts of the whole institution, rather than distinct institutions operating around the country. *Fifty Years of Blood Transfusion* indicates that there was a three Zone system with zonal administrative directors of each reporting to the executive director of the NBA (see p.83 of [NHBT0000028]). I have been provided a Department of Health briefing paper: *Plans for the Future of the National Blood Service* [CABO0000048_003]. This indicates various proposed changes to the BCs and the administration of the NBA.

274. I understand that, once part of the NBA, over time the BCs ceased to operate as separate centres. They became places where the NBA

delivered its services as a centralised SHA. Today, the position is the same for NHSBT. A recent account of NHSBT's exercise of its functions is found in NHSBT's annual report and accounts 2019 to 2020 [WITN0672044]. In addition to the BCs (as successors to the RTCs) there are other important locations from which NHSBT operates its service. In section 1 I discuss our sites today.

275. The legal rights and obligations of the RHAs in respect of the RTCs were transferred to the NBA on 1 April 1994. This legal position has been continued following 1 October 2005 and the establishment of NHSBT. Thus, from a legal perspective, there has been no distinction between the NBA (and, later NHSBT) and the 'transfusion centres' since 1 April 1994.

a. The authority NHSBT has over the day to day activities of the transfusion centres

276. As I understand the documents I cite above, from 1948 to 1993 there was no body which held authority over the individual transfusion centres as a national body similar to NHSBT today. The position prior to 1993 is detailed in chapters 2, 3, and 11 of *Fifty Years of Blood Transfusion* [NHBT0000028].

277. *Fifty Years of Blood Transfusion* [NHBT0000028] discusses the transfer of management of RTCs to the regional hospital boards (RHBs). It says that RHBs would exercise authority over their designated RTC. That RTC would then be accountable to that RHB. There was no formal body which had authority over all of the RTCs, although the regional transfusion director **('RTD')** meetings convened by Dr Maycock provided for some informal direction and management. At internal p.18 the authors of *Fifty Years of Blood Transfusion* [NHBT0000028] set out:

By 1970 there were 14 quasi-independent regional centres and two central laboratories. All were attempting to provide a uniformly efficient service but without central co-ordination other than the RTD Committee which had no formal authority.

278. I understand from meeting minutes from the 1970s that there were occasions on which it was proposed the NBTS become a centrally managed service. I have been provided with the RTDs' meeting minutes from 16 December 1970 [DHSC0002371_010] which says the following on the topic (this document is heavily redacted):

NBTS was a complex service which had grown unevenly because of its fragmented administration and the different responses of regional hospital boards to the needs of the service. One effect of this was uneven provision of capital works over the years.

The Directors of RTCs tried to operate NBTS as a service but were frustrated by the lack of appropriate administrative and financial machinery. In order to provide a uniformly effective service, it was essential that there was a uniform financial policy. This did not at present exist.

Although the various categories of staff in RTC were, in general, doing the same duties, grading and treatment in such matters as allowances were not uniform. These differences were a cause of dissatisfaction and were disruptive from the point of view of the service as a whole. An RHB could (and did) make local decisions regarding the administration and staffing of a centre which might fundamentally change the character of that RTC with respect to other RTCs and the NBTS.

Regional administration of the RTCs exposed them to the effects of personalities. A change of staff in an RHB headquarters might be

accompanied by a change of attitude towards the RTC. An efficient service could not be run in such an atmosphere.

Some activities of NBTS were necessarily the sequel to decisions taken centrally, others were influenced by centrally decided policy. Yet although the policy and the reasons for it were explained to RHBs an RHB was under no obligation to carry it out if it did not wish to or if a regional committee decided otherwise. When such differences arose an RTC might find itself unable to carry out a specific task in pursuance of a central policy to prevent abuse of the service.

The unique position of the NBTS in the NHS should be taken into account. The main reason being that the existence of the service depends solely upon the continuing goodwill of a large body of volunteers and that the successful running of the service requires an informed and sympathetic understanding of the professional, scientific, administrative and public relations problems which are inseparable from such a service.

Although there was a clear need for a strong and effective central body and a uniform basic structure from the service, professional freedom and scope for local variation and development must be preserved.

279. I have been provided with the RTDs' meeting minutes for 25 October 1972 [NHBT0016117]. I understand from what is recorded that a working party paper had been produced prior to this which was given to the CMO on 1 September 1971. I have not seen that paper. The meeting minutes say that Mr Gidden from the DHSS had attended to inform the Committee of the present position:

Mr Gidden said that as the Directors knew, the Government's White Paper on NHS organization left the responsibility for the provision of a blood transfusion service with the Regional Health Authority. In

general, it had been decided that the functions of the RHA's although extended to include present local health authority functions, should remain the same as those of Regional Health Boards now. Nevertheless, the Department recognised that the BTS, although a vital component of the hospital service, was unlike any other component, and that a degree of central co-ordination in its operation was highly desirable if not essential. This existed in an important measure already through the meetings of RTDs, which, however, had an informal and not a formal basis.

280. It would appear that the response of the Directors was not positive about the proposal. The minutes record that:

The meeting expressed the greatest disappointment at the Department's rejection of its proposals for a centrally controlled service and criticised the delay of more than a year between the presentation of the proposals and this meeting.

281. The meeting minutes provide examples of various difficulties faced by the blood service. Those set out include:

a. Whether the RTDs' meetings would become a statutory advisory committee. Mr Gidden said it would not.
b. Whether the DHSS proposed to take measures to ensure that advice given by the RTD meeting and accepted by the Department was applied uniformly and effectively in the regions. Mr Gidden said that the Department alone could decide what weight should be given to advice tendered by the RTD meeting.
c. Mr Gidden explained that the proposed planning cycle for the NHS would enable the Department to exercise much closer scrutiny of the RHAs. For example, it was unlikely a failure by a RHA to provide capital developments to an RTC would go unnoticed.

d. The current view set out in the minutes was that if the RHAs were to be responsible for the running of RTCs, the RTDs would be responsible to the authority itself and not one of its officers.
e. It was suggested that the working group that initially drafted the proposal paper might be able to assist the DHSS in special administrative arrangements to ensure coordination and administrative uniformity in the NBTS.

282. The minutes record that Mr Gidden explained that the RTDs' proposals were rejected not because of quality but other reasons. He went on to say that "*[o]ne reason was that in reorganising the NHS the Department had adopted the principle of devolution*".

283. My advisers have provided me a paper from November 1973 titled *Reorganisation of the National Blood Transfusion Service* [CBLA0000168] by Dr Bowley and Dr Darnborough. The paper explains two proposals for management structures for the blood service. The first had a special health authority created with an NBTS HQ accountable to it. The authority would then be accountable to the DHSS. The second proposal was an NBTS HQ accountable directly to the DHSS. In the conclusion the paper records: "*THE CENTRAL EXECUTIVE HQ IS THE ESSENTIAL AND MOST IMPORTANT PART OF THESE PROPOSALS OR INDEED OF ANY OTHER SCHEME WHICH MAY BE PROPOSED*".

284. As I understand it, the Central Committee of the NBTS was subsequently established on 19 June 1975 [NHBT0000028]. It would appear that the last meeting of that committee was in 1978, and it was disbanded in 1980 to make way for the Advisory Committee of the NBTS. I have been provided minutes of a RTDs' meeting from 8 December 1976 [DHSC0105496_010]. In respect of the Central Committee of the NBTS the following is set out:

Some RTDs were concerned that the Central Committee for the NBTS was not providing the central direction that they had hoped for and considered necessary for the NBTS. The Central Committee was advisory, without executive authority, and this made it difficult to manage resources on a national basis, e.g. by the elimination of wasteful duplication of activities between Regions. The arguments put forward to the Reid Committee in favour of a nationally organised service remained valid. Other RTDs thought that the Central Committee had not been provided with sufficient material to do a thorough job and suggested that RTDs themselves should adopt a more positive attitude to presenting their views to the Committee.

It was agreed that Dr Cleghorn and Dr Jenkins would prepare a paper on the problems of the present organisation, which would be discussed at the next RTD meeting.

285. I have been given the minutes of the following RTDs' meeting on 2 March 1977 [NHBT0016473]. A paper does not appear to have been prepared for that meeting.

286. As I explained in section 3 above, I understand the Advisory Committee on the NBTS was established in 1980. I set out the details of the committee above. I have been provided with the minutes of the first meeting held on 1 December 1980 [CBLA0001207]. As I understand from those minutes, the role of the committee was advisory to the DHSS and Welsh Office in respect of coordination of the development of the RTCs and CBLA in England and Wales, and with the English and Welsh Blood Transfusion Service with those in Scotland and Northern Ireland. It would appear that the question of whether the committee should have a *supervisory* role was set out in these minutes:

The proposal was made that the Committee should be changed to include the term 'Supervisory' in order to suggest an active role for the

Committee in monitoring developments in the Transfusion Service, especially the progress towards self-sufficiency in the collection of blood and the manufacture of products. The Chairman pointed out that a 'supervisory' committee would be contrary to the Government's overall policy towards devolving decision making to the National Health Service. He thought that the word 'Advisory' would in itself convey all that was necessary. Dr Tovey pointed out that on the question of increasing plasma supplies, for example, Transfusion Directors would be guided and advised by their Divisional Chairmen who were members of the Committee. That in itself was a form of supervision.

287. In *Fifty Years of Blood Transfusion* [NHBT0000028] at internal p.21 it explains that discussions surrounding a central service began again in 1984. I have been provided with a copy of a paper entitled *The National Blood Transfusion Service in England and Wales: An Organisational Study* produced by TA Kelly and SN Saunders of NHS Management Consultancy Services [CBLA0002392]. *Fifty Years of Blood Transfusion* [NHBT0000028] indicates that this paper was received by the DHSS in early 1988. The authors of that document say that this led to the formation of the National Directorate of the NBTS. The Organisational Study is a lengthy report which I will not set out in detail here. However, the report identified four underlying problems for the NBTS (see internal p.116):

11.1.1 the absence of reliable management information;
11.1.2 the inability of the two London regions to meet the needs of their hospitals from within their existing collection programmes;
11.1.3 the absence of co-ordination between individual RTCs and also between the BTS (and collective RTCs) and CBLA.
11.1.4 arising from 11.1.1 and 11.1.3 apparent inefficiencies both within and between individual RTCs.

288. The authors of the Organisation Study proposed three alternative solutions. The minimum change option proposed remedying some of the problems though evolution without change to the existing organisational structure save for a uniform management information system. The intermediate option maintained executive and financial accountability in the RHAs, but with the advisory role of existing bodies being enhanced by redefinition of their remits. This would also involve a new committee for NBTS/CBLA coordination. The paper noted that *"[t]he decisions and recommendations of the enhanced advisory structure, detailed below, would need to be recognised as of sufficient authority so that real account is taken of the merits and demerits of the situation before a veto is applied by an RHA*". The third option was a national option by which the NBTS was managed and funded centrally as an SHA.

289. *Fifty Years of Blood Transfusion* [NHBT0000028] summarises the three options proposed in the Organisational Study and identifies that, after "*wide consultation*" the DHSS chose "*to retain management by RHAs but with formal co-ordination of the work of RTCs*". That paper goes on to explain that on 1 October 1988 Dr Gunson became the National Director of the NBTS. He reported to Mr Graham Hart, Director of Operations on the NHS Management board. At that time an NBTS Coordinating Committee was established, and the Advisory Committee of the NBTS was disbanded.

290. The National Directorate is detailed at chapter 11 of *Fifty Years of Blood Transfusion* [NHBT0000028], and that information is not repeated here. The key objectives of the body were:

a) *to implement a cost-effective strategy for ensuring an adequate supply of blood throughout England and Wales;*
b) *to implement a cost-effective strategy for the supply of plasma to the blood products laboratory of the CBLA;*
c) *to co-ordinate the activities of the NBTS and the CBLA;*

d) to propose the efficiency of the NBTS.

291. As I understand it, the work of the National Directorate was again done without any executive authority over the RTCs as they continued to be regionally managed by the RHAs. In *Fifty Years of Blood Transfusion* [NHBT0000028] the authors record that the National Directorate's work was done through "*persuading the senior management in RTCs that the change was beneficial for the good of the service*". I have been provided with the minutes of the 210th Regional Transfusion Directors' meeting from 18 January 1989 [NHBT0018188]. I understand this meeting shortly followed the first meeting of the National Management Committee of the National Directorate. The minutes record that, from this date, the nature of the Regional Transfusion Directors' meetings changed to an annual scientific meeting.

292. Dr Gunson's statement for the HCV litigation [NHBT0000026_009] details in paragraph 15 the move from the National Directorate to the NBA. He set out there:

However, despite the successes the National Directorate was overtaken by national events. The devolution of budgets to Districts proposed in the NHS and Community Care Act 1990 meant that RTCs had to recover their operating costs through reimbursement for products and services. Inevitably, RTCs had to work closely with the hospitals receiving their products and services, and there was a tendency for the National Directorate to become marginalised as a result. The lack of any central executive authority had to be addressed. Taken with the plans then under consideration to reduce the number of RHAs, it became clear that further change was necessary.

293. The NBA was formed on 1 April 1993. The details of that formation have already been provided. The RTCs were transferred to the

authority of the NBA from 1 April 1994. The initial 3 years of the NBA is detailed in chapter 12 of *Fifty Years of Blood Transfusion* [NHBT0000028]. I understand that over time the individual RTCs, now BCs, became increasingly assimilated into the single service.

294. The details of the blood service, first as the NBA, and then as NHSBT, have already been described above. As was noted there, NHSBT operates its donor sites pursuant to its statutory functions. NHSBT therefore now controls the day-to-day activities of its static donor sites, which are carried out by NHSBT employees.

b. The role, if any, NHSBT plays in setting plasma targets for transfusion centres;

Collection of plasma since 1998

295. On 30 April 1998 the Committee on the Safety of Medicines recommended that UK plasma no longer be used for fractionation [WITN0672045]. This decision was made in response to concerns over the spread of vCJD (variant Creutzfeldt-Jakob disease), a human variant of BSE (Bovine Spongiform Encephalopathy). Instead, the NHS has fully relied on imports of plasma-derived medicinal products from other countries. The timescale for the implementation of the recommendation was to be agreed. Such use of UK plasma ended in 1999.

296. In 2020 following a comprehensive review of risks associated with using UK plasma for fractionation, the Commission on Human Medicines **('CHM')** on 8 and 9 October 2020 advised Ministers that the use of UK-sourced plasma to manufacture these treatments is safe and could recommence as the risk of vCJD transmission is now considered to be negligible [WITN0672046]. Ministers accepted these recommendations.

297. Following this decision, we were directed to collect COVID-19 Convalescent Plasma. I have provided letters from 24 November 2020 [WITN0672047] and 19 February 2021 [WITN0672048] to our CEO Betsy Bassis which deal with this programme. Following further correspondence on 17 March 2021 to our CEO we repurposed our convalescent plasma collection to collection of plasma for fractionation on a temporary basis [WITN0672049]. We were asked to retain 14 of the convalescent clinics for such collection and asked to collect 9,000 litres of plasma over the April to June 2021 period. The DHSC agreed to cover our costs up to £6.5 million in respect of this collection.

298. A further letter was then sent to our CEO dated 24 June 2021 [WITN0672050]. That letter indicated approval of a plasma business case, and NHSBT was instructed to continue collecting plasma for fractionation to the end of March 2022. Our targets for volumes collected were subject to analysis and the business case devised by the DHSC with input from NHSBT. The targets are national and although we divide these into individual collection centres volumes, this is purely a management tool to help us ensure that we are collecting sufficient plasma.

299. It was indicated this plasma would be for the manufacture of immunoglobulins (as the only product recommended by the Commission for Human Medicines). £53 million in funding was provided for years 2021-2022 for this provision. The letter indicated that we would collect plasma from whole donations and plasma by apheresis, with the aim of establishing a UK domestic supply of plasma for medicines, achieving 30% by the third year. The appointment of a fractionator will be led by NHS England. NHS England initiated the procurement process with publication of the Prior Information Notice – for Domestic Plasma Fractionation on 4 August 2021.

Summary of plasma collection prior to the 1998 decision

300. For ease of understanding my statement I should begin by pointing out the following. The answer to question 18(b) provided here concerns the setting of plasma targets. The answer to question 39 concerns the steps the blood service took over the years to meet those targets. The answer to question 40 concerns whether the blood service did in fact meet those targets. While I have tried to avoid needless repetition where possible, because of the closeness of the subject matter across these three questions, this has been difficult.

301. I will now set out how precursor bodies to NHSBT were involved in setting plasma collection targets prior to the cessation of collection in 1998, as I understand it from the documentation shown to me. I will divide these into timeframes for convenience, although in actuality the period is one continuous one. The documents to which I refer do provide information on specific plasmas, but I have not addressed those here as I have focused on what appear to be the main plasma targets.

302. The first period I have set out below is from 1973 to 1977. It would appear that targets for collection were set by an expert group in 1973 but were then significantly discussed and altered by Haemophilia Centre Directors by reference to need, and Dr Maycock by reference to capacity for production at BPL. There does appear to have been some confusion between particularly Dr Maycock and Dr Biggs on the amount of plasma required and hence the targets. As to the issue of dividing the target between individual RTCs, it would appear that the RTDs would agree how to divide up the target between locations.

303. The second period ranges from around 1977 to 1984. The detail of this period appears to indicate that the demand for Factor VIII was identified by the DHSS Working Group on Trends in 1977, which was then carried forwards into the proposals for production ceilings at the redeveloped BPL as the intermediary ceiling of around 90 million international units. This would also appear to be close to the 100

million international units advanced by the Haemophilia Directors and agreed with the RTDs. It would appear the precise amount of plasma required to satisfy this varied somewhat, but by the end of the period settled at around 435,000kg. I have been provided limited information about how each RTD agreed their targets, although it would appear to be linked to regional population and the introduction of pro-rata distribution of products by reference to the source material sent to BPL.

304. It would appear from the documents provided that over the period 1985 to 1989 plasma targets were negotiated between BPL and the NBTS. I understand that, while over this period the targets from the early 1980s remained in place, they were delayed due to period of delay that passed in the commissioning of work required at BPL. It would appear that capacity for processing was the limiting factor. Indeed, from some of the correspondence it would appear that there was some level of stockpiling at BPL of plasma.

305. For the period 1988 onwards, it would appear from the documents provided that over the period the plasma targets were negotiated between BPL and the Advisory Committee. In 1988 the Advisory Committee changed for the National Directorate, and later became the NBA. Based on the documents provided, it would appear that an issue over the period was an initial need to boost plasma production, followed by difficulties surrounding the amount of plasma that BPL would purchase from the blood service. It would appear that an aspect of setting plasma targets over this period for individual RTCs was bidding for plasma as part of cross-charging.

306. The three papers set out at the start of my answer to Q18 are significant sources for my answer here. In addition, I have been provided with the full draft 5 of the statement from Dr Lane of BPL for the HIV litigation [CBLA0000005_002]. His draft is particularly

pertinent from para 72. I do not attempt to provide here the detail set out in his statement.

307. Having seen these documents, I would make the following observations

a. I note that whilst the agreed aim was that of 'self-sufficiency' during this period, this was not a static target. The demand for Factor VIII was steadily increasing over the years from 1970 such that hitting a static defined target was not sufficient as the target was increasing year on year.

b. There is variety in the terminology used to express the targets. These are variably referred to in terms of numbers of donations, international units (i.u.) of Factor VIII, i.u. Factor VIII per 1000 population, kg or tonnes or litres depending on the perspective of the group. Whilst many at the time will have been skilled in translating between units, there is evidence of disagreement as to how much plasma was needed to supply a given number of i.u. Factor VIII (presumably due to variability in yield in the process of fractionation) and hence the most appropriate units to use. A single agreed terminology may have simplified discussions and there is evidence that a lack of agreement has, at times, caused some confusion, for example of including packaging in the weights.

c. There is no single overarching group or body that appears to be leading on agreeing the targets. Members of or groups themselves appear to be putting targets and views forward according to what they can deliver, manufacture, or need for patients and in the corresponding units. Thus, viewing from afar, there does not appear to be a system of collaborative decision making aiming to solve a specific and known goal – that of self-sufficiency.

d. The documents, in general, are hard to follow. Forecasting and planning appear to have generally been approached in a manner that was not rigorous or systematic. It would appear that Dr Maycock was asking for a ten-year target in 1976. I can see that there was a DHSS Working Group that followed in December 1977

which considered a 5-10 year target. Then in a meeting of the RTDs in March 1983 there is a table of a collection targets over the next five years, which shows a three-fold required increase over this time. In the early 1990s there were requests for three-year targets. There are references to documents suggesting Haemophilia Centre Directors were projecting patient needs. In most documents though, the minutes refer to a single target 'annually' at the time and this is reasonably consistent. I cannot see any long-term projected demand or targets set out and agreed in the documents available to me. This lack of an agreed longer-term plan would, it seems to me, likely to have made achieving the eventual target harder.

e. Finally, as has been noted before, the organisational structures and decision-making framework did not help in achieving efficient or effective decisions, either in terms of getting agreement, or in terms of negotiating or collaborating between regions. There was therefore a lack of what might be termed a systematic approach to firstly setting targets but also more broadly to solving the task of self sufficiency

Period 1973-1977

308. As I understand it, up until 1978 Dr Maycock was the director of BPL, Consultant Advisor to the DHSS, and headed the Regional Transfusion Directors' meetings. I have been shown a memo from 21 November 1973 which provides detail of Dr Maycock's role [CBLA0000166]. From his retirement in 1978, Dr Lane took the role of director of BPL, and Dr Tovey took the roles of Consultant Advisor to the DHSS and headed the Regional Transfusion Directors' meetings. My understanding is that, until at least the formation of the NBA the directorship of BPL was entirely separate to any leadership role at the blood service.

309. Plasma targets would have necessarily been related to the use of the fractionated products particularly Factor VIII. I have been provided with

a letter from Dr Waiter to Dr MacDonald dated 28 February 1973 [CBLA0000138]. That letter says that the chairman of the Haemophilia Centre Directors had recommended that an expert group on haemophilia be established to advise on likely trends in haemophilia treatment. I have not had access to the minutes of that expert group but this information would have been material.

310. I have been shown the minutes of the Expert Group on the Treatment of Haemophilia on 20 March 1973 [PRSE0004706]. Attendance included haemophilia centre directors, Dr Maycock, Dr Rizza, and staff from the DHSS and SSHD. At the meeting it was "generally agreed that 400,000 donations would be required to treat UK sufferers from haemophilia of all degrees of severity, and more if strenuous efforts were made to clear surgical waiting lists and if home treatment or eventually prophylactic treatment became accepted ways of dealing with the problem of haemophiliacs".

311. I have also been provided with minutes from a special meeting of the Regional Transfusion Directors on 20 June 1973 [CBLA0000153]. That document records that Dr Maycock reported that the expert group had accepted an estimate of the additional demand for plasma of around the equivalent of 400,000 donations annually. The minutes record that the RTDs agreed they would attempt to reach by 1975 a target of 250,000 donations per annum for fractionation to produce AHG (anti-human globulin). Paper RTD(73)22, which has not been available to me, was discussed and it was agreed the 400,000 donation target should be distributed among RTCs in proportion to the total number of donations of blood collected.

312. I have been shown minutes of another special meeting of the Regional Transfusion Directors from 27 September 1973 [CBLA0000160]. The paper RTD(73)24, which has not been available to me, was introduced to correlate the total donations and number of donations in each

region from which plasma would have to be separated in order to provide the amount of AHG estimated by Dr Biggs to be necessary.

313. I understand from minutes I have been provided with that there was a joint meeting of the Haemophilia Centre Directors and a small number of Regional Transfusion Directors on 31 January 1974 [CBLA0000187]. At that meeting Dr Biggs said an MRC report (called appendix B) suggested a need for materials derived from 500,000 to 750,000 donations annually [PRSE0002350]. Dr Maycock from his survey said he had "*obtained figures very similar to Dr Biggs's figures*". Following discussion, it was confirmed that Prof Blackburn, Sheffield Haemophilia Centre, would write to the DHSS and confirm that the report was approved, recommending that the document be used for future planning of Factor VIII needs in the UK. Dr Waiter, DHSS, could not confirm how the extra expense for this would be met, but she noted that purchasing commercial AHG was already costing the DHSS a lot of money.

314. Dr Lane's draft statement [CBLA0000005_002] at para 94 records that there was a UK Haemophilia Centre Directors (now Doctors) Organisation **('UKHCDO')** meeting on 1 November 1974 which Dr Maycock attended and discussed plasma targets. I have not been shown this document. Dr Lane says that the minutes record Dr Maycock as having noted that the expert group that advised the DHSS had suggested annual production of Factor VIII concentrate equivalent to 275,000 donations by 1975. In his statement Dr Lane himself says that this was well below the estimates of Dr Biggs.

315. I have been shown a letter dated 24 December 1974 from Mr Gidden to the regional administrators [CBLA0000239]. In that letter he identifies the need to immediately produce AHG equivalent to 275,000 donations annually and says the blood service is currently unable to meet the demand of clinicians. The need for 400,000 more donations is identified in the medium term. The letter identifies that BPL

production is limited by the supply of plasma from RTCs. To provide the facilities needed up to £0.5 million was earmarked in England and Wales (part of it recurring). It was noted that "*the cost of collecting 400,000 additional donations annually might be of the order to a further £1.0 to £1.5 million*". The letter concludes with a note on funding, addressed below.

316. I have also been provided with a letter Dr Maycock wrote to Dr Biggs to clarify the minutes of the UKHCDO meeting on 1 November 1974 [CBLA0000240]. He indicated that "*the target… was set not by me, but by you (!) at the first meeting of the Expert Group*". The letter goes on to reference the target at 275,000 donations annually by 1975.

317. I understand from minutes I have been provided with that there was a special meeting of the Regional Transfusion Directors on 19 February 1975 [CBLA0000225]. At that meeting there was a discussion of paper RTC (75)1 on the provision of fresh plasma, and how the number of required donations would be split between the individual RTCs. A draft version of that paper has been provided to me, which shows how the 275,000 donations were proposed to be allocated [NHBT0017090]. There were discussions over whether the number of donations devoted to haemophilia by each region would be based on regional populations or the amount of blood collected in 1973.

318. I can see at paragraph 102 of Dr Lane's statement [CBLA0000005_002] that he says there were 10 internal meetings at BPL through 1975 to discuss the increasing of capacity to the 275,000 donations annually.

319. I have been shown the minutes of a meeting held between representatives of BPL, PFL Oxford, PFC Liberton, the SSHD and the DHSS on 11 March 1976 [DHSC0100007_003]. The minutes I have appear to be a draft with many manuscript corrections. The minutes note that the minister of state had recently reaffirmed the intention to

achieve NHS self-sufficiency by the middle of 1977. It was also noted that he wished to achieve maximum cooperation between Scotland and England and reverse any preference some users might have for commercial products.

320. The minutes record some discussion of cryoprecipitate use in select locations, and difficulties that individual RTCs were facing in supplying sufficient plasma. Dr Maycock then discussed the target for plasma production set by the Expert Group on Haemophilia and the suggestion that there were people who thought the target should be considerably higher. The minutes include various discussions about yield, consistency of the nature of the product, and pricing.

321. On 21 June 1976 there was a meeting of the RTDs for which I have been provided the minutes [NHBT0017095]. In those minutes a recommendation of the ad hoc group on the Treatment of Haemophilia was considered:

The ad hoc expert group on the Treatment of Haemophilia had suggested that the demand for Factor VIII in the UK would rise to 35 million iu per year over the next 5 years, a figure in excess of the present target for NBTS Factor VIII production. However, the Department had not yet formed a view on the Expert Group's advice, the implications of which were considerable. RTDs recommended that the advice should be considered by the NBTS Central Committee. Dr Wagstaff had heard that the Haemophilia Centre Directors were proposing a meeting with RTDs to discuss Factor VIII supplies.

322. I have been shown minutes for a meeting on 26 July 1976 which was the first meeting of the Haemophilia Centre Directors, Regional Transfusion Directors and regional scientific advisors for the supra-regional territory for which Oxford haemophilia reference centre was responsible [CBLA0000391]. Dr Maycock and four RTDs attended. At this meeting supply of factor VIII was discussed.

Dr. Maycock said that he had a target of 15 million units of factor VIII per annum. This would include both cryoprecipitate and NHS intermediate potency freeze-dried factor VIII. The rate of production needed to reach this target should be achieved early in 1977. Dr. Maycock said that he was aware that a new target of 35 million units per annum had been proposed.

Dr. Rizza said that he had thought that the target for factor VIII was 35 to 40 million units of factor VIII and he wondered how the target of 15 million units had been decided.

Dr. Stewart said that the DHSS was committed to supply factor VIII within the NHS but that estimate indicated a shortfall of 20 million units per annum since the needs of patients had been estimated at 35 million units per annum.

Dr. Biggs said that the Haemophilia Centre Directors had never supported a target of 15 million units of factor VIII.

[…]

Dr. Maycock said that at present the total capacity for fractionation in England did not exceed 15 million units of factor VIII and thus large increases in the supply of plasma would not be helpful.

323. I have been shown a letter from Dr Biggs to Dr Maycock dated [CBLA0000488]. In that letter Dr Biggs queried the line "*had a target of 15 million units of factor VIII per annum. This would include both cryoprecipitate and NHS intermediate potency factor VIII*" in the minutes of the meeting of 26 July 1976. She noted that there was a misunderstanding in that line, because the current 1974 usage included 17 million units of NHS factor VIII. She noted that this included 14 million units of cryoprecipitate. She asked for clarification

as to whether Dr Maycock had meant the 15 million units was a target for freeze dried intermediate potency factor VIII. The manuscript note *"& that cryo was extra"* was added.

324. I have also been shown Dr Maycock's reply to Dr Biggs dated 28 September 1976 [CBLA0000464]. In that letter Dr Maycock explained the capacity of BPL and PFL for freeze dried concentrate was around 15 million units, and with some increase due to doubling output at PFL to a total of 17 million units. He concluded that the "*present target for concentrate BPL Elstree and PF Lab Oxford is about 15-16M iu p.a*". He also noted the production of cryoprecipitate separately and RTCs and discussed the volume of factor VIII produced based on number of international units per bag.

325. I have been shown the minutes of the RTD meeting on 6 October 1976 [NHBT0016475]. In those minutes it is noted that all RTDs had been invited to a meeting with the Haemophilia Reference Centre Directors in Sheffield on 22 October to discuss a revised target for Factor VIII output. It was noted that the meeting "*was to be purely professional, with participants speaking as individuals*".

326. I have been provided with minutes of an exploratory meeting of blood transfusion directors, haemophilia centre reference directors, and others, at Sheffield on 22 October 1976 [HCDO0000397]. Dr Maycock was in attendance. The meeting was called to discuss the production of Factor VIII. Much of the focus of the meeting was a presentation by Dr Biggs on the number of units of Factor VIII used in the UK and the "*urgent need to convert as much as possible plasma at present used for cryoprecipitate to a freeze-dried preparation*". She suggested doctors and patients may come to prefer the five commercial companies' preparations of Factor VIII over cryoprecipitate.

327. The minutes then provide somewhat of a summative transcript of the discussion. The following matters have been brought to my attention.

Of note in respect of quotas was the following. Dr Biggs thought 40 million units of Factor VIII concentrate to be less than realistic. Dr Cash agreed with this. Dr Maycock noted the expert advisers to the DHSS setting a target in 1973 but that the target had multiplied over three times by this point. He noted the difficulty of planning with such continuing escalation and asked for a primary target for the next ten years. In discussion Dr Tovey noted that the problem here was not collection but manufacture. Dr Maycock explained that at the time the production units were "*pretty well at the top of their capacity. The D.H.S.S. knows that something has to be done*". This was at 15 million units. Mr Watt noted that, at that time, production was 12-13 million units. With an investment of £20,000 it could increase to 24 million.

328. Prof Blackburn noted "*[i]t seems that sufficient plasma can be obtained from donors and that the real difficulty relates to staffing, premises and equipment for preparing concentrate*". Mr Watt noted his centre was clearly not working at full capacity. Dr Bidwell said they could double Factor VIII concentrate if they received the necessary plasma. Dr Bloom indicated that the Haemophilia Centre Directors would prefer "*100% freeze-dried*" when asked, between freeze-dried and cryoprecipitate. Dr Prentice recommended a target of the Haemophilia Centre Directors of 40 million units of concentrate currently, rising to 50 million in the next three years.

329. I have been provided the minutes of the RTD meeting on 8 December 1976 [DHSC0105496_010]. It is recorded that:

The meeting agreed that the figure of 50 million iu, in all forms, would need careful confirmatory examination and if it were in fact confirmed, long-term detailed planning would be necessary. Procurement of the plasma itself might not prove difficult (donor panels had doubled in some centres in the last 2 years without active recruitment). Some RTDs suggested that the planning of Factor VIII targets was yet

another reason for advocating that the NBTS should become a national service.

330. I have been provided with a set of minutes from the meeting of the Haemophilia Centre Directors on 13 January 1977 [PRSE0002268]. At that meeting Prof Blackburn reported that the blood transfusion service could supply sufficient plasma for fractionation to provide a minimum of 40 million units of Factor VIII per annum. There is also a discussion between Dr Waiter of the DHSS and Dr Biggs recorded:

Dr. Waiter said that the target of factor VIII requirements had shifted over the years. The DHSS had understood that the capacity at Elstree and Oxford was adequate. The request for 40 m. units was no surprise; even 50 m. units could be met. Dr. Biggs said that the target had not shifted. The first estimate given in recent years was 40-50 million units (Biggs, 1974). She did not know where the lower targets had come from; they certainly had not come from either the Expert Group on Haemophilia or from the Haemophilia Centre Directors.

Period 1977 to 1984

331. I have been provided with a report from the DHSS Working Group on Trends in the Demand for Blood Products dated December 1977 [DHSC0002189_014]. The report indicates that the working group was set up to "*consider the likely trends in the demand of blood products over the next 5 to 10 years, taking into account the practicalities of supply*". In doing so regard was had to a relevant Council of Europe study from 1976.

332. The report indicates that the working group expected a growth over the next five to 10 years of the basic minimum albumin supply from 100gm per 1000 population to 200gm per 1000 population. At that time production was 50gm per 1000 population in England and Wales. To achieve this there would need to be an increase in blood donations to 50 donations in 1000 population. That should provide for an

increase to 60 donations in 1000 population in the next 10 years although "*it should be borne in mind that too high a rate of normal blood collection will lead to an embarrassing excess of red cells*". The group accepted a Factor VIII estimate in the foreseeable future of 1000 iu per 1000 population per annum. To minimise loss of Factor VIII in storage the group recommended a long-term aim of complete transfer from cryoprecipitate to fractionated freeze dried concentrate. The paper concluded:

Considerable further investment in collecting, testing, processing and premises will be required to achieve these targets. It will be a major undertaking for most Regional Transfusion Centres to increase further both blood collection and output of red cell concentrates. It is not expected that, given adequate publicity, difficulty will be encountered in recruiting the additional donors needed to provide 200 grams albumin per 1000 population per annum, but increased blood-collecting resources, accommodation and equipment will be needed in the Regional Centres.

Additional fractionation capacity is also needed, even allowing for some possible expansion of the Liberton plant's output. The present UK capacity is less than half that we regard as essential. Additional major investment is, therefore, also needed for this.

Close attention also needs to be given to the possible future organisation of the Transfusion Services, particularly in relation to better national co-ordination, forecasting and planning.

333. This report is commented on in meeting minutes I have been provided for the meeting of the RTDs on 3 May 1978 [BPLL0007406]. It is noted by Mr Dutton that a meeting of the Standing Medical Advisory Committee confirmed the figures as a reliable estimate for future requirements "*(except possibly in the case of Factor VIII more of which might be needed than estimated)*". The Standing Medical Advisory

Committee supported the proposals in the report. It was also noted that the Department was currently engaged in examining the most effective methods of meeting the requirements in the report. This was both in respect of provision by regions and capacity at the Central Laboratories.

334. I have been shown a paper by Dr Lane entitled *The Function of Stop-Gap and Phased Redevelopment of the Blood Products Laboratory* dated 31 May 1979 [BPLL0001508] in which estimates for Factor VIII production are provided. On p.12 it is noted that a new fractionation laboratory at Elstree would provide for a production ceiling of 120m i.u. per annum with an intermediate target of 90m i.u. by the mid-1980s. Dr Lane thought this would translate into approximately 375,000 litres of fresh frozen plasma **('FFP')** for 90m and 500,000 litres of FFP for 120m. These figures are repeated in a lengthy discussion paper I have been provided with, from the Select Committee on Blood Transfusion dated 17 July 1979 [CBLA0000957].

335. I understand from minutes that have been provided to me, such as the minutes of the Joint Management Committee for the Central Blood Laboratories from 20 February 1980 [CBLA0001068] that there was progress towards proportional distribution of blood products to RTCs based on the amount of plasma and other source materials provided to BPL. This is addressed further in my answer to section 8.

336. I have been provided with the minutes of the first meeting of the Advisory Committee on the NBTS dated 1 December 1980 [CBLA0001207]. In these, it is recorded that supply of plasma was discussed at that meeting. Dr Tovey spoke to paper AC(80) 3 and 4. I have been provided AC(80)3 [CBLA0001209] which includes details of current and future capacity at BPL following upgrading. The paper provides a target for production from RTDs which is based on the population of each region. It provides both current numbers and future

targets. The paper notes the proposal of pro-rata distribution and the particular needs of certain locations. The paper also records:

4. The table shows that, with the exception of two regions (Mersey and SE/SW Thames), the others should be able to meet their targets without increased blood collection provided that they can improve the quality of their plasma to not less than 225 i.u./litre, and, where necessary, increase the proportion of usable donations converted to FFP to not less than 45%.

5. It appears from the survey that some regions (e.g. E. Anglia, N.W. Thames, W. Midlands and S. Western) may well be able to exceed their target of FFP. The Committee will wish to consider whether surplus plasma contributed by these regions should be "purchased" by any region which finds difficulty in meeting its target by 1982.

[…]

7. It is proposed that a report of this survey is circulated to each regional health authority and RTD to enable plans to be drawn up to meet the regions' target of FFP. This should be followed at quarterly intervals by a report from the Director of BPL to all regions showing the quantity and quality of the plasma being received at BPL.

337. The minutes report that AC(80)3 had been prepared with the RTC divisional chairmen, and set out the regional targets for collection of FFP by 1982. It was noted that, save for Mersey and SE/SW Thames, it was thought the regions could increase the amount of plasma supplied to BPL without increasing overall donation numbers if 45% of all donations were converted to FFP. It was noted that the targets were to be agreed with each director, and progress would be monitored by Dr Lane. The meeting also noted that demand for Factor VIII was predicted to rise to 90 million iu by the mid-1980s.

338. I have also been provided the Chairman's briefing note for the first meeting of the Advisory Committee [DHSC0002201_056]. That report notes that by the mid-1980s the Factor VIII usage was estimated at 90 million iu. It is also noted that the Technology Working Party estimated a redeveloped BPL would need 410,000 litres FFP to meet these requirements. The briefing note reports provision at that time to only be 75,000 litres.

339. I have been provided the minutes of the second meeting of the Advisory Committee on the NBTS on 23 February 1981 [CBLA0001287]. At that meeting it was noted that a letter had been sent to regional administrators setting out the scale of the increase in plasma supply needed over the next two years to reach 600 i.u. of Factor VIII per thousand of population. The minutes reference AC (81)1 which has not been available to me.

340. I have been shown a memo indicating information required by the Working Party for Self-Sufficiency in Blood Products from 18 March 1981 [CBLA0001313]. That document indicates that information concerning the national requirement of Factor VIII was to be provided by meeting with the haemophilia directors; and the volume of plasma required for fractionation would be provided by BPL.

341. I have been shown the minutes of a RTD meeting on 19 May 1981 [NHBT0018340]. At that meeting Dr Gunson presented a paper, RTD(81)13, on potential for plasma procurement. I have not had access to this paper. In respect of his survey Dr Gunson said:

123,000 extra blood donations were required for optimum working bringing the England and Wales total to 2.15 million. At this point 200,000 litres (assuming no cryoprecipitate production) would be available from approximately 50% of all donations. These figures were to be presented to the Central Advisory Committee. No account had

been taken of the possible effect that CPD adenine introduction might have on overall red cell unit needs.

342. I have also been shown a preliminary report from June 1981 of the working party chaired by Dr Gunson [CBLA0001377] (now under the title Working Party to Advise on Plasma Supplies for Self-Sufficiency in Blood Products). That report accepted 100 million iu as a reasonable estimate of clinical need for Factor VIII by the mid-1980s, and suggested that 500,000 kg of source plasma would be required to meet the requirement.

343. I understand from minutes that have been provided to me, that there was a third meeting of the Advisory Committee on the NBTS on 22 June 1981 [CBLA0001388]. Those meeting minutes identify that the 100 million iu of Factor VIII was a figure identified by the haemophilia directors. Dr Gunson spoke to paper AC (81)11 which has not, as yet, been available to me. He explained that the production of this amount of Factor VIII would require 500,000kg of plasma at current production.

344. I have been provided a report of the Protein Fractionation Technology Working Party from 1981 [DHSC0002213_021]. That document identified the "*internationally accepted requirements for plasma proteins for the National Health Service, production in England and Wales must be raised to fractionate 450,000 litres of plasma per year*". That number is qualified by a footnote indicating the Advisory Committee of NBTS could alter this figure, although it "*seems likely to be a reasonable estimate*". This report then goes on to say that the projected annual demand for Factor VIII of 90 million i.u. is such that production capacity at a new laboratory would need to be 450,000 litres per annum on current yields.

345. I have been shown minutes of a joint meeting of representatives of Haemophilia Centres and Blood Transfusion Directors from 23 April 1981 chaired by Dr Tovey [DHSC0002207_019]. I see from those

minutes that "*IT WAS AGREED THAT THE PROJECTED FIGURE FOR FACTOR VIII USAGE FOR THE MID 1980S WAS 100 MILLION I.U.*".

346. I have been provided with minutes of a meeting of representatives of the Haemophilia Directors, Blood Transfusion Service Directors and DHSS dated 15 September 1981 [CBLA0001448]. At that meeting it was recorded that directors agreed to accept a reduced need for high-purity concentrate and frozen cryoprecipitate. The result was that the plasma requirement could likely be reduced to 435,000kg. This figure was then confirmed at various meetings for which I have been provided with the minutes:

a. [CBLA0001457]: the fourth meeting of the Advisory Committee on the NBTS on 28 September 1981. Dr Gunson repeated the figure of 435,000kg discussed at the meeting above. It would appear they included a table of costings to RHAs. It was also recorded that the Haemophilia Centre Directors were "*aware of the need for close liaison with RTDs on the provision and usage of Factors VIII and accepted the need to provide an accurate picture of the extent to which Factor VIII was being purchased within their region*".

b. [CBLA0001565] a meeting of the Working Party to Advise on Plasma Supplies for Self-Sufficiency in Blood Products dated 18 December 1981 and chaired by Dr Gunson. A paper was provided by Dr JK Smith and it was accepted by the working party that there was "*no reason to alter the estimated quantity of 435,000 Kg. plasma to achieve self-sufficiency in blood products*". Reasons for that conclusion were provided.

c. [CBLA0001517]: a meeting of the Policy Steering Group for the Re-Development of BPL dated 18 December 1981. Dr Gunson reported the finding of the working party set out above. It was

noted that discussions would be had with RHAs about plasma supplies.

347. There was the fifth meeting of the Advisory Committee on the NBTS on 31 March 1982 where a further meeting of the Working Party on Trends was discussed and it was reconfirmed that the plasma required for self-sufficiency should remain at 435,000kg [DHSC0001136]. Also, at that meeting consultation with the RHAs about plasma supply was reported:

Mr Godfrey reported that DHSS had asked all RHAs for an indication of their ability and willingness to increase the supply of fresh-frozen plasma to BPL. 12 regions had replied to date, all of whom supported the principle of self-sufficiency. Several regions doubted their own ability to achieve their notional target (based on population) by the mid-80s and had suggested a gradual progression towards the target figure. The Committee felt that a phased build-up to 435,000kg was a reasonable proposition which would enable account to be taken of changes in product yield. The Secretariat was asked to summarise RHAs' response for the Committee's information.

348. I have also been provided the minutes of a meeting of the Joint Management Committee **('JMC')** of the Central Blood Laboratories from 27 April 1982 [DHSC0002217_011]. At that meeting RHAs were discussed and it was noted that "*[r]egions accepted the principle of self sufficiency but were unable to commit resources immediately to increase the plasma collection to the required level*". It was suggested that it would be necessary to build up supply in stages and "*this would be taken into account in planning the new Laboratory's capacity*".

349. I have been shown a paper on plasma supply which references a meeting of the RTDs on 28 March 1983 [CBLA0001778]. The date is not entirely clear. This document discusses plasma procurement at length. At Table 2 it provides a "*minimum plasma collection schedule*"

of FFP: 1983-1984 – 150,000kg; 1984-1985 – 170,000kg; 1985-1986 – 265,000kg; 1986-1987 – 405,000kg; and, 1987-1988 – 450,000kg.

350. I have been provided the minutes of a meeting of the CBLA on 27 April 1983 [BPLL0003987_002]. At that meeting Dr Lane explained that:

…in order to build up a sufficient supply of plasma for the new factory, the RTD's would need to start working on their budgets for September. However, there would be a two-year delay before they received any increase in returned product. It was agreed that this should first be made clear to RTD's and then Dr Lane and the Secretary should explain the situation to Regional Treasurers and to RTO's

Period 1985 to 1988

351. I have been shown a paper by Dr Lane and Dr Gunson from 17 January 1985 which discusses the difficulties in achieving the plasma targets set [DHSC0001472].Achievement of supply is dealt with in section 8 below.

352. I have also been shown the minutes of the RTD meeting on 23 January 1985 [CBLA0001995]. There is a discussion there on the difficulty of meeting self-sufficiency with current provision. The minutes note that there is a trial on charging between two regions and BPL from March, but that charging would appear a little way away at present.

353. I have been provided with minutes from the Regional Transfusion Directors' meeting from 1986 which discuss delaying of the plasma targets as a result of the delay in development at BPL. Document [CBLA0002307] is the meeting minutes for 24 April 1986 which explain that:

Dr. Moore advised the Directors that because of uncertainty as to when the B.P.L would be ready for full production, plasma targets

should be modified so that although eventual targets remained unchanged, the achievement of them could be delayed. It was hoped that substantial production would be achieved by the end of 1987.

354. I have been provided the minutes for a meeting of the CBLA on 3 June 1986 [CBLA0004781]. At this meeting Dr Moore reported on the issue of targets in light of the commissioning of BPL:

Dr Moore confirmed that the revised projection figures relating to plasma use, storage and production provided by BPL had been presented to the last meeting of the National Advisory Committee for the BTS. A major discussion element had been the commissioning of the new BPL and how this would affect the plasma supply requirement. It was noted that a further letter on this matter was now ready to be sent out to Regional General Managers.

355. I have been provided the minutes of a meeting of the RTDs on 9 July 1986 [CBLA0002312]. At that meeting there was a discussion of the issue of plasma targets:

Dr. Moore reported that he had not yet written to Regional General Managers because discussions were still taking place regarding the handling of stored frozen plasma. The Chairman asked when it was anticipated that the BPL would be fully operational. Mr. Armour indicated that the present projection was mid-1987. He also reported that the -40℃ cold room was almost ready for handover and use for plasma storage. Dr Wagstaff expressed widely felt concern that if there was nine months slippage on the projected completion date for BPL and a similar delay in the return of finished blood products to regions, the Regional Health Authorities will seek to recoup some of the funds that they have made available for plasma procurement. Dr. Darnborough asked if it would be possible to have further information about the size of the stock-pile of frozen plasma and what it represented for each Region in terms of finished product when that

became available. […]. Dr. Tovey raised the possibility that the BPL should pay part of the costs incurred by Regions due to the delay since they would not be spending money which they had otherwise expected to be spending.

356. I have been provided minutes from a meeting of the CBLA on 23 September 1986 [CBLA0004966]. Dr Moore reiterated that Regional General Managers needed to be aware of the issue concerning Factor VIII supply. He went on to discuss the plasma supply to 1990 and the problem of maintaining the flow together with storage at BPL. The minutes go on to say "*[h]e felt there was now a need for the Director of BPL and the Regional Transfusion Directors to discuss this, particularly in the light of the Authority's intention to achieve maximum throughput from available plasma*".

357. I have been provided the minutes of a CBLA meeting from around a year later on 24 September 1987 [CBLA0002385]. At that meeting Dr Lane reported that BPL was "*receiving adequate supplies at present but when we start full production in the new factory this would come under review*".

358. I have been provided with the meeting minutes from the 37th meeting of the CBLA on 28 July 1988 [CBLA0004826], again a year later. In that meeting Dr Gunson reported the findings of the plasma supply group medical sub-committee. The amount of plasma required had been based on Factor VIII production requirements in the following amounts: 88/89 – 350-400 tonnes; 89/90 – 450 tonnes; 90/91 – 550 tonnes. In the minutes for the 38th meeting of the CBLA (see below) these were corrected to: 89/90 – 350-400 tonnes; 90/91 – 450-500 tonnes; 91/92 – 550 tonnes.

359. I have been provided with meeting minutes from the 38th meeting of the CBLA on 22 September 1988 [NHBT0015546]. In those meeting minutes it is recorded that the plasma stockpile had been provided as

a gross weight figure rather than net, so packaging would make a 20% difference. Dr Gunson indicated that 550 tonnes was the maximum to be expected from RTCs.

360. I have been provided with a table indicating the FFP provision to BPL over the calendar years 1985 to 1988 for each RTC region [NHBT0015544]. Total supply in kilograms of FFP for the calendar years was: 1985 – 238,258; 1986 – 300,733; and 1988 – 353,340. In addition, this document provides the projected national targets for plasma supply to BPL for the years 89-94. Plasma to be supplied in tonnes was: 89/90 – 420; 90/91 – 490; 91/92 – 560; 92/93 – 590; 93/94 – 590. The document predicts the use of some plasma stocks stored at BPL over the period.

361. This period is described in the *Fifty Years of Blood Transfusion* document [NHBT0000028] at p.54. The authors say there:

When the building of the new BPL started in 1983 it was estimated that RTCs needed to provide 450 tonnes (450,000 litres) of fresh frozen plasma by 1986. It can be seen from Fig. 8·5 that this quantity was not reached until 1990. In the event, the provision of less than 300 tonnes during 1986 was not responsible for a failure to meet production targets as the new factory was not fractionating effectively until 1988. This delay allowed stocks of fresh frozen plasma to accumulate and in the year ending March 1989, 470 tonnes of plasma were processed.

Period 1988 onwards

362. I have been provided the minutes of a meeting of the RTDs on 4 October 1988 [NHBT0018189]. At that meeting there was an extensive discussion of the plasma supply. The Chairman summarised the issues as follows:

1. *The need to increase plasma between now and the end of March 1989 by 10%.*

2. *In 1989/90, the need to increase from 350 tonnes to 450 tonnes per annum.*

3. *The question of yield is being actively pursued with an immediate target of improving from 145 iu/kg to 165i.u./kg.*

4. *Fractionation at 550 tonnes per annum would not achieve self-sufficiency for Factor VIII unless treatment policy was reviewed by the Haemophilia Directorate.*

5. *There is a need to provide information to the Department of Health both for Ministers and for RHA's about obstacles to these targets.*

6. *The Department of Health would circulate a document informing regions of pricing policies.*

363. I have been provided with the minutes of the first meeting of the NBTS/CBLA Liaison Committee. I understand from these minutes that this followed the establishment of the National Directorate of the NBTS. The minutes are dated 10 January 1989. [NHBT0015545]. Papers (which have not as yet been available to me) on plasma supply were discussed. The minutes indicate that the target for plasma production was 8.82 tonnes per million of the population for year 1989/1990. It was indicated that an appraisal of each RTC would then follow in determining the plans for 1991. Issues with proposals for cross-accounting were also discussed at this meeting.

364. I have also been provided the minutes of the meeting of the RTDs on 18 January 1989 [NHBT0018188]. At that meeting Dr Gunson reported that the CBLA/NBTS Liaison had discussed a DH Plasma Supply Group paper and recommended option 2 which delayed maximum

fractionation until 1991. RHAs were to be told of the need to achieve 8.82 tonnes per million by the end of 89/90. There was also an extensive discussion of how cross-accounting would work, which was due to be introduced on 1 April 1989.

365. I understand from *Fifty Years of Blood Transfusion* [NHBT0000028] p.76 that cross-accounting was introduced in April 1989. That document, and other documents discussed in section 8, indicate that this had a significant impact on the demand for plasma from BPL. As is noted in some minutes from the 1990s, it also led to an aspect of allocating plasma targets between RTCs by bidding for plasma. I have been shown minutes of the National Directorate from 30 October 1991 [NHBT0046751] which indicate that bidding was by that time an aspect of the setting of regional plasma targets.

366. I have also been provided with the minutes of a meeting of the Management Committee of the National Directorate for 29 August 1989 [NHBT0000188_033]. The minutes provide the estimate for 1989/90 as 430 tonnes and 1990/91 as 480 tonnes. The minutes record that the 1990/91 total "*represented a conservative estimate*". The minutes go on to record that consideration would be given to the target for 1990/91 and 1991/92 in the next few months.

367. I have also been provided the minutes of a meeting of the NBTS/CBLA Liaison Committee dated 16 November 1989 [NHBT0017187]. At that meeting the Chairman reported that:

At a meeting at the DH on 14th November 1989, from the NBTS point of view, the policy of National self-sufficiency in all plasma products had been accepted and that the provision of 480-490 tonnes of plasma for BPL in 1990/91 was approved.

368. I have been provided the minutes of a meeting of the NBTS/CBLA Liaison committee on 1 February 1990 [NHBT0000063_047]. At the

meeting Dr Gunson said the plasma target for 1990/91 was 490 tonnes. There was a discussion about flexibility of receipt and Dr Lane considered the ideal situation was an even supply of 40 tonnes per month. It was hoped plasma supplies would increase in early 1990 because of the implementation of increased collection in Birmingham and Liverpool and a reduction in use of plasma at BPL due to higher yield of Factor VIII.

369. A report from Dr Moore dated 7 February 1990 has been brought to my attention [NHBT0010489]. In that report Dr Moore addresses the concern of "*serious financial consequences for BTS should BPL be unwilling to purchase the full planned quantity of plasma produced by BTS*". The report included the following paragraph in respect of the 1990/91 plasma targets:

BTS plasma targets are the outcome of long-standing planning and investment. Financial planning for 90/91 in all RTCs is based on income from their contribution to the 490 tonnes target set 2 years ago. If BPL do not take this quantity then RTCs will have no option but to cut-back on collection in order to balance budgets.

370. Dr Moore notes that:

RTCs have provided BPL via the Directorate with detailed estimates of their projected usage of BPL products in 1990/91. This estimate accounts for around 70% of BPL potential output and could be manufactured from an estimated 380 tonnes of plasma.

It is known that Districts also purchase blood products from commercial sources using their own budgets. The extent of this purchasing is unknown and has always been outside the control of RTCs.

371. Dr Moore also provides a section on the "*way forward*". In that section the following is set out:

The National Directorate on behalf of the BTS is working closely with BPL to draw up a national agreement for the supply of products and plasma in 90/91. It is hoped that BPL will have sufficient confidence in the talent of their sales force to reaffirm their agreement to take 490 tonnes of plasma (of CBLA Budget Preface [sic]). However, BTS will not be in the position to agree to purchase all the product from that quantity of plasma.

372. I have been provided the minutes of a meeting of the Management Committee of the National Directorate of the NBTS for 25 October 1990 [NHBT0071860_002]. At that meeting it was noted that the demand for Factor 8Y was already above target and expected to increase further. It was noted that the NBTS would need to collect 500 tonnes of plasma or 9.7 tonnes per million population.

373. I have also been provided the minutes of a meeting of the Management Committee of the National Directorate of the NBTS for 30 October 1991 [NHBT0046751]. At that meeting there was a discussion of plasma requirements for 1992/93:

Dr. Gunson confirmed that the bids from RTCs for normal plasma totalled 534 tonnes for 1992/93. Mr. Crowley had accepted this total and this had been confirmed at the last CBLA meeting. Dr. Moore will inform RTCs of their targets and will formally invite RTCs to bid for provision of specific plasma.

374. I have been provided the minutes of a meeting of the NBTS/CBLA Liaison committee for 10 April 1991 [NHBT0000077_056]. Plasma targets for 1991/92 were discussed. It was noted that BPL had requested 497 tonnes. The RTCs bids were accepted to supply that

plasma but the provision was 11 tonnes over target. It was thought this would allow some slippage.

375. I have been provided the minutes of the NBTS/CBLA Liaison committee on 9 September 1991 [NHBT0097471_015]. At that meeting the budget proposed for the 1992/93 plasma requirement was 497 tonnes, of which 12 would be specific plasmas and 80 tonnes obtained by apheresis. It was noted that the figures should only be used for guidance, and that RTCs would be shortly asked to make bids.

376. I have been provided with the minutes of the NBTS/CBLA liaison committee from 12 December 1991 where plasma targets and plasma contracts were discussed [NHBT0017208]. In respect of plasma targets for 91/92 it was noted that supply to the end of November was 4% down against target. However, it was hoped that the shortfall would be made-up by March 1992. In respect of future targets:

RTCs are currently preparing definitive plans for 1992/93 targets. Mr. Crowley confirmed that CBLA would take all the 534 tonnes of plasma currently anticipated next year. In a move to re-align their functions, CBLA rather than BPL will be the party formally holding the plasma in 92/93.

377. There was also a discussion about CBLA formally contracting with RHAs for the supply of plasma:

Formal contracts between CBLA and RHAs for the supply of plasma had been proposed. In discussion it was agreed that the present method of negotiation and outcome monitoring between CBLA and the Directorate had worked well. Neither was there any MCA need for contracts.

However, RTCs would welcome 3 year forecasts of plasma requirement so that they could manage their own investment in collection more effectively. This was particularly important for specific plasma donors and BPL were urged to look at the European market for specific plasma products.

BPL agreed to supply 3 year forecasts but emphasised that they would be 'forecasts' rather than 'actuals'.

378. There was a meeting of the NBTS/CBLA Liaison committee on 19 March 1992 [NHBT0010346]. At that meeting the forecast for the years 1993/94 and 1994/95 for plasma excluding specifics was 530-540 tonnes.

379. I have been provided with the minutes of a meeting of the Management Committee of the National Directorate of the NBTS dated 2 April 1992 [NHBT0097468_003]. At that meeting there was a discussion of plasma targets for the years 1993/94 and 1994/95. It was thought this would be between 530 and 540 tonnes with 50 to 80 tonnes additional plasma being processed from the stockpile.

380. I have also been provided the minutes of a meeting of the Management Committee of the National Directorate of the NBTS dated 7 September 1992 [NHBT0071601_001]. At that meeting it was noted that usage for 1992/93 was expected to be 573 tonnes with an additional 12 tonnes of specific plasma. The target collection for that period was 531 tonnes with an additional 8.6 tonnes specific plasma. The forecast usage by BPL for 1993/94 was 560 tonnes.

381. I have been provided the minutes of a NSBT/CBLA Liaison committee meeting on 10 December 1992 [NHBT0010333]. At that meeting the plasma targets for 1993/94 were reported as agreed at 540 tonnes in total made up of 542 tonnes FFP with 8 tonnes specific plasma. It was

noted that DH set the price for such plasma, but BPL had recommended an increase in price paid in line with inflation.

382. I understand that on 1 April 1993 the NBA was formed and replaced the National Directorate. I have been provided with minutes of the fourth meeting of the RTDs/Chief Executives/General Managers dated 27 July 1993 [NHBT0016372_001]. At that meeting BPL indicated that it would need 480 tonnes of normal plasma in the year 1994/95. It was added that with the "*impending introduction of recombinant Factor VIII (the effect of which was unknown at present) he could not envisage more than 500-510 tonnes being required for each of the years 1995/96 and 1996/97*".

383. I am aware that there was a meeting of the RTC/BPL liaison committee on 27 October 1993 [NHBT0015802]. The minutes note:

Centres have been asked to cut down on their plasma pheresis programmes as BPL required less plasma next year. The smaller centres have made a reduction of 18 tonnes and Mr Savery was meeting the four main centres next week to discuss their proposals and look at the cost implications.

384. In April 1994 the RTCs came under the control of the newly formed NBA. I understand that this negotiated approach between BPL and the RTCs continued in some form within the NBA until the collection of UK plasma for the production of factor products was ended as a result of vCJD risk in 1998. I have already discussed the position from 1998 in the introduction to this answer.

c. The role, if any, NHSBT plays in setting funding levels for transfusion centres;

385. The three papers set out at the start of my answer to Q18 are significant sources for my answer here. As has been detailed

elsewhere, from 1948 to 1994 the RTCs were under the authority of the RHBs, later RHAs.

386. As I understand it, this meant that the predecessors of NHSBT had no role to play in the setting of funding levels for the transfusion centres. This was controlled by the RHAs, and by any funds specifically provided by the Department of Health. NHSBT's predecessors could use persuasion to try and convince the RHAs and the Department of Health to undertake certain funding steps. I provide some examples here which are dealt with elsewhere in my evidence and other evidence provided by NHSBT.

a. In section 8 I address the funding difficulties faced by RTCs in increasing their plasma production to reach self-sufficiency. I have been provided with a survey from 1984 in which various funding difficulties are recorded: [CBLA0001800].

b. In the lookback response of Dr Robinson, the issue of funding for anti-HCV testing, which was in the hands of the RHAs and Department of Health, is addressed.

c. I have been directed to *Fifty Years of Blood Transfusion* [NHBT0000028] at p.76 where the difficulties concerning the introduction of cross-accounting and use of funds by RHAs in the purchase of blood products is discussed. This is considered further in section 8.

387. I have also been shown occasions on which the DHSS itself used persuasion in respect of the devolved budgets held by RHAs. I have also been shown a paper produced by Dr Gunson dated 13 February 1984 for a CBLA meeting on 25 January 1984 [DHSC0001967]. The issue of funding for RTCs to increase plasma production is addressed in that document. In respect of DHSS involvement in increasing funds it is recorded:

This approach could be supplemented by additional advice from the D.H.S.S. However, this has already been tried and although most R.H.A.'s agreed in principle, few have actually allocated finance for the purpose of the additional supply of plasma.

388. The situation changed on the establishment of the NBA on 1 April 1993 and the transfer of the RTCs on 1 April 1994. From this point the NBA was an SHA which received its funding directly from the Department of Health. As has been discussed above, the RTCs became increasingly assimilated into the NBA as the BCs. Funds were then provided to these bodies as constituent parts of the national service.

389. Today, NHSBT does not set funding levels for transfusion centres. NHSBT's donor sites and blood centres are an operating cost in the exercise of its functions, which is reflected in its annual accounts. NHSBT's income largely consists of revenue from contracts and service level agreements with customers, the majority of customers being NHS hospitals. NHSBT also receives a small amount of income from non-contractual supplies; this includes income from training and royalties as well as for ad-hoc supply of products or services. Other revenue is largely grant-in-aid funding (for Organ Donation and Transplantation and Stem Cell functions), from the DHSC as NHSBT's sponsor as an executive non-departmental body, and other departmental health authorities in line with funding agreements for the financial year.

d. The level of accountability of transfusion centres to NHSBT.

390. The position on accountability was and is essentially the same as set out under the answer to Question 18(a). The accountability of the RTCs is really the corollary of NHSBT, the NBA, RHAs, or any other body exercising their authority at any given time.

391. Up until the formation of the NBA and the transfer of the RTCs to it on 1 April 1994, the RTCs were formally accountable to the RHAs (previously, the RHBs). After that date the RTCs (now BCs) were constituent parts of the NBA (and now NHSBT).

19. Does NHSBT issue organisational guidelines or directives relating to transfusion safety/best practice, or blood safety more generally, to its transfusion centres? If so, please provide copies of such guidelines that NHSBT deems to be relevant to the Inquiry's terms of reference.

392. I note at the outset the decentralised structure of the blood service prior to 1994 and lack of executive authority over RTCs. From the papers available it is difficult for me to go into the specifics of how each RTC received and worked in accordance with guidelines and directives received. I have tried to identify examples of the guidance and directives issued nationally.

393. The blood service has used various handbooks as organisational guidance and directives passed on to the RTCs and their staff. I have discussed these in question 46, but the most pertinent one appears to be *Notes on Transfusion*. I have seen that this document was being produced in the 1970s and 1980s. For example:

a. I have seen the minutes of an RTD meeting on 22 March 1972 where there is a discussion about revision and publication of the next edition of *Notes on Transfusion* [NHBT0016125].
b. I have seen the minutes of an RTD meeting on 20 September 1982 where an upcoming revision of *Notes on Transfusion* is discussed [CBLA0001623]. In the discussion the view is expressed that it should be the definitive document of the blood transfusion service and should include content aimed at junior and medical staff.

394. While lacking executive authority, the various different high-level bodies of the blood service would produce minutes with guidelines and directions for the RTCs. It would appear that these were usually, but not always, put into action on the terms set out by those high-level bodies. My answers throughout this response are peppered with such examples, ranging from the RTDs in the 1940s and 1950s to today (e.g. donor selection). For further detail at a high level about decision-making authority and direction from these high- level bodies, the paper *Fifty Years of Blood Transfusion in (1996, Volume 6, Supplement 1) Transfusion Medicine* by Dr Gunson and Dr Dodsworth [NHBT0000028] provides a considerable number of examples (e.g. the chapter on the National Directorate sets out clearly examples of such guidance being issued and followed).

395. Many of the directives that the blood service followed came from outside of the service. See for example the role of the Committee on the Safety of Medicines in the 1980s and its direction in respect of factor concentrates and AIDS (discussed in section 9) or health circulars issued by the Department of Health over the years. For these external decisions, the blood service would sometimes attend such meetings as part of a panel of advisors who would provide information to the decision-makers. There are also the various laws which have been implemented over the years which provided strict rules for the service.

396. Various government committees have also been important in the setting of guidance and directives. For example, SaBTO includes within its remit advising '*on the most appropriate way to ensure the safety of blood, cells, tissues and organs for transfusion / transplantation*'. SaBTO provides independent advice on risk management for Ministers, UK Health Departments, NHSBT and the wider NHS. Its forerunners were the Advisory Committee of the Safety of Blood **('AVSCB')** and the Committee on the Microbiological Safety of Blood and Tissues for Transplantation **('MSBT')**. The role and remit

of these bodies is discussed below and in other blood service responses.

397. JPAC has played a significant role since the mid-1990s, which I have already discussed above. Part of its role is advisory to the UK blood services. Another of its functions has been preparing detailed service guidelines which are contained in the Red Book. An important aspect of this role is converting the high-level SaBTO recommendations into operational guidance. These guidelines in the Red Book were produced to secure a unified approach across the UK to blood transfusion. I have been provided a copy of the first edition [NHBT0000027_030].

398. Alongside the Red Book, JPAC also produces the *Handbook of Transfusion Medicine* in collaboration with the British Committee for Standards in Haematology. This is more directed to the clinical use of blood and blood products.

399. Further detail on this question can be found in the answers to section 10 and question 16.

20. What record keeping requirements does NHSBT place on its transfusion centres? Is record keeping centrally managed by NHSBT or is it delegated to individual transfusion centres? Have these practices changed over time?

400. As has been set out elsewhere, NHSBT does not have transfusion centres. Because the control of the RTCs was devolved and not in a central body as it is today, the NBTS in its various forms had far less control of the record keeping arrangements at each centre. There was no central location from which the blood service was run so, unlike today, there was no central place to retain documents.

401. I lay out the chronological journey to how we keep records today. I would say, in part due to the devolved nature of RTCs, that historically, record keeping systems in place across the RTCs were not particularly consistent, or necessarily robust. There was site by site variation in the type of records created in local systems and then archived; the volume of records archived; the date ranges of records archived (and required retention periods); and the approach to the sorting and filing of paper records, including physical storage, such as in the use of microfiche as well as the date when computerisation was introduced and by what system. Much of this appears to have been dictated by local conditions in terms of funding, staffing and physical space.

402. I also note in the recent history prior to computerised records the accurate keeping, maintenance and storage of paper records is difficult and has been for most organisations. NHSBT and precursor bodies are no different. We have learned through searching for documents for this Inquiry, that finding all relevant documents and, indeed, understanding all the contents of 90,000 boxes of paper records is a challenge.

403. My answer to question 8 describes record keeping today. The regulatory and legal requirements mean that much more robust record keeping systems exist today, particularly with respect to traceability since BSQR was introduced, than existed historically.

Prior to 1980

404. There is at least one case from the 1940s where poor record keeping was identified as an issue following 2 to 3 cases of post-transfusion jaundice [DHSC0100009_022].

405. I have been provided a note from 1957 from one RTC where it is suggested that transfusion records should be kept for 10 years and in some cases for even longer, where a donor is still active. It further advises directors of RTCs not to destroy record cards after a year or

so and explains this may not be in accordance with instructions regarding records [DHSC0100013_133].

406. In 1964, a circular was sent out referencing the recommendations of the WHO Expert Committee which included recommendations regarding the selection of donors, record keeping, and the need for adequate records in hospitals. As I understand it, hospital blood banks were not in the control of the blood service. It was these hospital blood banks that were responsible for keeping a record of the use of blood or blood components in the hospital [DHSC0101588].

407. Issues around record keeping, computerisations and 101 cards were sometimes raised by RTDs and DHSS representatives. I have been provided with the following papers from 1972:

a. Minutes from the RTD meeting held on 12 January 1972: Mr Walters (from DHSS) stated [NHBT0015759_001]

any computerised system should be able to produce at least all the information about a donor available from manual systems and be able to accept requests for transfer of records. Dr Jenkins [RTD] considered it essential to maintain NBTS 101 manually for each donor even if the donor-panel were computerised. In the discussion the following points were made:

1. If donor-panels were computerised, they should conform to standard NBTS programme. Local additions could be made to the programme.

…

iii. A joint meeting of RTDs and RDOs would then, if necessary, be held. Dr Bird [RTD] suggested that, in association with this meeting, a symposium on the computerisation of donor-panel

records should be arranged at RTC Birmingham, where computerisation of the records was well advanced.

b. Minutes from the RTD meeting held on 22 March 1972 [NHBT0000086_005] explain that *"there was general but not complete uniformity of practice in the design and use of donor cards."* It was further agreed that *"donor records should be transferred when a donor moved from one region to another and a standard form for requesting transfer of record cards was being prepared".* At this meeting, the RTDs also considered the feasibility of using computers for donor records and came to an agreement that *"it was most desirable that any centres using computers adopted at least the same basic programme."*

c. Minutes from the RTD meeting held on 7 June 1972 show that [NHBT0016123]:
   i. The DHSS *"was preparing a standard form for use in requesting transfers of particulars of a donor from one Centre to another."*
   ii. There was also a mention of a "*helpful*" meeting held at Birmingham RTC "*at which the computer programmes in use at Birmingham and Manchester has been discussed by those concerned in the work at these centres".*
   iii. Of particular interest were the comments of Dr Stratton who *"pointed out that the systems in Birmingham and Manchester differed in that the former dealt with ordinary sessions and the latter only with two daily sessions held in the centre itself."* He was thus of the view that *"[c]omparisons might, therefore, not be entirely straightforward."*
   iv. It was also determined that a *"central computer for NBTS"* was not recommended at this time.
   v. Dr Drummond (RTD) *"expressed the view that for each donor there should be a written or typed record containing all particulars from the time of his recruitment to his retirement."* Following this, it was agreed that a paper should be prepared

and circulated to RTDs and a special meeting held, if necessary, on computerisation.

Early to mid-1980s

408. In or around 1981, an audit review in Northwest Thames showed that recording arrangements varied across hospital pathology departments. I have been provided that audit [DHSC0101582]. The audit identified a number of problems:

a. failure to record issues [of blood and blood components] received from the RTC;
b. regular transfers of blood between hospitals to an unrecorded basis;
c. failure to record/identify whether time-expired packs had been returned;
d. no inspection of registers.

409. In March 1982 and following reports about the misuse of blood at one hospital, inadequacies in respect of records held at one RTC were raised by DHSS. It was stated [CBLA0012795]:

The control of stock in hospital blood banks is, of course, the responsibility of the consultant haematologist. Nevertheless, on the face of it, it would seem entirely reasonable for Regional Transfusion Centres to require certain records to be maintained at hospital blood banks and for regular returns to be made of this information to the Centres.

Whilst the Department appreciates that a more comprehensive system of record keeping at Regional Transfusion Centres and in hospital blood banks may present certain administrative difficulties, it is nonetheless felt that such a system is necessary in the interests of maintaining a full and proper accountability for blood as a national resource.

410. In the same letter, the DHSS' Principal Medical Officer requested Dr Wagstaff of Trent RTC Department to investigate this matter urgently with fellow Directors, with a view to preparing a report on record keeping in the NBTS and hospital blood banks for the Advisory Committee on the NBTS which next met on 31 March 1982.

411. A survey was carried out in March 1982 [DHSC0002215_099] on *Record Keeping Procedures at RTCs in Relation to Issues of Blood and Blood Products to Hospitals* which was: '*designed primarily to find out whether RTCs have records of the disposal, at Transfusion Centre level, of all units of blood and components intended for hospital use'.* It found that: '*from the returns on items (1) and (2) in the survey, cover at this level is excellent. There is variation only in respect of returns of blood products from hospitals to RTCs and this variation is inevitable in view of the sporadic way in which components other than red cells are returned to the Centres. As an example, it will be understood that the return of plasma harvested at hospital level from red cells and of outdated plasma products such as platelet preparations, fresh frozen plasma, and cryoprecipitate, have dropped to virtually nil since a major effort has been started within the NBTS towards the provision for fractionation at Blood Products Laboratory of fresh frozen plasma. The keeping of records of requests received from hospitals, as itemised under (3) in the survey, also appears to be good. The only significant divergence between Centres is in the recording of the actual name of the member of hospital staff initiating the request, as against simply recording the identity of the hospital itself*'

412. I note that this survey also refers to '*the need for completion of the original NBTS47 forms, returned to DHSS on a monthly basis'* and to the fact that '*All Centres have evidently retained this facility'.* I understand form NBTS47 to be a monthly or quarterly submission of donations collected and issued by all RTCs, which were collated annually by DHSS' Statistics and Research Division at Fylde.

413. The survey also found that on-line links between RTCs and Hospital Blood Banks would probably be necessary before unified documentation of a unit of blood, including identities of donor and recipient, would be feasible and that:

The attempted handling in a manual system of returns from hospitals to RTCs of records including patient details is thought by RTDs to be unmanageable, from the point of view of sheer bulk of information, if nothing else'. For the time being, *'hospital blood banks should be encouraged to produce their own computerised record systems, with emphasis on compatibility with the system used in the "parent' RTC. The similarity of computerised systems so far adopted at RTC level is striking, and the comprehensive cover provided by such a system would appear to make their institution in the remaining RTCs a matter of the highest priority'.*

414. In the same year, the Secretary of State requested a full review of record keeping arrangements with regard to blood in RTCs. The minutes from a meeting held in 1982 explain that [DHSC0101582]:

Blood banks should record collection receipt and issue of blood. The Department has said very little about recording and control the only guidance being issued in 1951 and 1964 (RHB(51)89 and HM(64)5 respectively) which advocated:-

- *that there should be a uniform system in blood banks*
- *the use of printed registers obtainable from BTCs*
- *inspection of registers by Regional Transfusion Directors who should consider instances of waste, misuse or extravagance*

Not surprisingly, no reference was made to the private sector, but the Department's 'expectation' has been that where blood is issued to private hospitals, blood bank registers should record the amount and

type of blood supplied. There is no overt control over private hospitals' records.

415. According to a private letter written by S Godfrey, copied to Mrs Stockton in March 1982, the expectation around this time would have been as follows [DHSC0101593]:

Each unit of blood is individually numbered. The RTC keeps a record of all its issues so that, at present, if it is necessary to trace an individual unit (because the donor has been found to carry a particular disease) it is (or should be) a relatively simple task to find out to which hospital blood bank it has been delivered…Difficulties start at the hospital blood bank. All blood banks should keep registers of incoming blood and blood issues. If the unit in question is used within that hospital, then there should be very little difficulty in tracing it to the patient who received it. If, however, the unit was one of a number sent to a smaller hospital serviced by the blood bank, the register will record only that. There is no guarantee that the blood has been used at the hospital to which it is sent. The receiving hospital should have a note of blood coming in, the use of which it is put to etc. but we have reason to doubt whether this is so and Regional Medical Officers…have been asked to look at this aspect of record keeping.

416. The letter indicates that, at this point, there was a desire for the advisory committee of NBTS and RTDs to produce terms of guidance on record keeping in relation to blood. The goal was always to create a record keeping system which enables the blood service to trace each unit from "*start to finish*." The general view was that records should be kept for a period according to local or national requirements, which in many countries was for a minimum of five years (see the report of the Committee of Experts on Blood Transfusion and Immunohaematology from the Council of Europe report from 1984 [NHBT0010658_016]).

417. Record keeping was raised at the Regional Transfusion Directors' meeting dated 22 September 1983 [CBLA0001742], in which it was asserted that DHSS needed more expert advice on this matter and suggested a Working Party be set up to consider the question.

418. In early 1984, the DHSS released a circular DA(83)16 entitled '*Blood Transfusion: Record-Keeping and Stock Control Arrangements*', which asked health authorities to review record keeping and stock control arrangements in RTCs and hospital blood banks. It clearly stated that *"consultants responsible for blood banks make monthly statistical returns to the Transfusion Centres showing an analysis of the units received."* The purpose of this requirement was to check that what the RTCs have in their records as issued to a hospital was, in effect, received by that hospital [NHBT0105294].

419. Its contents were endorsed by the Advisory Committee on the National Blood Transfusion Service [CBLA0001819]. The key point is that records kept at RTCs must permit the tracing of any unit of blood from collection to transfusion or disposal. Health authorities were asked to ensure that the systems employed at RTCs did so.

420. In March 1984, HC(84)7 was issued on stock control and record keeping in RTCs. Ministers accepted the advice of the Advisory Committee to the NBTS and agreed to the issue of the recommended guidance to the field [CBLA0001835].

421. A report from SNBTS sets out the modified recommendations of Central Management Services (CMS) from the Health Services Division 1 (HS1) of DHSS in respect of improvements to record keeping processes [PRSE0000525] (see also [DHSC0002223_091]), which included the following:

a. RTCs should accept a formal responsibility for encouraging good practice in those Hospital Blood Banks for which they are responsible for supplying blood and blood products;
b. stocktaking in the Hospital Blood Banks is instituted on a regular basis and the information transmitted to the RTC to enable tallying with records held at the Centre;
c. with each delivery of blood and blood products from the RTC there is prepared a delivery note (in triplicate) which would include a record of the number of units issued, type of unit, blood group (if relevant) and individual donation numbers (or batch number). A copy would be retained at RTC and one of the two sent to the Hospital Blood Bank would be returned to the RTC — confirming receipt;
d. RTCs should record all returns from Hospital Blood Banks by unique number;
e. PFC should consider the practicability and feasibility of numbering individual bottles (vials) with a unique number to facilitate a system for recording blood transfused and improved stock control;
f. there should be a delivery system and statistical recording of issues and returns of blood products which follows a similar system to that employed for blood;
g. to facilitate the tracing of units of blood, a chronological file of details showing patient's name, unique number of the units cross-matched and a signature for the removal of a unit from the Blood Bank should be kept. The decision whether this takes the form of a register or a file of back copies of request forms should be left for the Hospital Blood Bank Haematologist in charge to decide, in the light of existing practice and the evaluation of it;
h. stock control recording systems should be based on a daily inventory record supported by delivery notes and a record of returns and disposals;
i. where possible, statistics are kept in the Blood Banks for blood products on a similar basis to those for blood. Figures for those products which are replaced by commercial;

j. the need for a record in patients' notes of the batch number of SPSS transfused should be emphasised and guidance issued to those concerned at the Ward level;
k. if Hospital Blood Banks are reviewing their request and recording systems and inventory control systems for blood and blood products, reference should be made to RTCs and the Information Services Division of the CSA, for information about suitable systems.

422. A meeting note records that the view was that the most essential of these recommendations simply confirmed practices which should be carried out in any case [SCGV0000083_020]. By the end of this period, there was an expectation that most of the recommendations of the CMS report would be dealt with following the introduction of computers into the Transfusion Centres. See the minutes of an SNBTS meeting on 20 June 1985 [PRSE0001423].

Late 1980s

423. In 1987, there was an inspection at South London Regional Blood Transfusion Centre, which provides some insight into record keeping at one RTC. The subsequent report explained [NHBT0006256]:

The donor call-up and records system is now computerised, although the overall integrated computer System at the Centre is not yet operational.

For called donors, a computer-printed record sheet is available at the session; walk-ins have a similar sheet filled out by hand.

At the clerking table, when donors have completed the medical checklist and consent form, a set of eight bar-code labels is issued, together with a set of blood-group labels in the case of known donors, and the Day Worksheet is filled out. This contains the donor's name,

blood group (from past history) and two eye-readable donation number labels.

New donors are entered on a separate Day Sheet and their bar-code labels are identified with pink stripes at the sides. Blood group labels are assigned to them on the basis of ABO tile-grouping performed at the session and all being assigned as Rh positive.

Haemoglobin estimation is carried out using the copper sulphate method, the limits for acceptance being 125g/litre for females and 130g/litre for males. The copper sulphate solutions are bought in from BDH and are not checked. If a donor fails the copper sulphate test, a venous sample is taken and labelled with a bar-coded donation number label. The copper sulphate test is repeated on this sample and, if the donor passes, a donation is taken. If the sample fails the copper sulphate test, then a Haemocue haemoglobinometer test is performed on the sample. If the donor passes, a donation is taken. If the donor fails, then the tube containing the venous sample is sent to St George's hospital for haematological profile.

Accepted donors are given their record sheets, with the bar-code labels and blood group labels clipped to them and join the queue for a bleed bed. The Team Leader (usually) calls the donor when a bed is available and a donor attendant prepares the donor prior to the MO performing the venupuncture. Lignocaine is used routinely but the batch number is not recorded…

Bar-coded donation number and blood group labels are attached to the packs once the donation is underway. Excess labels are dropped undamaged into a waste-bin. Donation is monitored on balances which are regularly checked and donations are timed with a bleeper alarm. Packs from slow bleeds are identified with a red sticker.

At the end of the donation, the tube is clamped and cut. A "floating' donor attendant strips the bag while the bedside attendant takes the two samples (one wet, one dry). The Sample tubes, packs and record sheet are than all put into a polythene bag and placed in a box under the bed to await collection by the technician.

The technician, having collected the boxes, checks that the tubes, sheets and packs match up, racks the tubes, packs the bags which are to be used for platelet preparation into cardboard boxes (in fact, these are empty blood bag cartons) and sorts the Record Sheets. The technician also fills in a Blood Collection Record and the driver collects the bags, samples and paperwork.

…

Procedures for clerking-in donors with a Day Sheet are similar to those used at mobile sessions but the donor records have not yet been computerised and a card system is still in use. Each called donor has a folder ready prepared containing details of the previous history.

424. The report further explains that *"the computerisation is being worked-up and eventually will comprise an integrated system right through from donor records to product issue".*

Early 1990s

425. I understand that, between around 1990 and the implementation of Pulse between 1996 and 1998, RTCs used in-house computer systems – now heritage computer systems. These heritage systems were diverse, as was the format in which records were archived, and they were installed at different times at different centres.

426. In April 1992 Dr Huw Lloyd, Dr Alan Beal and Mr Tony Martina produced a document entitled Records Storage Report for the National Directorate of NBTS. I have been provided this paper [NHBT0071590_001]:

It is clear that the time limits on potential litigation have previously been seen as being directly related to time limits in various Acts of Parliament such as the Consumer Protection Act and in certain Health Service regulations. Now with cases such as Buck vs English Electric and the recent HIV litigation these time limits are no longer appropriate. The HIV litigation was looking at policy decisions being made 15 years previously and in the Buck case there was at least an 18-year delay. With slow viruses, disease may only become apparent after even longer periods of time.

It is recommended that all major records are retained for at least 30 years. As most RTC's are not currently retaining records for more than 10 to 12 years, there will be sufficient time to review this policy before any Centre has retained documents for this 30-year period. It may be necessary to increase the storage period further, but the situation can be reviewed again in 10 years' time.

427. The outline recommendations then broke down the storage categories into three. These were:

a. Long Term: *"The long-term storage period recommendation is 30 years. This covers Donor and Donation records and policy and management records as well as records directly linked to Donor and Donation records such as QA reports."* The report went on to say of long-term storage:

Records for long term storage should be retained for 30 years from the date of creation or date of last entry. In the light of future experience this period may need to be revised upwards. It does however at this stage concur with the 30-year rule on local retention of documents for permanent preservation under the Public Records Acts and the 30 year requirement on personal monitoring records required under the COSHH regulations.

b. Intermediate Term: *"The intermediate term storage period recommendation is 10 years. This covers routine personnel records, financial records, (other than annual accounts) and reports, and may of the routine documents on the day to day running of the service."* The report went on to say for intermediate term storage:

This covers a range of records, many of which require to be held for specific periods of time. Rather than have a series of sections each for specific numbers of years this category provides a pragmatic solution. None of these records will be required for permanent storage under the Public Records Act. The means of storage can be adapted to individual Centre's requirements. Appendix 5, which is an extract from HC(89)20 shows that there is a profusion of storage times for various documents which are not for permanent storage.

c. Transient Term: "*The transient term storage period recommendation is 2 years*". The report went on to say for the transient term:

Those records for transient storage will normally be held locally in their original form. It would be inappropriate to convert them into different storage media. Two years is arbitrary but can be adjusted locally to take account of local needs.

428. The report then goes on to comment on what would fall into each of these categories. All of this has not been repeated here, but it should be flagged that: (1) donor and donation records; (2) donation related records; (3) quality assurance records; and, (4) safety records linked to identifiable individuals, would all be long term storage. Donor complaints records would be allocated depending on the seriousness of the complaints. Patient incident records would need to be classified

into long term or intermediate term storage. The report also recommends that RTCs adopt an annual policy statement record.

429. The report goes on to recommend that all RTCs adopt a policy, and notes that *"as long as that policy has been reached after due deliberation and is not clearly unreasonable or unlawful, the RTC will have a significant degree of protection should records not be available in the future".* It provides recommendations for the basics of such a policy based on the above. The report concludes with the following summary:

A simple, robust scheme for managing and storing records has been proposed. Three categories, Transient (2 years), Intermediate (10 years) and long (30 years) is proposed. To facilitate the long-term storage element in particular, consideration should be given to a central facility for Transfusion Services in England and Wales. The possible move to novel storage systems such as Optical discs should be pursued, although at present it is not known whether this type of record will be acceptable as evidence in court. Microfilming remains an acceptable alternative for certain categories of data although paper records will still need to be retained in certain instances and will be the most appropriate for the two-year storage of transient records. All RTC's should have a written policy, implemented correctly with written instructions in the form of SOP's or Procedural Documents. A Senior Manager should have responsibility for the records storage programme. A records officer might be accountable to the Quality Assurance Manager. The systems should be included in Internal Audit programmes. The presence of a properly implemented, documented policy with accurate records of the destruction of documents, data or records is at least as important as the final duration of the storage of the records.

430. Appendix 4 of the document includes an extract of HC(89)20 which states in respect of personal health records: *"[a]lthough personal*

health records of patients will not normally be preserved permanently, arrangements may be made for samples to be taken…".

431. It would appear that throughout this period record keeping was regularly discussed. The minutes of the meeting of the National Management Committee **('NMC')** of the NBTS highlight that throughout this period, there was difficulty in reaching an agreed position.

a. Minutes of 1 March 1990 Meeting [NHBT0071867_001]: set out agreement that Dr Huw Lloyd be asked to chair an ad hoc group to consider the retention of records at RTCs within the general framework that records necessary to identify the donor to the donation should be retained for 15 years.
b. Minutes of 30 October 1991 Meeting [NHBT0046751]: explain that Dr Entwistle agreed to take over the lead of the Working Party on the Retention of Records.
c. Minutes of 7 September 1992 Meeting [NHBT0071601_001]: make it clear that members were concerned that a 30-year storage period would cause problems.
d. Minutes of 3 December 1992 Meeting [NHBT0017528]: explain that a Task Force was to be established to develop an implementation strategy for record keeping requirements and having regard to the 'Record Storage Report.' The Task Force would *"recommend which BTS records were primary records and recommend appropriate storage technologies. It would evaluate Regional, Division and National storage options and make recommendations."* It was agreed at the end of this meeting that the NMC would be dissolved.

432. I have not been provided minutes after this date which discuss the report produced by Dr Lloyd, so it is not entirely clear to me whether it ended up being implemented.

Late 1990s /Early 2000s

433. The minutes of the meeting of the Advisory Committee on the MSBT show that record keeping continued to be an issue into the late 1990s.

a. 4 June 1998 Meeting [DHSC0004026_033]: Paper MSBT 15/5 sets out the NBA's position on record keeping when blood components and products were used to treat patients - requiring a permanent record in the patient's notes of the component or product, the date given and the unit or batch number. However, patients' records often did not reveal what the patient had received, and it appeared that good practice guidelines were needed. Dr Gorst observed that a good laboratory recorded conscientiously, but that the 'chaos' of the ward made it more difficult to be methodical in that setting. Chief Executives needed to be reminded that a secure method of recording this information was needed. Members suggested that this be picked up as part of CMO's initiative on the appropriate usage of blood, and that guidance be disseminated widely in the NHS to clinicians and Chief Executives in line with clinical governance and total quality improvement.

b. 29 October 1998 Meeting: Reference was made to a Health Service Circular due to be issued on 27 November, and that all the major points would be included [DHSC0004026_032].

434. In 1999, the British Committee for Standards in Haematology, Blood Transfusion Task Force, in collaboration with the Royal College of Nursing and the Royal College of Surgeons of England produced a document from which local policies and written procedures could be developed for the documentation of transfusions and general guidelines for record keeping in this area [AHCH0000049]. However, these guidelines were not produced by NHSBT.

435. On 20 June 2002, the CJD incidents panel held a meeting [DHSC0014975_133] in which they discussed Hospital Records

Keeping, with some criticism directed at the short length of time in which some hospitals retained their records. While this is relevant to the blood transfusion process and record keeping as a whole, records retention in hospitals would not have been the responsibility of NHSBT or its predecessors.

436. On a final note, greater consistency in record keeping was subsequently achieved by the implementation of a national computer system, Pulse, between 1996 and 1998; coupled with the placing of a national paper archiving contract, initially with TDG in 1999 and then with Iron Mountain ('IM') from 2003, and national operating procedures. More detail on this issue is provided in my answer to section 2.

Current Position

437. As to the current position, that is set out in the response to question 8.

21. What information sharing requirements, if any, exist between NHSBT and its transfusion centres? Have these requirements changed over time?

438. For the historic position, I have described in my answer to question 20 above the issue of transfer of donor cards. From the documents I have seen, I have not noted any particular rules about information sharing between RTCs. As to the current position, the responses to questions 17 and 43 provide information about the requirements and mechanisms in place to share information between NHSBT and other stakeholders, including the other UK blood services.

439. Because the blood service, as both the NBA and now NHSBT, is centralised, information is shared appropriately throughout the organisation. An important feature of this is the Pulse database and its

central storage of information. Further detail is provided in my answer to section 2.

22. Does NHSBT impose information sharing requirements between transfusion centres? For example, regarding donors who had been excluded from donating at one centre because they posed a risk to the safety of the blood supply, or otherwise infected donations received by a transfusion centre?

440. The answer provided in response to question 21 above can be relied on also in response to this question.

Section 5: Relationship of NHSBT to government

One of your responsibilities is "to provide expert advice to other NHS organisations, and the four UK health departments".

23. Please explain NHSBT's relationship to government departments, in particular the Department of Health. Has this relationship changed over time? If so, please provide details.

441. In other answers in this response, I have provided some evidence relevant to this question. I do not propose to repeat that information here save for where it is relevant in providing new evidence. The other relevant answers are:

a. Question 3-4: taken with the *NHSBT Family Tree*, provides details about the structure of the blood service and its form and functions.
b. Section 3: provides additional detail about the different committee structures that have existed over the time of the blood service's existence. This includes information concerning interaction with all four UK health departments.

c. Question 18: details examples of the relationship with government departments, particularly in relation to funding of the blood service and how it was set up.
d. Section 8: in respect of the relationship between the blood service and government departments for maintaining the sufficiency of the blood supply.
e. Section 9: in respect of the relationship between the blood service and the MHRA, an executive agency of the DHSC.
f. Section 9-10: in respect of the relationship between the blood service and government departments for maintaining the safety of the blood supply.

442. I address accountability and decision-making authority in my answer to question 24 and try not to repeat that evidence in my answer to this question. Any information about the historic position is obtained by review of documents which have been provided by those advising me.

Current – Structure of Relationship

443. The current relationship between NHSBT and the Department of Health is set out in the 2014 Framework Agreement [WITN0672051], which defines how the two organisations work together, setting out roles, responsibilities, governance and accountability arrangements. The Framework Agreement also briefly defines NHSBT's relationship with the other UK Health Departments. NHSBT's accountabilities to the Scottish and Northern Irish health authorities are governed via NHSBT's Board arrangements and through Income Generation Agreements, where requested. NHSBT is responsible for the delivery of policy objectives set for it by all of the four UK governments.

444. The Framework Agreement explains that NHSBT and senior DHSC officials and ministers are linked at the executive level by the Senior Departmental Sponsor (SDS), who acts as NHSBT's designated, consistent point of contact within the Department. The SDS is appointed by the Permanent Secretary and is currently the Director

General for Public Health. The SDS's role is both facilitative, enabling direct engagement between NHSBT and government, and supervisory, supporting the Permanent Secretary to hold NHSBT accountable and provide assurances on its performance.

445. The SDS is supported by a Departmental sponsor team, who are the principal daily point of liaison between the parties. NHSBT's accountability to the Department is discussed in detail in my answer to Question 24.

446. Beyond the processes in place to determine decision-making and ensure accountability, the Department of Health and NHSBT have agreed to a set of shared principles, which are set out at paragraph 6.1 of the Framework Agreement. These include respect for the autonomy of individual organisations within the system, but also working together constructively and collaboratively. To support the shared principles, both organisations follow an 'open book' approach of keeping one another informed of policy developments, or issues relevant to policy. There may be reciprocal expectations of consultation on some issues, and the organisations will make these expectations clear to one another as they arise. The sponsor team is responsible for ensuring the effectiveness of this approach.

447. The DHSC sponsor team may facilitate discussions as appropriate with other DHSC or governmental teams as beneficial to both parties, for example with the Office of Life Sciences in the Department for Business, Energy and Industrial Strategy on topics related to Cellular Therapies or Genotyping.

448. NHSBT has a relationship with the National Institute for Health Research **('NIHR')** (part of DHSC) by the relationship in R&D where the NIHR provides funding for four Blood and Transplant Research Units whereby academic institutions are funded to deliver research relevant to NHSBT requirements. NHSBT academics will also have

relationships with the UK Research Institute through applying for and being granted funding.

449. I have a relationship with senior doctors in both the Chief Medical Officers office in the DHSC and through NHS England **('NHSE')**. Examples of these include membership of the UK Caldicott Guardians Council and the Responsible Officer network. Additionally, I am a member of the CMO Therapeutics Taskforce Programme Board for COVID-19.

450. The Framework Agreement also sets out that NHSBT will work with the Department and other public health bodies to support effective emergency preparedness and response. Although NHSBT does not have statutory duties under the Civil Contingencies Act 2004, it is subject to NHS England's Emergency Preparedness Framework, which requires all NHS funded organisations to comply with the principles of the Act. NHSBT must also comply with the terms of its Service Level Agreement with the Department on emergency preparedness, and with the relevant core standards in NHS England's Core Standards for Emergency Preparedness Resilience and Response and provide an annual statement of compliance to the EPRR Partnership Group. The Secretary of State is ultimately accountable for the health system's emergency preparedness.

Current – Recent Developments and Relationships with Other Bodies

451. In March 2020, the DHSC instructed NHSBT to collect Convalescent Plasma. This was a new initiative, and an obvious change to the organisations' existing relationship. NHSBT has also been supporting DHSC with a business case to collect plasma for fractionation, and in April 2021 DHSC directed NHSBT to start collecting plasma for this purpose. This activity is overseen by the DHSC/NHSEI Plasma Board and the agreed governance structure within the DHSC. Further detail of this is provided in my answer to section 18.

452. The Framework Agreement states that "*As a manufacturer of biological products and related clinical services to the NHS the primary relationship between NHSBT and the DH family is that of a regulated entity under relevant legislation. In this regard NHSBT is inspected by the Care Quality Commission, Human Tissue Authority and the Medicines and Healthcare Products Regulatory Agency."* Both the HTA and MHRA are sponsored by the DHSC and executive agencies of the DHSC.

453. Annex D to the Framework Agreement details the key relationships that NHSBT has with other bodies across the UK health system, some of which are governmental in nature. In addition to the above, this includes conducting research and development for the Health Research Authority.

454. To a lesser extent, NHSBT has relationships with the Department for Transport (Blue Lights), and with the Charity Commission in relation to charitable funds administered by the Trust Fund Committee.

Historic Relationship – Institutional Structure

455. As the detail of the relationship with government has already been addressed elsewhere in this answer, I provide this by way of brief summary.

456. Until 1994 the RTCs' main relationship with government was with their local RHAs (previously RHBs). The relationship with the Department of Health in its various forms was in large part mediated through that direct relationship with the regional institutions. After the NBA was established in 1993, and the RTCs transferred to it in 1994, the relationship between the RTCs (as the NBA) and the Department of Health was that of an SHA and its sponsoring government department.

457. An important connection between the Department of Health and the blood service since around the 1940s has been the role of the

Consultant Advisor (held, successively, by Drs Maycock, Tovey, and Gunson).

458. Representatives of the various departments of health around the UK have been attending (and sometimes leading) blood services meetings since the 1950s. At the earliest stage this was the RTD meetings convened by the Consultant Advisor. This went on to include chairing, for example, the Advisory Committee on the NBTS. This continued and included appointment of non-executive members of senior management committees in the NBA and now NHSBT (see my answer to question 6).

459. While the direct relationship was until 1993/1994 with the RHAs, the relationship with the Department of Health was still a significant one. Important national decisions (such as the AIDS advisory leaflet – see section 9) were managed through the DHSS. Clinicians in the service would observe directions as appropriate from the DHSS and senior clinical staff therein (e.g. the CMO). The DHSS was in a position to provide funding directly (as they did with the £0.5 million provided in the 1970s), although the usual position was that funding came through the RHAs.

460. The DHSS had overall control of the form of the blood service. This is addressed in some detail in section 3 of this answer, and in more detail in Question 24 below. However, it would appear from the documents I have read that the blood service was first expressing an interest in being a single unified service in the 1970s (see my answer to Question 18). The relationship between the DHSS and the blood service was one where the blood service could only advise, and executive authority to make significant changes to the structure of the service in England and Wales remained in the Department of Health.

461. Of the documents that have been available for review, it does not appear that there was anything in the same way as formal as the

current framework agreement that is now in place between the DHSC and NHSBT.

Historic Relationship – Key Events

462. The historic relationship between the DHSC and NHSBT's predecessors can also be understood through the key moments in those relationships over time, which I will briefly set out below. These include:

a. Discussions regarding the organisation and collaboration between, and the proposed centralisation of, the blood services
b. Discussions regarding getting sufficient funding for plasma self-sufficiency
c. Discussions regarding whether production of Factor VIII should be continued or attempts to move back to the production of cryoprecipitate should be furthered
d. Discussions regarding the AIDS leaflet in 1983
e. Discussions regarding the introduction of HTLV III testing in 1985
f. Discussions regarding the introduction of HCV screening in 1991 and the eventual lookback in 1995

Mid-1970s: Centralisation Efforts

463. I have set out in Question 16 that there was historically no UK-wide approach to policy development and implementation overall.

464. I understand from meeting minutes which I have seen from the 1970s that the Regional Transfusion Directors at various meetings proposed transforming the NBTS into a centrally managed service, in the form of an SHA. I have set this out in detail in my answer to Question 18. Briefly, I understand that the directors produced a working party paper on centralisation: however, their proposals were rejected by the DHSS, which chose to retain the regional system, as envisaged in the White Paper on NHS reorganisation. In relation to the Regional Transfusion Directors' meetings, which the DHSS characterised as the

key measure of central coordination, this included retaining the informal and non-statutory footing of such meetings.

Late 1970s to Early 80s: Issues with the Regional Health Authorities, Plasma Supply, and Funding for BPL

465. In my answer to question 18 I have discussed the setting of plasma targets generally. Here I have tried to limit myself to some additional examples where funding was an issue in the setting and meeting of targets. There is some cross-over with my answers to question 39 (concerning the steps taken to meet targets) and question 40 (whether the blood service did meet targets). I have tried my best to avoid unnecessary repetition and this answer here is a brief outline and must be considered with those answers.

466. In essence, it was the policy of central government, with which the RTDs in principle agreed, to achieve self-sufficiency in the blood supply. There was however disagreement at times between both, and with the CBLA, in relation to the precise levels at which supply targets should be set. The RTDs also faced practical difficulties in achieving targets, some of which were related to funding. I have focused on the Department of Health in my answer to question 18, so here I have placed more emphasis on RHAs. The picture in respect of agreeing these policies, and providing sufficient funding, appears to be more confused and depended on the Region. It would appear the Department of Health also had some role in encouraging the Regions to progress and fund plasma production.

467. I set out in my answer to Question 18 how plasma targets were apparently initially set by an expert group in 1973, but that there was some confusion as to what target had been set, and what target RTDs were able to meet. I do not repeat that information here. However, I set out below documents that explain the requirement for funding, in order for RTCs to be able to meet the targets.

468. However, before the establishment of the NBA, the DHSS had no formal authority over the RHAs in relation to financial matters, and there appeared to be problems with persuading the RHAs to allocate enough funding to increasing blood supply. As I set out in my answer to Question 18, a letter from the DHSS to regional administrators on 24 December 1974 identifies short-term and medium-term donation targets; identifies that BPL production is limited by the supply of plasma from RTCs; and notes that that "*the cost of collecting 400,000 additional donations annually might be of the order to a further £1.0 to £1.5 million*" [CBLA0000239].

469. I would highlight the December 1977 report of the DHSS Working Group on Trends in the Demand for Blood Products [DHSC0002189_014], which outlined the Group's expectations for trends in demand for blood products over the next five to ten years. The paper concluded that *"considerable further investment"* would be required to meet these targets, which would be a *"major undertaking"* for RTCs. The paper noted that increased resources would be needed in the Regional Centres (in addition to additional fractionation capacity in the UK). The report also recommended that close attention be given to the future organisation of the Transfusion Services, "*particularly in relation to better national co-ordination, forecasting and planning."*

470. I note that in my answer to question 39 I discuss a meeting of the JMC dated 19 December 1979 [CBLA0001041]. At that meeting Dr Lane noted that "*some regions had made it very plain that they would not produce more plasma unless they could be assured of a proportional return of blood products*". As I set out in my question 39 answer, this appears to have progressed to Regional Administrations and Regional Treasurers being generally in favour of pro-rata distribution of product.

471. I note that Paper AC(80)3 [CBLA0001209], which was discussed at the first meeting of the NBTS Advisory Committee on 1 December 1980, provided a target for production from RTDs based on each

region's population, and proposed that the report was circulated to RHAs and RTDs *"to enable plans to be drawn up to meet the regions' target of FFP".*

472. I also note from the minutes of the Advisory Committee's second meeting on 23 February 1981 [CBLA0001287] that a letter had been sent to regional administrators setting out the scale of the increase in plasma supply needed over the next two years to reach 600 i.u. of Factor VIII per thousand of population, which would require funding.

473. Discussions as to suitable targets continued within government and within the BTS across 1981. I provide the detail of the 90/100m iu of Factor VIII target (and the requirement of 435,000kg of plasma to fractionate) in my answer to question 18 and do not repeat it here.

474. In my answer to question 39 I discuss the meeting of the Advisory Committee on the NBTS dated 22 June 1981 [CBLA0001388]. It would appear from those minutes that the introduction of plasmapheresis was dependent on "*substantial investment from RHAs*". There was further discussion of how that matter would be raised with them. In the later meeting on 28 September 1981 [CBLA0001457] (which I also discuss in question 39) it was proposed that the agreement of Ministers be sought to consult with RHAs on determining supply levels of plasma for the redevelopment of BPL.

475. It was noted in an Advisory Committee meeting on 31 March 1982 [DHSC0001136] that the DHSS had asked all RHAs for an indication of their ability and willingness to increase the supply of fresh-frozen plasma to BPL, and that twelve had replied to date. All supported the principle of self-sufficiency, but some doubted their ability to achieve their notional target by the mid-80s and suggested a gradual progression towards that figure. It was elsewhere recorded in a JMC meeting at around the same time [DHSC0002217_011] that regions

were "*unable to commit resources immediately to increase the plasma collection to the required level".*

476. In my answer to question 40 I discuss a CBLA meeting dated 27 April 1982 [DHSC0002217_011]. At that meeting it was noted Regions accepted the principle of self-sufficiency but were unable to commit the resources immediately to increase plasma collection to required levels. It was thought necessary to build up in stages.

477. In my answer to question 40 I also discuss a meeting of the Advisory Committee on the NBTS on 10 April 1984 [CBLA0001835]. At that meeting Dr Gunson noted that RTDs were less optimistic about reaching plasma supply targets because of resource constraints within Regions. Indeed, some Regions were finding it more economical to purchase commercial Factor VIII than invest heavily in plasma collection or procurement.

478. At a meeting of the CBLA on 28 November 1984 [DHSC0001101] it was reported that the DHSS sent RHAs a letter in November 1984 seeking commitments in relation to plasma supply. It was recorded that three or four regions had not given any commitment to plasma supply, either in finance or in time. I set out that Dr Gunson had linked the lack of regional commitment to finance plasma supply beyond their own population to the need for *'some kind of national integration.'*

479. I note that at a meeting of the RTDs on 23 January 1985 [CBLA0001995], there was a discussion on the difficulty of meeting self-sufficiency with current provision. It was noted that only six RHAs had agreed a plan within the timescale for self-sufficiency, with two regions opposed to the estimate of plasma required. Dr Gunson noted that the amounts proposed were "*too little for self-sufficiency and too little for optimum working of BPL*".

480. In my answer to question 39 I comment on a meeting of the CBLA on 18 September 1985 [CBLA0004979]. It was noted there that the DHSS was pursuing RHAs on the subject of plasma supplies. It was noted that "*if the Regions concerned had not produced satisfactory explanations for their position in the near future, the matter would be the subject for parliamentary debate in October*".

481. As is discussed in my answer to question 40, there were delays in the mid-to-late-1980s in the commissioning in BPL. In that question I discussed a meeting of the Advisory Committee on the NBTS dated 17 June 1987 [BPLL0007202]. At that meeting Dr Fraser raised the concern "*that RTDs had lost credibility because of the delays which had occurred at BPL; he thought there would now be more difficulty in obtaining funds from Regions and the future plasma supply would suffer.*"

482. I note the minutes from an RTD meeting on 4 October 1988 [NHBT0018189], again record the need to provide information to the Department of Health, both for Ministers and for RHAs, about obstacles to achieving plasma targets.

Consideration of a Return to Cryoprecipitate Production

483. In Section 9 I have discussed the possibilities of a return to cryoprecipitate production from the production of factor concentrate in the 1970s and 1980s. I set out that, in light of the high demand for factor concentrate and consistent pressure on RTCs to supply plasma to BPL, I thought it may have been difficult for the blood service itself to catalyse the shift back to cryoprecipitate without agreement between all parties. This pressure on RTCs came from many quarters, including BPL and haemophilia doctors but also DHSS, as recorded in a May 1979 report by Dr Lane [BPLL0001508].

484. Minutes which I have seen from a December 1977 meeting of the DHSS' Working Group on Trends in the Demand for Blood Products

reflect the group's view that *"we believe that the long term aim should be the complete transfer of cryoprecipitate to a fractionated freeze dried concentrate. However, guidance will be needed on a continuing basis from Regional Transfusion Centres on the time scale for such a development"* [DHSC0002189_014]. The Working Group concluded the meeting by noting that *"Close attention also needs to be given to the possible future organisation of the Transfusion Services, particularly in relation to better national co-ordination, forecasting and planning".*

485. From the documents which I have seen and set out elsewhere, it would appear that in the late 1970s up until at least 1981, most people were planning for and assuming an eventual 100% shift from cryoprecipitate to fractionated freeze dried concentrate. I would highlight the meeting of representatives of HCDs, RTDs and the DHSS dated 15 September 1981 [CBLA0001448], at which it was recorded that directors agreed to accept a reduced need for high-purity concentrate and frozen cryoprecipitate.

486. I note from my answer in section 9 that 1983 appears to have been a difficult time with RTDs assessing US information and the use of cryoprecipitate. This was around the time that the decision was made to advance the AIDS leaflet. From the correspondence I have seen, I can see that Dr Gunson at least referred to the difficulties of BPL switching to cryoprecipitate and his being unsure what the best solution would be.

487. I note the meeting of the Committee on the Safety of Medicines on 13 July 1983 [DHSC0001208], at which Professor Bloom and Drs Craske, Galbraith, Gunson and Mortimer were present as expert advisers on AIDS. The withdrawal of concentrates and replacement with cryoprecipitate was discussed, but it was concluded that it was *"not feasible in the UK on grounds of supply".*

488. I note that at a meeting of UKHCDO attended by members of the SNBTS and NISC on 17 October 1983 [PRSE0004440], some haemophilia centre directors also discussed reversion to cryoprecipitate due to patients refusing Factor VIII because of fear of AIDS. Despite the ready availability of cryoprecipitate in some regions, it appears that it was ultimately agreed that patients should not be encouraged to go over to cryoprecipitate for home therapy, but should continue to receive NHS or commercial concentrates in their usual way.

Early 1980s: the introduction of the first AIDS leaflet

489. From 1983 to 1985, the Department of Health (in conjunction with the blood service) produced and revised the first AIDS leaflet, aiming to reduce the risks of AIDS transmission through blood donation, in consultation with the RTDs. In my answers to Section 9, I address in great detail the process of producing and revising the first AIDS leaflets from 1983-1985, and I do not propose to replicate that detail here.

490. However, I would highlight that when the RTDs first endorsed the 'leaflet' option for managing the risk of AIDs, it was hoped that this leaflet would be drawn up within six weeks of the proposal. Instead, the initial leaflet took between three and four months to publish: the revised leaflet was published some eight months after being broadly agreed with the RTDs. It is clear from the documents which I have seen, including a DHSS memo [DHSC0002273_002], that the initial leaflet took significant time to review. The memo records that "*the delay between drafting and issue caused considerable concern amongst RTDs. In view of the need to issue a further redraft I suggest that before it goes to RTDs we should ensure that there will be a smooth uninterrupted path to its issue.*"

491. There was also disagreement between some of the RTDs and the DHSS as to the wording of the leaflet, with some of the RTDs

favouring more forceful discouraging wording, and with DHSS adopting a cautious approach towards stronger wording in the first edition. There was further disagreement in relation to including in the revised leaflet wording discouraging donors from African countries. I can see these were difficult decisions at the time, although they do now look easier with the benefit of hindsight.

Mid 1980s: government involvement in HIV testing

HTLV-III testing

492. In my answers to Section 9, I set out in detail the development of AIDS testing in the 1980s, in particular as this occurred prior to and following Food and Drug Administration **('FDA')** approval of HTLV-III tests in America on 2 March 1985. I do not intend to replicate the full detail of that answer but I would note the following developments.

493. On 28 June 1984, Drs Gunson, Tyrrell (MRC Committee), Tedder, Wallington and Contreras met to discuss setting up an MRC study on blood donors which would detect anti-HTLV III as a possible marker for AIDS transmission risk [PRSE0003901]. It was agreed that this should begin as soon as possible, although as a research project, rather than being introduced into routine screening without proper appraisal. Among other considerations, Dr Gunson pointed out that to carry out routine screening, every RTC would require additional staff and equipment, and some would need additional space. Dr Gunson advised that a major decision would therefore be required to proceed to routine screening, particularly when the incidence of positive reactors would probably be very low. However, he doubted it would be possible to resist pressure from various sources when dealing with a potentially fatal condition. He requested that this topic be placed on the agenda for their meeting on 7 August 1984.

494. I have also seen a DHSS memo dated 19 October 1984 [DHSC0002323_009], which among other things suggested that there was a danger in making testing too public, in case high risk groups

began using blood donations as a means of testing for their HTLV antibody status (with the risk of thereby making the blood supply less rather than more safe). It also stated that the DHSS were yet to know of a case of AIDS reliably related to blood transfusion.

495. I note the setting up of the NBTS Advisory Committee's Working Group on AIDS, and its relationship to the DHSS' own advisory group, EAGA. As I set out in Section 9, the NBTS Working Group appears to have been conceived by Dr Harris of the DHSS, Chairman of the NBTS Advisory Committee on or by 31 August 1984 [CBLA0001875]: the group first met on 27 November 1984 [CBLA0011985]. The group's Chairman, Dr Abrams of the DHSS, circulated a paper in advance of the meeting [CBLA0001934_001; CBLA0001934_003] which set out the issues on which the group's views were sought in order to protect the blood supply from the prevalence of AIDS. I have set these out in detail in Section 9: in particular, the paper queried whether the UK should adopt the US model of informed consent for blood donors, whereby a sample of blood would be saved to test for infection at a later date, pending the institution of the screening test for all donations.

496. I set out that the minutes from the first meeting of the NBTS Working Group [CBLA0011985; DHSC0002251_011] record a unanimous strong view that the antibody test for HTLV-III must be used for all NBTS donors as soon as possible. The Group also agreed that donors *should* be told that they would be screened for HTLV III testing.

497. I note the combined meeting of blood service members on 10 December 1984 [HCDO0000394_117], at which it was noted that limited resources made it impossible to undertake routine testing. The members discussed whether DHSS financial support might be forthcoming, with BPL being available to coordinate the endeavour if resources were available. Dr Smithies was to revert to the DHSS.

Concern was recorded that no central organising body was being contemplated for the test programme.

498. I note the minutes of the RTD meeting on 23 January 1985 [CBLA0001995], in which the RTDs were of the opinion that the NBTS Working Party had been unproductive, there being as yet no new leaflet, no finance and no positive move towards full donor screening. The DHSS had also set up their own AIDS Working Party (EAGA), and the RTDs were unhappy that no information had been given to them. The RTDs also felt that DHSS should be pressed to make any test available to the community before its use in blood donor screening, to avoid high-risk donors attending purely to be tested.

499. I note from the minutes of the first meeting of the DHSS Advisory Group on AIDS on 29 January 1985 [PRSE0002734] that the DHSS was not certain how soon a screening test would be available. The Chairman reminded the group that the NBTS Advisory Group on AIDS had recommended availability as soon as possible. The DHSS group broadly concurred and set up a sub-group to consider how best to introduce the service.

500. I also note in my answer to Section 9 that RTDs wanted a common date for the test's introduction into the NBTS, and that this position was later endorsed by the EAGA Screening Test Subgroup.

501. It appears that by March 1985, the RTDs and DHSS were in broad agreement that all blood donors should be tested for HTLV-III antibodies, and that this was a matter of urgency, but that bodies should proceed with caution as to the reliability of currently available test systems. I note that the DHSS intended to evaluate all known test kits and advise the NHS on their reliability for use. These sentiments are echoed in Mr Kenneth Clarke's press release on behalf of the DHSS on 27 June 1985 [DHSC0001184].

502. Following FDA approval of several tests, the DHSS made plans for a two-stage departmental evaluation of test kits. First, a preliminary assessment of each diagnostic kit would be made at the Public Health Laboratory Service **('PHLS')** Virus Reference Laboratory. Secondly, tests found to be sufficiently sensitive and specific would then be evaluated in a field trial in the NBTS.

503. I note that the RTDs commented that Dr Smithies of the DHSS's attendance at an RTD meeting on 18 February 1985 [PRSE0002062] was very valuable, and that the RTDs would support extending further invitations to DHSS and CBLA officials to improve communication [PRSE0002906].

504. I note the DHSS EAGA's recommendation that the RTDs devise an agreed procedure for centres to follow. This was ultimately laid out in a report dated 11 July 1985 [DHSC0000406], which was approved by the Directors of the NBTS and SNBTS, and subsequently endorsed by the EAGA. This report laid the framework for the introduction of routine screening in the UK from a target date of October 1985. It outlined recommended procedures for informing donors that their blood would be tested, the management of positive results, the care of positive donors and significantly, lookback in respect of recipients of positive donations.

505. The report set out that there should be an NBTS evaluation of different test kits, but that given the degree of urgency, in the meantime RTDs should make arrangements with their respective RHAs.

506. I note the NBTS and DHSS shared concerns that the BTS should not be the first or only testing point, in order to avoid the risk of attracting high-risk donors. Thus, on 30 July 1985 the DHSS wrote to Regional General Managers asking them to provide testing and counselling facilities outside the BTS [DHSC0000515].

507. I note the letters from Dr Williams of the DHSS to all RTDs in England and Wales (copying in Dr Cash) [PRSE0003215], which updated the RTDs on DHSS' communications with district general managers, and which advised RTDs to prepare to introduce routine screening, in particular by immediately approaching their RHAs if they not done so already, in order to secure funding and arrange laboratory space and staff training. Dr Williams sent a further letter to RTDs in relation to testing on 22 August 1985 [NHBT0004236]: see also [NHBT0096480_027] as addressed in Section 9. It appears to me that, in the context of where the views of the RTDs and the DHSS aligned, there was good communication and collaboration. This certainly would appear to be the case in the run-up to the introduction of routine testing in October 1985. This appears to have continued up to the point of launch, in particular through Dr Smithies' attendance at RTD meetings: see [DHSC0002365_002].

HIV-2 Testing

508. In relation to the introduction of HIV-2 testing, which I have also addressed in Section 9, I would highlight the meetings of the RTD AIDS Working Group on 5 May 1987 [CBLA0002373], in which it was agreed that on the evidence available, routine screening of blood donations for anti-HIV 2 was not necessary at that time, however it would be desirable to introduce a procedure whereby additional testing of blood from donors who had visited West Africa was undertaken. This was formalised in a letter from Dr Gunson to all medical officers and clerks at RTCs on 11 June 1987 [NHBT0004131], which outlined the procedure to be followed at blood donation sessions.

509. Dr Gunson then outlined the approach to DHSS and other officials at a meeting on 26 February 1988 [NHBT0004121], but it was noted that no samples had yet been received from RTCs beyond the four pilot RTCs. It was therefore agreed that Dr Gunson should write to all RTDs again inviting them to take part in the scheme and advising them to inform the DHSS in the event of resource issues, which he did on 18

March 1988 [NHBT0003698]. It was also agreed that it would be advisable to extend the amount of screening for HIV 2 in GUM clinics.

510. I also note the minutes of the EAGA meeting on 12 April 1988 [MRCO0000003_137], in which the DHSS agreed that routine testing at RTCs for HIV-2 was not presently justified, but should be kept under review.

511. I note Dr Gunson's letter to the RTDs on 18 August 1989 [NHBT0010869], which stressed the importance of acting in a coordinated manner nationally and with Scotland regarding introducing routine screening, and that DHSS approval would be required, but that there was no evidence of an urgent need for testing. Ministerial approval for routine testing was not given until 23 March 1990 [NHBT0004168]: once given, it was set out that the combined test was to be introduced UK wide as soon as possible at a date to be agreed within the NBTS and communicated to DHSS.

512. Finally, I note that by 1 June 1990, all RTCs had commenced the routine screening of all blood and plasma donations with the combined anti-HIV 1 and 2 test, except for the Bristol RTC who had commenced on 14 June 1990 and the Cambridge, Manchester and Lancaster RTCs who had commenced on 2 July 1990 [NHBT0001674].

Late 1980s to early 1990s: the establishment of the National Directorate and, subsequently, the NBA

513. I address the establishment of the National Directorate, its impact on accountability and government oversight of decision-making, and its advisory role in my answers to Questions 24 and 25. In Question 24, I also discuss the establishment of the NBA.

Early-mid 1990s: HCV screening and HCV lookback

514. As I set out in my answers to Section 9, three former NHSBT senior clinicians have provided answers to rule 9 requests which address the

history of surrogate testing for HCV; the introduction of HCV screening in 1991; and the undertaking of the HCV lookback from 1995. They are Dr Patricia Hewitt, Dr Lorna Williamson, and Dr Angela Robinson. Since these members of staff have significant first-hand knowledge of the events they discuss, and are therefore in a far better position than me to provide evidence, I will not seek to add to their accounts in relation to HCV testing and lookback. Instead, I will aim to highlight some of the key events which illuminate the relationship between the blood services and the DH.

Introduction of HCV Screening in September 1991

515. Dr Robinson's statement sets out the early attempts that the blood services made at surrogate testing for HCV in 1989 (see Question 6). I would highlight the letter which Dr Gunson wrote to Mr Hart at the DH on 2 October 1989 [NHBT0000288_056], indicating his belief that a decision would need to be made to introduce routine screening during 1990. He estimated the national cost and stated that each RTC had been advised to include a bid in their forthcoming development programme.

516. Dr Robinson sets out that at a meeting of the UKACTTD of the NBTS (see Question 25) on 9 October 1989, the Committee was asked to approve in principle routine testing of donations for anti-HCV [NHBT0000043_034].

517. According to the subsequent meeting of the DH's own committee, the Advisory Committee on Virological Safety of Blood **('ACVSB')** on 6 November 1989 [NHBT0005043], the recommendations of the BTS were that routine screening should be introduced only after a confirmatory test became available, the FDA had approved the test and an urgent pilot study had been carried out in the UK. The ACVSB view was that whilst the test represented a major step forward, they needed to know a great deal more about it, and that while awaiting FDA approval, several pilot studies should proceed to establish the

feasibility of making the test routine. The ACVSB would support the general introduction of the Chiron test if the FDA approved it but there was no case for using surrogate tests for NANBH (Non A Non B Hepatitis) [NHBT0005043, paras 28-29]. Subsequently, Dr Gunson prepared a draft protocol, which he sent to the directors of the trial RTCs [NHBT0000014_083]. The DH agreed to fund £25,000 for the pilot study.

518. The documents referred to in Dr Robinson's statement reveal that of the two parallel committees, the ACVSB (the DH Committee) took the decisions as to whether and when to recommend to Ministers that testing be introduced: see for example [NHBT0000042_032]. It would appear that this was not something which the UKACTTD of the NBTS had the power to do. Their role was to advise. This was despite Dr Gunson's presence at ACVSB meetings.For example, at the ACVSB meeting on 17 January 1990, Dr Gunson reported that the transfusion service was under a great deal of pressure from private companies, the press and clinicians and that he felt they must now consider setting up the test [PRSE0001477]. On 21 November 1990 the ACVSB agreed to the introduction of HCV testing as soon as practicable [NHBT0000073_018].

519. Among other factors, the need for and practicalities of donor counselling was clearly considered to be an important issue, both within the DH's ACVSB and within the BTS. For example, at the request of Dr Rejman from the DHSS [NHBT0000042_048], Dr Gunson presented a paper on donor counselling at a meeting of the ACVSB on 21 November 1990 [NHBT0000073_018]. Dr Gunson stated that the UKACTTD of the NBTS would be meeting to discuss this issue, as well as lookback. Within the SNBTS, a paper was produced on the issue by Dr Gillon, and within the NBTS there was a paper by Dr Contreras.

520. Dr Robinson records that the donor counselling processes put forward in a UKACTTD meeting on 3 June 1991 [NHBT0086153] were based on the HIV processes which included lookback and appear to have assumed that lookback would be performed.

DH Response to Dr Gunson's HCV Report

521. In addition, I would highlight the DH response to Dr Gunson's paper on Hepatitis C (HCV), entitled *Hepatitis C Viraemia in United Kingdom Blood Donors: A Multicentre Study.* A draft that appears to be from before the events set out below was provided to me [PRSE0000281].

522. I have seen a copy of a letter dated 11 September 1991 from Dr A Rejman of the Department of Health to Dr Gunson in his capacity as National Director [NHBT0000015_117]. In the letter, Dr Rejman outlines a number of amendments which the Department of Health proposed that Dr Gunson should make to his report. It is noted that Dr Rejman is writing subsequent to a telephone conversation the day before, and that *"as I mentioned, our anxieties were that there were several changes needed in the paper some of which were simply to correct inaccuracies while others might prevent misinterpretation which is often very relevant in these litigious times".* One of the inaccuracies alleged is that the references to RIBA-2 should actually be to RIBA since RIBA-2 had only been available more recently.

523. One of the more substantive proposed amendments arises from anxiety that *"the final sentence in the first paragraph of the Introduction could be read as being critical of the UK for not introducing screening of blood donations earlier, and so we feel that the beginning of the third paragraph of the introduction on page 4 should be amended to defend our position".* The letter goes on to propose deleting the first two sentences of said paragraph and drafts a quite substantial proposed replacement paragraph dealing with the reasons for, and process of completing, the prospective study funded by DH. The letter asks to see a copy of Dr Gunson's proposed letter to Dr Garson.

524. I have also seen Dr Gunson's response to Dr Rejman dated 16 September 1991 [NHBT0000015_119], which is said to attach a copy of his response to Dr Garson [NHBT0016548]. Dr Gunson stated that he had included most of the suggested points: *"However, I do not think that we should attempt in a scientific article to try to justify any alleged delayed introduction of anti-HCV screening."* For similar reasons he asked for the last sentence of the first paragraph to be deleted. Dr. Gunson went on to state that:

"I am sure that the tests were performed using RIBA-II but I have asked for clarification. I do not think any delay was caused by RIBA-II not being available. There was a delay between the two phases of the study, but this was caused by the sheer logistics of transferring samples from three RTCs to each of their confirmatory laboratories and the fact that 65 PCRs took a long time to complete".

525. I have not been provided with a final copy of this paper so do not know what became of the changes that Dr Gunson suggested should not be included.

526. Dr Robinson's written statement sets out at the beginning of Question 5 that other than in relation to the lookback in 1995, the blood services did not undertake any notification or awareness raising exercises for 'patients' at risk of HCV, as this would be a matter for the government. However, it was within the blood services remit to run awareness campaigns for donors: see the launch of the BTS safety awareness campaign referred to in [NHBT0000077_103]. The blood service would also apply exclusion through screening, or in the absence of screening would identify risk factors. The service also worked to raise awareness among clinicians and the medical profession.

HCV Lookback

527. Dr Robinson's statement sets out in full the substantive reasons why a lookback policy was not adopted before 1995, and I do not propose to replicate these here. Instead, I aim to highlight the relationship between the BTS and the Health Departments in relation to the discussions surrounding the introduction of a lookback policy.

528. The Terms of Reference and inter-relationship of the various committees who debated HCV lookback were set out in April 1989 [PRSE0001865; PRSE0001189; PRSE0004113]. As explained elsewhere in this response, there was a DH committee called the ACVSB, which was later renamed the MSBT and then subsequently became SaBTO even later. The relevant committee within the NBTS was initially termed the UKACTTD, and later became SACTTI. Through SACTTI, the UK BTS formulated recommendations to MSBT in relation to undertaking a lookback. The MSBT had the role of advising Ministers.

529. From the documents cited in Dr Robinson's statement, it is clear that the question of whether the BTS should have a lookback policy was discussed in the first half of 1990. It was mentioned at an ACVSB meeting on 24 April 1990[CBLA0000069_118], and was raised by Dr Cash in a letter to Dr Gunson in a letter dated 1 May 1990 [NHBT0000189_131]. It was also being discussed within the SNBTS in May 1990 [NHBT0000189_131]; at an NBTS/SNBTS Liaison Committee on 27 June 1990, which Dr Gunson attended, "*it was agreed that whilst tests and policies are evolving it would not be appropriate to establish a lookback policy and that AVCSB should take a view in due course*" [NHBT0000189_173]. Dr Cash from the SNBTS again wrote to Dr Gunson pressing the issue of lookback on 26 November 1990 [PRSE0002167], and on 17 June 1991 [NHBT0000192_091]. However, many other minutes from this time period primarily discussed the prospective introduction of HCV screening, and delayed consideration of initiating a lookback process.

530. In his letter of 26 November 1990, Dr Cash also mentioned that the UKACTTD minutes would be available to the ACVSB. It would therefore appear that the DH had access to the minutes of relevant meetings within the NBTS and were able to consider their advice. Conversely, I understand that the minutes of ACVSB/MSBT were confidential and not available to UKACTTD/SACTTI beyond the presence on that committee of the blood services national director (later medical director of the blood services).

531. On 20 June 1991, Dr Gunson told Dr Cash [NHBT0000192_095] that Jean-Pierre Allain would provide a prospective lookback study which he would circulate to members of the UKACTTD committee. However, it would appear that when Jean-Pierre Allain wrote to the RTDs on 26 June 1991 setting out the aims of the prospective study [NHBT0000050_016], he omitted any reference to lookback.

532. At the ninth meeting of the UKACTTD on 13 August 1991 [NHBT0000062_096], chaired by Dr Gunson, it was noted that no decision appeared to have been made on lookback by the ACTTD or by the AVSCB. It was agreed that lookback may have legal implications and that the matter should be considered. It was agreed that an *ad hoc* group should be formed consisting of Drs Gunson, Contreras and Mitchell, and Professors Cash and Tedder or Mortimer.

533. Dr Gunson wrote to Dr Mitchell, Dr Contreras and Professor Cash on 15 August 1991 [NHBT0000044_039], urging that they should meet *"fairly soon"* and consider the advice to give on lookback. However, there is no record that can presently be identified of any further substantial developments before or immediately after the introduction of HCV testing in September 1991. It is unclear to me both whether there are, generally, missing documents which would assist here, and (more fundamentally and specifically) whether there were discussions, or other factors, which explain why this was not pursued further, assuming it was not.

534. Indeed, the next key reference to lookback which I have seen came in a meeting of the SACTTI on 18 January 1994. It was noted that Dr Dusheiko advocated look-back; that this would require funding; and that *"the committee supports the concept and encourages grant seeking for this difficult but potentially clinically beneficial undertaking"* [NHBT0000088_006].

535. Lookback was raised at the SACTTI's next meeting on 19 April 1994 [PRSE000986], but it was merely stated that the value of lookback, questions of responsibility for lookback, and subsequent patient management were difficult to assess; needed resolution; and were to be examined in more detail by a group to be convened to consider it further. Doubt as to the value of lookback was linked to conflicting impressions of the effectiveness of antiviral treatment for HCV infected patients.

536. In May 1994, Dr Robinson became the National Director of the NBA. Dr Robinson sets out that many within the blood service had assumed that a lookback process would take place in relation to HCV after the introduction of HCV screening, but that this did not occur. Dr Robinson's understanding was that this was a decision taken by the DH. In her statement, she sets out that lookback was a key priority for her when she assumed the role of National Director.

537. On the 18 May 1994, the Ayob paper was published [PRSE0001046]. It set out that recent clinical trials suggested that beneficial treatment for some patients with acute hepatitis C may be a possibility, and that the blood service was, in consultation with medical colleagues, assessing if any benefits might be gained from a 'look-back' exercise.

538. Also on the 18 May 1994, Scottish officials discussed lookback [PRSE0003685]. The minutes record a Scottish BTS official expressing doubt that the SSHD had locus in the matter of lookback,

and that the SNBTS should make a decision based on professional judgment. The official nevertheless asked for time to discuss the issues within the Health Department. Once the SSHD position was communicated to Professor Cash, and if the SSHD was in agreement, Professor Cash would formally advise NBA, NIBTS, SACTTI and MSBT of the SNBTS policy.

539. On 21 June 1994, Dr Cash sent a memo to SNBTS consultants [PRSE0003344] setting out that "*As a consequence of the position in Scotland and the position adopted by NBA (that the NBA will not move to consider establishing an HCV lookback until it receives advice from ACTTI, the ACTTI Chairman (Dr F Ala) will convene an extraordinary meeting to consider this topic as soon as possible'.*"

540. I would highlight in particular the meeting of members of the blood service in August 1994, attended by Drs Robinson and Hewitt, which Dr Robinson states was designed to prepare a case on HCV lookback for presentation to the Department of Health. I believe this is the meeting of 5 August 1994 [NHBT0009383].

541. In that meeting, it was '*generally acknowledged'* that '*we, in the Blood Transfusion Service, do have an ethical responsibility and duty of care towards recipients of potentially infectious blood components such that they deserve to be identified, counselled, tested and offered treatment where that is appropriate. It was felt that, despite the current uncertainties regarding long-term efficacy of treatment, and its impact upon the natural history of hepatitis C, we have a moral obligation to inform and advise surviving potentially infected blood recipients'.* Members then considered the operational options for the BTS. Having concluded that there was a serious case for considering the implications of an HCV lookback in its operational detail, members wished to refer the topic to the MSBT with a recommendation that such a policy be implemented.

542. Subsequently, a draft *Recommendations of the Standing Advisory Committee on Transfusion Transmitted Infections to the MSBT* was circulated to the Transfusion Centres for comment [PRSE0001236]. This report stated that BTS members could comment on feasibility and logistics, but that desirability was a wider issue. The paper was presented to the ACVSB/MSBT by Dr Robinson on 29 September 1994 [PRSE0003670].

543. Dr Robinson reported back to the SACTTI on the MSBT's reservations at a meeting on 19 October 1994 [NHBT0010970]. However, she noted that MSBT had agreed to convene a group to examine the implications of look back. The sub-committee re-convened on 3 November 1994 [NHBT0005791], by which point written comments had been received from MSBT members which were overwhelmingly in favour of instituting a lookback programme,with certain provisos .

544. On 15 December 1994, the MSBT met again [NHBT0005791], and were recorded as recognising the duty of care which had been outlined by the SACTTI. Issues including the legal implications of instituting a lookback exercise years after the introduction of screening were considered. However, the MSBT ultimately agreed that their advice to Ministers would include that guidance should be drawn up as soon as possible on procedures for identifying those at risk [NHBT0005857_002]. The MSBT agreed that these recommendations should be passed on to all four UK health departments.

545. The Scottish Office wrote to SNBTS on 22 December 1994 [PRSE0000661], asking them to take forward as expeditiously as possible an HCV lookback exercise for all areas in Scotland and to keep the Department informed. The national lookback exercise in England was announced by the Department of Health on 11 January 1995.

24. To what extent is NHSBT accountable to government departments? To what extent is NHSBT's decision-making authority affected by government oversight?

546. Those answers I cite as relevant to Question 23 are also relevant to my answer here. In addition, Question 18, Section 8 and Sections 9-10 are relevant and their contents are not repeated in detail in this answer.

547. Some of the details of the current relationship with the DHSC has been provided by colleagues in NHSBT's governance department. Any information about the historic position is obtained by review of documents which have been provided by those advising me.

Current

548. I set out at Question 4(f) that NHSBT is currently accountable to the four UK Health Departments for the delivery of organ donation and transplantation, and to the English DHSC for providing a blood service.

549. NHSBT's accountability to the Department of Health (now DHSC) is further delineated in the Framework Agreement. In England, the Secretary of State is accountable to Parliament for the English health system, including NHSBT. This includes setting national priorities; monitoring the whole system's performance; setting budgets including for NHSBT; setting NHSBT's high-level objectives; accounting to Parliament for NHSBT's performance and the overall effectiveness of the health system; and supporting the integrity of the system by ensuring that funding, legislation and accountability arrangements protect the best interests of patients, the public and the taxpayer.

550. The DHSC's Permanent Secretary, as the Principal Accounting Officer **('PAO')**, is also accountable in Parliament for NHSBT's performance, compelling him or her to be assured that NHSBT is properly discharging its duties and meeting its strategic objectives. The PAO

has appointed NHSBT's Chief Executive as its Accounting Officer (AO), who may also be called to Parliament to account for NHSBT's performance.

551. The Framework Agreement sets out that the PAO's oversight of NHSBT relies on the provision of information and processes to enable performance review. The information which NHSBT accordingly provides to the Department includes its monthly Board performance report; full Board papers in advance of each bi-monthly Board meeting; and formal financial reporting such as quarterly monitoring reports. NHSBT also publishes an Annual Report and Accounts: drafts are circulated to all the UK Health Departments, and the final report is laid before Parliament.

552. The NHSBT Board has internal responsibility for ensuring the organisation is able to account to Parliament and the public for how it has discharged its functions. The Board is led by a non-executive Chair: the SDS ensures that there is an annual objective setting and review process for the Chair.

553. The Framework Agreement further sets out that NHSBT is responsible for delivering its objectives, and there are limited circumstances in which the DHSC will intervene in its activities. Constraints include the Secretary of State's power to terminate the tenure of the non-executive Chair or a non-executive member in the circumstances set out in Statutory Instrument 2005 No. 2531, as amended. However, the Secretary of State is also empowered to give NHSBT Directions, if there are unresolved concerns about NHSBT's discharge of its functions. If NHSBT fails to comply with these Directions, the Secretary of State in consultation with the other UK Health Ministers may make his own arrangements for the discharge of NHSBT's functions. NHSBT must also have regard to any guidance issued by the Secretary of State.

554. The Secretary of State also has a general power to direct NHSBT to disclose to him such information as he feels necessary to fulfil his duties. The Department expects to have full access to NHSBT's files and information when required.

555. Current processes in place to ensure oversight include quarterly accountability reviews chaired by the SDS or a representative, involving the NHSBT Chair, Chief Executive and other relevant executive directors (as determined by the Chair). There is also an annual accountability review: this additionally includes a full review of NHSBT's performance in the previous year, and a review of the effectiveness of the DHSC/NHSBT partnership and includes the Chief Medical Officer and the Finance Director. Section 13 further states that the Department will undertake an *"in depth review of NHSBT"* on *"at least a triennial basis".*

556. The last NHSBT Triennial Review was announced in mid-2015, with a final report issued in September 2016 [WITN0672140]. The review was conducted in two stages with the first stage considering "Form" and "Delivery Model" and the second stage reviewing "Governance and Relationships, "Strategic Leadership" and "Efficiency".

557. The report was positive and concluded that:
    a. all of the functions identified by the Triennial Review Team should continue and that NHSBT should continue to deliver them as a Special Health Authority.
    b. NHSBT is an organisation that takes seriously both the needs of donors and patients, plus efficiency for the taxpayer, and is able to point to a range of successes in relation to all of these areas.
    c. NHSBT recognises the challenges that it faces and areas for potential improvements.

558. The report made eighteen recommendations with progress against them regularly reported to the Board. Of these, two (Recommendations 1 and 3) confirmed that NHSBT's functions and

form should continue. Of the remaining 16 recommendations, a review by the Board in 2018 concluded that 12 were complete with four carried forward within existing strategies and plans.

559. Welsh representatives attend the accountability review meetings and attend the NHSBT Board as observers. Scottish and Northern Irish officials have similar arrangements. In addition, Welsh Government officials hold separate six-monthly meetings with senior NHSBT executive team members to discuss Welsh-specific issues.

560. Further, an SDS representative attends all NHSBT board meetings, and representatives from the other UK health departments are also invited. An SDS representative also attends the Governance & Assurance Committee meetings. There are also *ad hoc* meetings between the DHSC and the NHSBT Chair, Chief Executive and other executive directors. Finally, NHSBT submit their summary strategic plan and annual budget to the Department for annual review and planning: this process is set out in detail in Section 3 of the Framework Agreement.

561. NHSBT's monthly performance report is shared with the Department to facilitate performance review and risk management. Risks are also to be flagged in the quarterly accountability meetings. NHSBT and the Department were also to agree a process and trigger points for the escalation of risks to the DH Audit and Risk Committee, where those risks will have a potentially significant impact on NHSBT, DH or the wider system that requires a coordinated response.

562. The Framework Agreement also sets out that the delegated authorities which are issued by the DHSC include areas where NHSBT must obtain the Department's written approval to proceed with a matter. To my knowledge these areas are determined according to the nature of the issue or the value of the expenditure.

563. The NHSBT Standing Orders provide for the NHSBT Chief Executive to delegate power internally: current delegation arrangements are set out in the March 2021 Scheme of Delegation [WITN0672052].

Accountability Beyond the Department of Health

564. NHSBT has some accountabilities beyond the Department of Health. For instance, cross-government clearance is required for major new policy decisions as defined by Cabinet Office guidance (3.8). Further, section 6 of the Framework Agreement stresses that both organisations have individual responsibilities to account to the public and Parliament. Accordingly, the Department and NHSBT have agreed a public and Parliamentary accountability protocol, which sets out how they will work together to secure public and Parliamentary confidence.

565. NHSBT's Board members comply with the corporate governance guidelines set out by HM Treasury, and with the Cabinet Office's Code of Conduct for Board Members of Public Bodies.

566. NHSBT is subject to expenditure controls and delegated limits determined by the Cabinet Office and the DHSC. In July 2021 the DHSC informed the arms-length bodies that these financial delegations were due to change.

567. NHSBT must demonstrate that it is delivering its functions in the most efficient manner and must provide timely returns to the Department where required to do so by government.

Historic – introduction

568. As I have set out in my answer to Question 18, it is difficult to talk of NHSBT's historic accountability as if it crystallised within one institutional structure. Prior to the formation of the NBA in 1993, the RTCs were formally accountable to the regional health authorities (previously, the regional health boards). The RTDs were formally

accountable to the RHAs, despite the attendance of DHSS officials at their meetings.

569. Since the NBA was formed on 1 April 1993 and the RTCs were transferred to it on 1 April 1994, it has existed as an SHA funded directly by the Department of Health. After this point, the RTCs were increasingly assimilated into the NBA as BCs, and funds were provided to these bodies as constituent parts of the national service. The BCs are now constituent parts of NHSBT.

Meetings of the RTDs

570. Although the RTDs were accountable to the RHAs, they nevertheless had a relationship with central government, which exercised a fluctuating amount of oversight over the directors' periodic and informal meetings.

571. As set out in my answer to Question 14, from 1948 the Consultant Advisor on Blood Transfusion to the DHSS chaired ten regional directors' meetings each year. It would appear from the documents I have seen that this arrangement continued into the 1970s and 1980s, with DHSS officials occasionally, but not always, attending the directors' meetings.

572. This arrangement allowed for dialogue between the regional directors and the DHSS on matters including policy and funding proposals. For example, it provided an avenue for DHSS to report back to the directors on policy decisions which had been taken by central government, such as the decision in the 1970s to reject the RTD's centralisation proposals. The extent to which this arrangement allowed the directors an advisory role is addressed in my answer to Question 25.

Historic – decisions related to organisational structure

573. I have been shown a number of documents about the organisational structure of the blood service over the years. I have already addressed some of this in my answer to Q18, and the results of the changes in organisational structure can be seen in Q3-4 where the nature of the blood service over the years is discussed. It appears from these documents that there was a drive internally within the blood service from at latest the mid-1970s to return to a centrally managed service. However, I can also see from these documents that ultimately the organisational structure was a decision for the Department of Health. When the NHS was restructured in the 1980s, the regional model for the NBTS was maintained. The requests for a centrally managed service do not appear to have been adopted as government policy until the early 1990s and the establishment of the NBA.

574. I have elsewhere referred to the RTDs attempts in the 1970s to achieve centralisation of the NBTS.

575. I have also been provided with minutes of the 179th meeting of the RTDs, which was held on 25 June 1980 [SBTS0000290_004]. At that meeting, Dr Harris from DHSS explained that *"the Regional Transfusion Service would not be affected in any major way by the re-structuring of the National Health Service. However, the effects of cuts in central spending would be felt throughout the Service, including the Transfusion Service".*

576. The minutes record further discussion in relation to regional funding and the adequacy of blood supply:

"Directors were concerned that if the BPL required more plasma Regions would also have to be geared up accordingly, and where necessary more funds injected. Mr Harley [DHSS] explained that discussions would take place with RHAs on how best the demands for extra plasma could be met. Regions would have to be reminded that NHS blood products were cheaper than those imported commercially.

Directors accepted that under the reorganisation Districts would be deciding what the priorities on spending would be, and if there were to be greater demands on the Transfusion Service it was thought that there might be a case for charging authorities for blood products".

577. Finally, the minutes record that Dr Harris from the DHSS stated that *"it had now been recognised that there was a need to set up as soon as possible an advisory committee for the NBTS as proposed by the Chairman [Dr Tovey], which would receive plans and exchange ideas on the aims and development of the Transfusion Service, including the Central Laboratories, and generally advise on coordination".* The Directors were concerned that the Committee should not only consider the supply of plasma and blood products, but also wider questions and matters of policy for the NBTS. Dr Cash stated that Scotland was pleased to hear of the proposals for an advisory committee.

The Establishment of the Advisory Committee

578. At the 180th RTDs meeting on 15 October 1980 [DHSC0002365_021], it was recorded that Ministers had agreed to the replacement of the Central Committee of the NBTS with an Advisory Committee, who would meet on 1 December 1980. Its terms of reference were *"to advise DHSS and the Welsh Office on the co-ordination of i) the development and work of Regional Transfusion Centres, and the Central Blood Laboratories in England Wales [sic]; ii) as necessary – the English and Welsh Blood System with that of Scotland."*

579. The minutes from that meeting also recorded the Directors' opposition to private industry's involvement with the fractionation of blood products, which it was felt could harm the Transfusion Service. It was recorded that *"Because of exploitation of plasmapheresis donors in developing countries and the risks of transmitting hepatitis international opinion was recommending national self-sufficiency in blood products. The Chairman [Dr Tovey] pointed to the failure of the*

Travenol/Red Cross collaborative project in the USA." The Chairman suggested launching an appeal to donors to fund BPL's redevelopment. The Chairman requested a statement of the Directors' views, and it was suggested that Directors in Scotland might wish to add their views.

580. In the minutes of the fifth meeting of the Advisory Committee on 31 March 1982 [DHSC0001136], it was recorded that following a report by the Committee of Inquiry, which had investigated allegations of misuse of blood and blood products at the National Heart Hospital, *"the Secretary of State had asked Dr Wagstaff, as Chairman of RTDs, to undertake a survey of record keeping in the NBTS",* and that this survey was now complete.

581. In discussion of that survey, the minutes record that *"it was felt that computerised record keeping systems, with links between the RTC and hospital blood banks, would provide better control but it was recognised that the resource implications of installing such a system had to be carefully assessed and balanced against the potential benefits. Members stressed, however, that it was in the interest of patients' and donors' health for each unit of blood to be traceable from donation to transfusion or disposal. Accountability, whilst important, was secondary to the safety of patients".*

582. The committee agreed that DHSS Management Services Division should be consulted about options for record keeping systems for blood and blood products, and that DHSS guidelines on supplies of blood to hospitals should be updated and should draw attention to the *'Notes on Transfusions'* booklet which RTDs were currently revising.

583. The full report on stock control and record keeping was summarised at the seventh meeting of the Advisory Committee on 10 January 1983 [DHSC0002223_091]. Mr Godfrey noted that the study *"reinforced"* the need for updated DHSS guidance, and stated that the report made

"wide-ranging recommendations", some of which *"restated what should be, in most blood banks, good practice"*. It was recorded that following the report DHSS had prepared a draft health circular (Annex B to AC(83)1), and that the Committee's views were sought on the report, circular and *"the distribution of the report"*. At the Committee's ninth meeting on 10 April 1984 [CBLA0001835], it was reported that Ministers had accordingly issued the recommended guidance in March 1984, as HC(84)7.

584. I have further addressed the composition and remit of the Advisory Committee in my answer to Question 18. It appears from the documents listed there that a 'supervisory' role for the committee was proposed by the regional directors but was seen as contrary to central government's overall devolution policy.

585. I further discuss the advisory role of the Advisory Committee in my answer to Question 25.

Establishing the CBLA

586. From the minutes which have been made available to me, I can see that the CBLA was preceded by a Joint Management Committee which was chaired by Dr Harris and composed of both DHSS officials, and officials from the North West Thames RHA. These minutes record the development of governmental decision-making in relation to the long-term management structure for the CBLs.

587. At the JMC's 13th meeting on 23 October 1981 [DHSC0002211_063], Mr Godfrey from the DHSS reported that Ministers were still considering the CBLs' management structure. The JMC stressed the difficulties that would occur if the matter were not decided before the completion of the proposed feasibility study on redevelopment. Mr Smart reported that the Policy Steering Group on BPL's redevelopment had so far met three times and that *"its work was*

hampered to an extent by the lack of Ministerial decision on long-term management arrangements".

588. In terms of funding, Mr Harris reported that in principle Treasury approval had been obtained but that economic justification for decisions would be required. Mr Smart stated that the Group was prepared to provide these.

589. The JMC clearly had an advisory role. For instance, in its 11th meeting on 20 March 1981 [CBLA0001315], it was stated by Dr Walford that *"following the advice of the Committee at its last meeting",* she and other Department officials had been in further discussions with Celltech Laboratories regarding supplying blood to BGRL.

590. The minutes record that the RHAs' decision whether or not to take on the project management was linked with the outcome of the Department's discussions on the possible role of the RHA in the long-term management arrangements. The minutes go on to state that:

"Now that the Region knew what the Department's preference was, it could accept the task of project management, provided that agreement could be reached on arrangements for accountability and control. The RHA had much experience and expertise in undertaking project management, but accepted that it would have to call upon outside expertise on such matters as pharmaceutical processing and fractionation technology […]

12. The Chairman said that it was now important to consider who should be appointed to serve on the steering group which would provide policy direction, and the Department would pursue this in consultation with the RHA. He thought that the group would find it most helpful to have advice from the Scientific and Technical Committee".

591. I have also seen minutes of the JMC's fifteenth meeting on 5 October 1982 [CBLA0001631]. An update on long-term management was given, which noted that the Statutory Instruments had been submitted to Ministers, and that the draft Regulations provided that there could be as many members as the Secretary of State saw fit, provided that at least two members had industry experience, and at least one was a member of an existing health authority.

592. BPL's draft agreement with Wellcome to produce a joint RIA (radioimmunoassay) test was discussed and it was suggested by Dr Gunson that *"BPL's control of the finished product should be emphasised in order to allay Regions' fears concerning the reliability of the test."*

593. The minutes further record that at the final meeting of the Scientific and Technical Committee on 21 June 1982, the Committee had asked the Regional Transfusion Directors, through Dr Gunson, to consider the production of a Manual of Recommended methods for blood serology procedures, and that initial discussions on this manual were in hand.

594. Finally, the 1981-1982 Draft Annual Report from BGRL was tabled. Dr Holburn emphasised the importance of centralising production of reagents and stated that this would require the assent of the RTDs whose RTCs manufactured reagents. The report suggested discussing this at the NBTS Advisory Committee.

595. I have been provided with the minutes of the CBLA's first meeting on 3 December 1982 [CBLA0001644]. Dr Harris' introduction highlighted the *"unique management structure within the NHS".* It was further recorded that the CBLA *"was a Special Health Authority with the full powers of a corporate body. It was unusual to have DHSS representation on the Authority, but this had been done to utilise the specific expertise of Dr. Harris".* Mr Godfrey was to act as the Liaison

Officer between DHSS and the CBLA *"in a similar manner to the attendance of officers from the Regional Liaison Division to Regional Health Authority Meetings".*

596. It was noted on the agenda that the NBTS Advisory Committee's terms of reference had been amended to include advising on the coordination of the laboratories' work with that of the RTCs.

Late 1980s

597. I have seen the minutes from the eleventh meeting of the Advisory Committee on 6 November 1985 [CBLA0002277]. I have set out the contents of these insofar as they relate to sufficiency of blood supply in Section 8. The Committee also discussed the arguments for a reorganisation of the NBTS, which had initially been prompted by RTDs' concerns about plasma supply. The arguments in favour of re-organisation were summarised as follows:

"a fully co-ordinated system could achieve the national aims more readily and would enable shortage in Regions to be assisted, improve liaison with central laboratories and produce savings on purchasing. RTDs had considered a Working Group should be set up to report to the Advisory Committee. Some members expressed concern about a trend in some Regions to devolve blood transfusion to District control: this was opposed in principle and because Districts were not funded to provide this service".

598. Mr Williams from the DHSS explained that any plans to restructure the NBTS would need to be examined by the Department. He outlined that experts from the Management Services Division would be asked to consult the RTD's Working Party and would circulate their report to the Advisory Committee. No managerial changes were to be made pending the report's completion. The minutes also record that the Price Waterhouse report on inter/intra-regional charging should be considered as part of the MSD's study.

599. I have also been provided with minutes from the twelfth meeting of the Advisory Committee on 12 March 1986 [PRSE0000128]. Insofar as relevant to accountability and oversight of decision-making, these record that:

a. It was agreed that the new Research Committee should report jointly to all UK health departments.
b. It was envisaged that an NHS/DHSS steering group would supervise the fresh examination of the NBTS' organisation. Terms of reference were to be prepared for the next meeting of Regional Chairmen. The Welsh Office wished to reserve its position to withdraw from any re-organisation which removed regional autonomy.
c. A clear policy needed to be laid down by DHSS before donated blood could be supplied to commercial firms.

600. I have also been provided with minutes from the thirteenth meeting of the Advisory Committee on 17 June 1986 [BPLL0007202]. Insofar as relevant to this question, they record that the fieldwork for the NBTS organisational study had been completed and had identified an *"overwhelming need for a Management Information Service (MIS")*. The options suggested *"ranged from minimal change to Special Health Authority status; all options would include a MIS".* The Advisory Committee would be asked to comment on the Steering Group's proposals and Regional General Managers **('RGMs')** would be consulted. The report was expected in the autumn.

601. The Chairman also flagged the need for a national research committee now that the MRC's Committee had been disbanded. The minutes record that *"he and the Chief Medical Officer were not prepared to leave the issue in limbo lest the UK should slip behind. Dr Napier asked if the formation of the new body would improve the possibility of research funding. The Chairman advised that no funds were presently*

available; this would be pursued with Ministers. Members agreed that a UK approach was needed and hoped the new Administration would address the issue quickly".

602. The plasma supply to BPL from the RTCs was also discussed. Dr Fraser, the Chairman of the RTDs, stated that RTDs had lost credibility because of delays at BPL, and stated that he thought *"there would now be more difficulty in obtaining funds from Regions and the future blood supply would suffer".* Dr Tovey asked whether a charging system would be introduced, to which Dr Moore replied that this was currently being considered in the Management Services Report. The Chairman advised that *"the Management Board would be informed of progress; meanwhile continuing regional support for plasma collection was imperative".*

603. As I have set out elsewhere, the organisational study is available to the inquiry at [CBLA0002392], and according to *Fifty Years of Blood Transfusion* [NHBT0000028] was received by the DHSS in early 1988 and led to the formation of the National Directorate. In my answer to Question 18 I have outlined the four underlying problems identified in the report:

11.1.1 the absence of reliable management information;
11.1.2 the inability of the two London regions to meet the needs of their hospitals from within their existing collection programmes;
11.1.3 the absence of co-ordination between individual RTCs and also between the BTS (and collective RTCs) and CBLA.
11.1.4 arising from 11.1.1 and 11.1.3 apparent inefficiencies both within and between individual RTCs.

604. I also outlined the three alternative solutions proposed, which I will also repeat here briefly for the sake of clarity and ease of reference. The minimum change option proposed remedying some of the problems though evolution without change to the existing

organisational structure save for a uniform management information system. The intermediate option maintained executive and financial accountability in the RHAs, but with the advisory role of existing bodies being enhanced by redefinition of their remits. This would also involve a new committee for NBTS/CBLA co-ordination. The paper noted that *"[t]he decisions and recommendations of the enhanced advisory structure, detailed below, would need to be recognised as of sufficient authority so that real account is taken of the merits and demerits of the situation before a veto is applied by an RHA*". The third option was a national option by which the NBTS was managed and funded centrally as an SHA.

605. *Fifty Years of Blood Transfusion* [NHBT0000028] identifies that, after "*wide consultation*" the DHSS chose "*to retain management by RHAs but with formal co-ordination of the work of RTCs*".

The National Directorate of the NBTS

606. I have also addressed the establishment, remit and organisational structure of the National Directorate in my answers to Question 18 and Questions 35-40.

607. On 28 July 1988, the National Directorate of the NBTS was formed, with the aim of formally coordinating the work of the RTCs which, to that point, had been entirely managed by each of the respective Regional Health Authorities. However, the National Directorate had no executive authority and the RTCs remained the primary responsibility of the RHAs [NHBT0000026_009]. Dr Harold Gunson was appointed Director on 1 October 1988, whilst maintaining his role of Consultant Adviser in Blood Transfusion to the Chief Medical Officer at the Department of Health. Dr Gunson reported to Mr Graham Hart, Director of Operations on the NHS Management Board.

608. At that time an NBTS Coordinating Committee was established, and the Advisory Committee of the NBTS was disbanded. The National

Directorate was run by the NMC, whose members included Drs Gunson, Ala, Contreras, Fraser, Harrison, Lee, Moore and Wagstaff, and Mr Cosgrove.

609. I have set out that while the National Directorate provided a form of centralised management, it had no executive authority. Thus, for example, at a meeting of the NMC on 5 July 1990 [NHBT0046958_002], a paper from the Provision of Donors Committee on communication strategies in relation to donors was discussed: it was strongly *recommended* that RTCs adopted the paper's proposals.

610. The Directorate did however provide a degree of central management, and in for example orchestrated the provision of blood through inter-regional distribution in order to meet shortfalls.

611. I have seen a copy of Dr Robinson's written statement in response to the request addressing lookback, which comments on the formation of the National Directorate, noting both substantial improvements and that difficulties remained with implementing policy where additional funding was required, since funding still had to be sourced from individual RHAs (Question 10).

612. I have seen the minutes of the NMC's sixth meeting on 2 November 1989 [NHBT0046964_001]. The NMC discussed the introduction of the Management Information System (MIS): an order for computers and software had been placed, and various groups and committees were in action. It was recorded that *"the introduction of the MIS will proceed in stages in line with Regions' ability to complete necessary tasks. It was accepted that the manpower implications of the system may be a problem for some Regions. It remained a firm commitment of the DH Coordinating Committee to introduce the system by April '90."*

613. The NMC also discussed *"whether the existing arrangements for maintaining good communications within RTCs were adequate",* with reference to the ongoing difficulties with provision of service. It was noted that some RTDs held regular meetings with heads of departments, and this was *"commended to all RTDs".* Similarly, in discussion of the use of group 0 Rh positive blood, it was noted that *"members of the Committee undertook to recommend that RTCs should identify disproportionately high users of – Rh positive blood and discuss possibly reductions in the use for patients of other groups".*

614. The minutes also recorded that concerns had been expressed about possible disputes between RTDs and Quality Assurance Managers regarding plasma specification. Guidance on this had been included in the UK BTS/NIBSCC Guidelines, but it was noted that *"if the QA Manager was over-ruled then the RTD may be liable for any defects."*

615. The activities of the Apheresis Working Group, which reported to the NMC, were discussed. The NMC agreed that the Group should advise the National Directorate of areas where national contracts may benefit the BTS. In relation to printing a set of guidelines published by the group, it was *"suggested that if each Region made a small contribution it would be possible to produce around 400 copies for distribution to RTCs and Apheresis Centres".*

616. At the NMC's seventh meeting on 4 January 1990 [NHBT0071870_002], it was recorded that the full MIS system would begin operation in April 1990.

617. It was also recorded that the NMC had considered the first draft of the National Directorate's report for *"the accountability review to be held on 24th January 1990".* Among other things, the NMC felt that there was a need to stress that the BTS was *"not merely a collecting and issuing service but one which has a considerable input to clinical medicine",* including through *"providing advice on and solving*

haematological problems; and the ongoing work in establishing Hospital Transfusion Committees fostering good practices and reducing morbidity". The NMC further agreed that the future of the NBTS would be discussed more fully later in the year.

618. The activities of the NBTS/CBLA Liaison Committee were discussed and it was recorded that:

"11.8 The National Directorate and the CBLA had agreed to prepare a joint paper for Regional General Managers and Regional Treasurers on cross-accounting, reviewing the options for appropriate budget holders and the preferred supply channels for BPL products to maximise their uptake in the NHS.

The CBLA chose to ignore the advice of the National Directorate and proceeded to issue a letter to RGMs and Treasurers without agreeing its contents with the Directorate.

The Directorate has, therefore, disassociated itself entirely from this document and finds this level of 'co-operation' increasingly difficult."

619. The minutes further record the Eastern Division's agreement that the National Directorate should set a standard price for red cells.

620. At the NMC's eighth meeting on 1 March 1990 [NHBT0071867_001], Dr Wagstaff's paper on Medical Audit in the NBTS was welcomed. It was agreed that the paper should be reviewed by Divisions and SNBTS: a set of detailed proposals would then be put forward. Following publication Dr Gunson would write to RMOs concerning the establishment of Transfusion Committees.

621. It was also noted that Dr Moore had prepared a draft statement on NBTS Quality Policy, which would shortly be the subject of consultation with Divisions and QA Managers. There was an

accompanying proposal to establish a special Sub-Committee of the National Directorate to implement the quality assurance strategy.

622. The activities of the NBTS/CBLA Liaison Committee were reported, including that *"Following the discussion concerning distribution of the BPL products, proposals have been put forward for a national agreement with respect to purchase of plasma and products. Replies from RTCs were not yet complete and a decision based on these would have to be taken within the next few days. This will be communicated to RTDs."*

623. I have been provided with the minutes from a special meeting of the NMC on 9 April 1990 [NHBT0071867_001]. The NMC discussed options for managing budget devolution to the Districts, agreeing that a contractual arrangement for the supply of blood products to Districts would be most appropriate, and that this might with advantage be called a Service Agreement. The Financial Sub-Group was to consider the formulation of the Service Agreements, and it was recorded that *"assistance should also be obtained from DH on the nature and philosophy of contractual arrangements so that these could be presented to Treasurers in a form which would prove acceptable."*

624. The leaflet for donors was also discussed and it was recorded that *"the DH would be asked to fund the printing of the leaflet and also postage costs for a single drop so that the leaflet could be widely distributed in as short a period as possible".*

625. I have seen the minutes from the NMC's tenth meeting on 5 July 1990 [NHBT0046958_002]. The NMC considered a summary paper on the NBTS medical audit, which included a draft bid for funds from the DH amounting to £150,000. If successful, the funds were to be managed by the National Directorate.

626. An update on the MIS was given, setting out its phased introduction, and that all Regions had made some data returns on blood and products, although several Regions had not provided sufficient data to make the national summaries meaningful. It was recorded that *"Regions are urged to do their utmost to provide the information necessary to realise the full potential of MIS."*

627. Communications between the National Directorate and RTCs were discussed, and it was recorded that *"the recent proposals concerning improving communications within the NBTS had been discussed at Divisions and whilst accepting the need for better communications it was felt the arrangements for consultation could best be left to RTCs."* It was agreed that RTDs should circulate the NMC agenda and appropriate papers to their staff.

628. The NMC considered a draft proposal from the Directorate to the DH for the national management of the NBTS. It was noted that:

"The primary aim of the paper was to gain approval in principle to national management. A financial and implementation strategy would need to follow that approval.

There was lively discussion with a substantial majority in favour of the proposal.

It was agreed that the paper would be circulated to RTDs for their personal comments on 1) the principle of national management and 2) the paper itself."

629. Budget devolution was further discussed, including that a specimen service agreement would be produced and that *"there is considerable advantage in a common approach".* The Eastern Division's opposition to devolution was recorded.

630. Further dissatisfaction was recorded with the CBLA's approach to communication on the NBTS/CBLA Liaison Committee, in particular the CBLA's short notice announcement that they would not pay for anti-CMV (anti-cytomegalovirus) plasma from July 1990. It was noted that affected RTDs would need to consider this matter and would be asked to advise the Directorate accordingly.

631. I have been provided with the minutes of the NMC's eleventh meeting on 3 September 1990 [NHBT0071715] and note the following:
    a. The notes detail a bid to DH for medical audit funding.
    b. A paper was sent to DH from NBTS concerning NBTS's organisational structure, and a "*view from the DH on whether the proposal merits further work is anticipated within three months.*"
    c. The paper also shows that NBTS was liaising with DH regarding the provision of red cells for NEQAS, with DH "*notifying participants of the new arrangements*" and arrangements for NBTS to liaise with RTDs to coordinate the *"provision of serum, plasma and red cells for NEQAS exercises"*.
    d. The Directorate also proposed to DH that "*plasma prices in 1991/92 should be increased in line with inflation. However, it was noted that CBLA had been instructed by DH to use 1990 prices for the purposes of their budget estimates for 1991/92".*

632. I have been provided with the minutes of the NMC's twelfth meeting on 25 October 1990 [NHBT0071860_002]. The meeting minutes detail a response from Dr D. Macpherson of the DH, in response to the Directorate's request for funding for medical audit. While the letter acknowledged the worthwhile and comprehensive nature of the proposals, it stated that "*central support could only be given for costs incurred in the national audit exercise".* RTCs were advised to bid for RHAs for support. The minutes also record that Dr Gunson updated the NMC that the proposal for National Management of the NBTS had met resistance within DH.

633. I have been provided with the minutes of the NMC's thirteenth meeting on 1 February 1991 [WITN1567014 NHBT0071804]. The NMC:

a. Sought to make progress in the introduction of medical audit in the NBTS on the basis that eight regions did not have a regional transfusion committee.
b. Noted that funding of this additional layer of audit would come from the Minister of Health on the basis that "*a further £47 million had been allocated for the introduction of medical audit and RTDs could bid to their RHAs for some of these funds".*

634. In the meeting, members received an update on their request for anti-HCV testing, despite DH's recognition that "*devolved budgets as presently allocated will not cover increased costs".* DH's proposed approach was for Managers to find money from other budgets by prioritization. This approach caused concern at the Committee.

635. I have been provided with minutes of the NMC's fifteenth meeting on 16 January 1992 [NHBT0071673]. The notes contain an update on the reorganization and management of the NBTS – reporting consensus at the RTD meeting that a "*National Blood Authority would establish contractual arrangements with RTCs for cellular components of blood and plasma".* These views were to be forwarded to DH, and a meeting was scheduled for 8 July 1991.

636. I have been provided with minutes of the NMC's sixteenth meeting on 2 September 1991 [NHBT0071771]. The notes detail that the revised version of the AIDS leaflet "*has been criticized by representatives of the Commission for Racial Equality at a recent DH meeting."* Actions were taken to adjust the meeting minutes. The meeting also detailed that "*DH have provided a clarification to EL(91)78, which they say was intended to maintain the status quo as regards blood supplied for MOD hospitals."*

637. I have been provided with minutes of the NMC's seventeenth meeting on 2 September 1991 [NHBT0046751]. Further revisions were made to the AIDS leaflet and the EAGA was to decide on the amendments on 10 December 1991. DH was asked to reach a national agreement with the Commission for Racial Equality.

638. I have been provided with minutes of the NMC's eighteenth meeting on 30 October 1991 [NHBT0097469_014]. The minutes detail further revisions of the AIDS leaflet on the basis of Guidelines from the European Commission. They also contain updates from the NBTS/CBLA Liaison Committee, including that *"BPL has requested DH for extra funds to cover the payment of distribution costs incurred by RTCs distributing BPL's products".* DH updated that RTCs which had distributed these products for some time were already funded for this activity.

639. I have been provided with minutes of the NMC's nineteenth meeting on 2 April 1992 [NHBT0097468_003]. The meeting records that the central publicity budget for 1992/93 has been cut by a third by DH to £700,000 and stated that "*strenuous efforts are being made to reverse this decision"*.

640. I have been provided with the Notes of a Special Meeting of the NMC on 30 September 1991 [NHBT0001877]. This note considered the formation of the NBA, provided details of the proposed NBA, and contained a wide-ranging discussion. Relevant issues concerning the oversight of the RTCs included an item discussing the reduction in the number of RTCs, and a requirement for all RTCs to consult users on the proposed changes.

641. I have seen the notes of the 3rd meeting of the NBTS/SNBTS Liaison Committee on 7 January 1991 [PRSE0001721]. The notes show that NBTS/SNBTS were awaiting a decision from DH on the implementation and funding of the Anti-HCV test, and that

NBTS/SNBTS communicated that "*it will be important for RTCs to start testing on an agreed date."* The notes also show that DH agreed changes in charges to the private sector, leading RTCs to enter into "*service agreements with private hospitals in their catchment area in the same way as the NHS hospitals".* Finally, the notes show that NBTS liaised with the Medicines Control Agency (the regulator for blood components) on how to apply for a Manufacturer's Licence (Specials).

642. I have been provided with minutes from the twentieth meeting of the NMC on 7 September 1992 [NHBT0071601_001]. It was recorded that Dr Gunson was to chair a multi-disciplinary group to study the methodology of donor selection, as *"Members agreed that this was an important QA challenge for the NBTS".* In relation to HBV vaccination of staff, it was noted that *"present National Directorate policy has been that RTCs should follow RHA policy".* The minutes also record that a DH paper had been sent to all RTDs which set out the Department's plans for a new Special Health Authority, the NBA, to directly manage the RTCs and BPL. The National Directorate was accordingly to be dissolved from 31 December 1992.

643. I have been provided with the minutes of the NMC's twenty-first meeting on 3 December 1992 [NHBT0017528]. These recorded that a Working Party had now been formed to create the NBA. The minutes also record a statement by Dr Lee that a study of hepatitis B core antibody (anti-HBc) testing should be carried out and coordinated by the National Directorate. Dr Gunson replied that a study was being undertaken by Glasgow and Cambridge RTCs and the results were awaited. The minutes also record Dr Entwistle's concern about North London RTC being allowed to supply Whittington Hospital, to which Dr Gunson replied that *"he had tried to have this arrangement halted for the coming year but, since it had been agreed by both NW and NE Thames RHAs and by the DH there was little he could do".* At the end of the meeting, the NMC was dissolved.

The Establishment of the NBA

644. The NBA was established in 1993 by Statutory Instrument 587 of 1993, at which point it was responsible for the CBLA. As amended by SI 589 of 1994, it assumed responsibility for the RTCs from the individual RHAs: thus, the two SIs provided for the creation of a single national service. This transition was completed in April 2000. The remit of the NBA is set out in detail in the *NHSBT Family Tree* provided as an exhibit in section 1.

645. Dr Gunson continued in post as the National Director of the blood transfusion service, until replaced by Dr Robinson in May 1994. Dr Robinson notes that she sat on various decision-making committees, including MSBT - formerly ACVSB.

25. Does NHSBT report to or advise government departments in respect of its responsibilities or functions? If so, please provide details. Are such reports and/or advice provided on a regular basis or are they provided on request? What form do these reports and/or advice take?

646. Those answers I cite as relevant to question 23 are also relevant here and I do not propose to repeat that information.

647. As with the previous answer, the detail of the current relationship with the DHSC has been provided by staff in NHSBT's governance department. Any information about the historic position is obtained by review of documents which have been provided by those advising me.

Current

648. I have set out in detail in my answers to Questions 23 and 24 the processes which are currently in place for NHSBT to report to the Department of Health and the other UK health departments.

649. Beyond the reporting processes delineated in the Framework Agreement, NHSBT will advise and report to DHSC on an *ad hoc* basis, either when the need arises or on request. On both the COVID-19 Convalescent Plasma Project and in setting up the collection and manufacturing of plasma for fractionation, mechanisms have been set up to report to and advise DHSC.

650. NHSBT doctors and scientists are members of governmental advisory committees such as SaBTO either in their capacity as an independent expert or as an expert in a role, e.g. blood services representative. These are detailed in section 9. In this respect, NHSBT does not itself advise government departments but individuals in their roles on an advisory committee may be involved in recommendations from that committee, but this is through a separate process to NHSBT.

651. NHSBT will respond to governmental consultations as a body in response to those which affect us, for example the consultation on Organ Donation Opt-Out or the CQC service provision model consultation this year.

Historic – Introduction

652. Historically, the RTCs and RTDs had no formal or regular reporting or advisory role. On policy and funding matters, for example, their influence was persuasive only, in relation to both the RHAs and the Department of Health. This is underlined by the funding difficulties which RTCs faced in increasing their plasma production to reach self-sufficiency, as I have outlined in Section 8. In relation to funding matters this changed with the establishment of the NBA in 1993, when the service became funded directly by central government.

Historic – the Advisory/Reporting Role of the RTDs

653. I have set out that DHSS officials attended some meetings of the RTDs, facilitating a dialogue between them. However, the documents which I have seen do not suggest that this functioned as a direct

channel by which the RTDs could or would advise central government. Instead, there is evidence that the RTDs would attempt to influence policy through, for example drafting and circulating papers.

654. One example which I set out in Question 18 is a 1974 meeting of the RTDs and HCDs which was attended by a DHSS official. It was agreed at the meeting that one of the HCDs would write to the DHSS, recommending for future planning of Factor VIII a report which suggested a need for 500,000-750,000 donations annually [CBLA0000187]. The DHSS official in attendance stated that she could not confirm how this extra expense would be met. Although it was an HCD Director who was to write the letter, the minutes are indicative that the function of RTD meetings was to enable dialogue and discuss policy proposals, but that the meetings *per se* were not strictly advisory.

Historic – the Consultant Advisor

655. I have set out the importance of the role of Consultant Advisor to the DH, which was filled successively by Drs Maycock, Tovey, and Gunson. Until 1978, Dr Maycock was Consultant Advisor and was also the director of the BPL and the chair of RTD meetings. I have set out his role, in particular in relation to the setting of plasma targets in the 1970s, in my answer to Question 18. Dr Robinson has characterised Dr Gunson's role as Consultant Advisor as *"to seek to encourage uniformity of practice and give advice to the Department."*

Historic – the Advisory Committee

656. The NBTS Advisory Committee, which met on 14 occasions between 1 December 1980 and 8 February 1988, was composed of both RTDs and DHSS officials. Its members and observers included attendees from the three other UK Health Departments ([BPLL0004826] (pp.10-12)). It established committees including the Working Group on AIDS. The membership was broadly from the English service but included Dr DBL McClelland as an observer [CBLA0001934_002].

657. I have been provided with the minutes from the first meeting of the Advisory Committee on 1 December 1980 [CBLA0001207]. These meetings were chaired by Dr Harris of the DHSS. I have already set these out above, but the committee's terms of reference bear repeating here:

"To advise DHSS and the Welsh Office on the co-ordination of:-
i. The development and work of Regional Transfusion Centres and the Central Blood Laboratories in England and Wales,
ii. and as necessary – the English and Welsh Blood Transfusion Service with that of Scotland."

658. DHSS had suggested that this be amended to state *"and Northern Ireland";* the minutes also record that the Committee may want to reconsider retaining the inclusion of *"as necessary".*

659. The minutes recorded that *"the reasons for setting up this new Committee are set out in paper AC(80) 1. Part III of this paper gives an indication of some of the matters on which the Committee's advice may be sought. This list is not exhaustive and suggestions from members will be welcome".* The two key issues for discussion at the first meeting were increasing plasma supply, and pro-rata distribution of blood products. The issue of ensuring sufficient blood supply occupied the Advisory Committee to a considerable extent: I have addressed these aspects of the committee's discussions and activities in my answers to Section 8.

660. It was noted later in the minutes of the first meeting that the Committee itself could not advise RHAs, this not being within its terms of reference. This was noted in relation to the recommendation in Dr Tovey's paper AC(81)2 that the purchase and distribution of blood products should be restricted to the remit of RTCs only (rather than commercial suppliers). The minutes therefore recorded that *"Dr Tovey*

to be asked to outline the advantages of restricting the purchase and distribution of blood products to RTCs".

661. In the minutes of the second meeting on 23 February 1981 [CBLA0001287], it was recorded that the Advisory Committee were to decide whether paper AC(81)2 should be put to RMOs, RTs and Regional Supplies Officers *"for discussion".* It was also recorded that in line with the committee's suggestion, a letter setting out the scale of plasma increase required had been sent to Regional Administrators, presumably by DHSS. It was also recorded that Paper AC(81) 3 [CBLA0001294] set out the issues on which the DHSS sought the Committee's advice in relation to the pro rata distribution of certain blood products.

662. The long-term management of the Central Blood Laboratories was discussed, and it was recorded that *"Now that Ministers had decided against commercial management of BPL, other long-term solutions were being considered. The Chairman outlined in confidence some of the options which would be put to Ministers."* Members were invited to write to the Chairman (Dr Harris) with their views.

663. In the minutes of the third meeting on 22 June 1981 [CBLA0001388], it was recorded that Lorne Laboratories had put forward a proposal for a collaborative venture with the NBTS, AC(81)12. The Chairman is recorded as stating that *"the Committee's advice would be an important factor in Ministers' consideration of the proposal".* Members then express a variety of views. In the minutes of the fourth meeting on 28 September 1981 [CBLA0001457], it is recorded that *"Ministers had accepted the advice of the Advisory Committee that the Service should collaborate with Lorne Laboratories on the provision of surplus red cells, and with the British pharmaceutical company on the provision of hepatitis carrying plasma".* It was agreed that if further requests for surplus products were received from other industrial firms, the Department would consult the committee *"where necessary".*

664. Also at the fourth meeting, the Chairman sought the Committee's views on how charges which the Department was considering introducing for the private sector should be calculated.

665. In the fifth meeting of the committee on 31 March 1982 [DHSC0001136], Mr Godfrey of DHSS stated that DHSS Finance Division was seeking the Committee's views on the principle and practicalities of charging for CBL products and intra-regional charging by transfusion centres. Members were equivocal on the benefits and disbenefits of charging for CBL products and doubted the benefits and practicalities of intra-regional charging, but Mr Layzell offered to consult District Treasurers and report back. At the sixth meeting on 15 September 1982 [C], Mr Layzell reported a mixed response, with few treasurers expressing strong feelings either way: the Advisory Committee concluded that *"the time was not yet right for the introduction of a scheme which could present considerable practical problems and that further consideration should be postponed".*

666. At the sixth meeting of the Advisory Committee on 15 September 1982 [CBLA0001621], the Committee agreed to expand its terms of reference to include coordination with the CBLA. The minutes also record the MRC's recent decision to wind up the NBTS Research Committee, *"despite advice to the contrary".* It was recorded that *"RTDs were discussing options for stimulating and co-ordinating NBTS research."* Dr Gunson proposed to present a paper at the next meeting outlining options for a new advisory body to take over this role, which was to be *"purely advisory".* At the seventh meeting of the Advisory Committee on 10 January 1983 [BPLL0007254_001], it was recorded that the CBLA would consider whether this research committee could be broadened to cover this remit, and that Dr Gunson was to report back.

667. At the seventh meeting, it was also recorded that the Exchequer and Audit Department had concluded their report to the DHSS on the blood transfusion field, in particular the redevelopment of BPL. Mr Godfrey stated that the *"brevity"* of the report was *"in itself a compliment to the NBTS".*

668. The eighth and ninth meetings of the Advisory Committee, on 17 October 1983 and 10 April 1984 [CBLA0001763], [CBLA0001835] discuss the AIDS leaflet produced by the Department in conjunction with the RTDs. I have addressed the production and revision of this leaflet in great detail in Section 9 and do not intend to replicate that detail here.

669. At the Advisory Committee's tenth meeting on 8 November 1984 [PRSE0004783], it was noted that the Committee had established a new working group on AIDS, whose terms of reference were *"to consider the implications for the NBTS of testing blood donations for antibody to HTLV III and to report."* I have set out in Section 9 the terms of the paper which this Working Group received from their Chairman, Dr Abrams of the DHSS, in advance of their first meeting, setting out the issues on which their views were sought.

670. Also at the tenth meeting of the Advisory Committee, the recent blood shortages set out in AC(84)12 were discussed. In response, it was recorded that *"the Committee advised closer liaison between RTCs."*

671. It was also recorded that the CMO of Scotland considered there was a need for a research committee to advise the UK, rather than England and Wales. It was recorded that present MRC and CBLA committees on BTS services *"lacked the necessary formal constitutions",* and that Scottish and NI representatives had agreed that the matter should be discussed between the respective Departments.

672. The last three meetings of the Advisory Committee discussed the establishment of the National Directorate: I have addressed this in my answer to the previous question.

The Advisory Role of the National Directorate

673. Within the National Directorate of the NBTS was the *UKACTTD*. This was chaired by Dr Wagstaff with members including Drs Gunson, Barbara, Cash, Follett, Mitchell and Mortimer and Mr Cosgrove.

674. I have been provided with the minutes from a meeting of the UKACTTD on 19 May 1989 [NHBT000088_001]. The Committee discussed HTLV1 testing. The National Director (Dr Gunson) was to "*approach the Minister of Health and advise him of the urgent need to organise the Blood Transfusion Service's response to the problems of evaluating commercial tests; confirmatory tests; quality control support; and research and development.*"

675. The activities of the UKACTTD were referred to by Dr Gunson in the sixth meeting of the NMC on 2 November 1989 [NHBT0046964_001]. Dr Gunson informed the NMC that: *"the Advisory Committee [UKACTTD] was advising DH that the HTLV I trial involving 200,000 donors should go ahead as soon as possible. It seemed unlikely, however, that the study would be anonymous as previously envisaged."*

676. Later, the UKACTTD became SACTTI.

677. As set out in the written statement of Dr Angela Robinson, there was also the Department of Health Advisory Committee on the Virological Safety of Blood, ACVSB, on which Dr Gunson was the blood service representative. The ACVSB first met on 4 April 1989. It was later renamed MSBT.

678. The ACVSB was set up to advise the four UK health departments on, among other things, the screening of blood donations for NANBH. A fuller account of its activities can be found in Dr Robinson's written statement.

Section 6: Relationship of NHSBT to laboratories

26. Please outline the laboratories currently engaged in manufacturing blood products for England (and, where relevant, Wales) from plasma procured by NHSBT.

Summary

679. I preface my answer to this section with a comment that the nature of the question is not clear to me. It appears to relate to laboratories that are involved in the manufacture of blood products (such as BPL eg a fractionator). However, there are many laboratories involved in the manufacture of blood components and blood products. I have included them all in my answer below for the avoidance of doubt.

680. In relation to laboratories (or fractionators) that manufacture blood products today I have addressed, in my answer to question 39, the fact that plasma collection only recently started again this year and that a fractionator is not yet appointed.

681. I would say though that with respect to laboratories more generally involved in the collection and provision of plasma to fractionators (once appointed), the same laboratories are involved as are used in the manufacture of blood components.

682. At the outset, it is worthwhile defining my use of the terms blood components and blood products; these have been used in inconsistent ways over the years and I have tried to be consistent in how I refer to these throughout this statement. I use the term 'blood components' to mean those components of donated blood that are prepared in the blood transfusion centre directly from donations of whole blood,

apheresis platelets or apheresis plasma. These include red cells, platelets, FFP, cryoprecipitate, granulocytes and occasionally whole blood itself. 'Blood products' are medicinal products derived from plasma derived either from a donation directly (such as plasma collected by apheresis) or from a component of a blood donation (such as plasma not required for FFP from a whole blood donation) and that are treated or manufactured to make a substantially different product, these are also sometimes referred to as 'plasma derivatives'. They are treated as medicines and have different regulatory requirements in the current day. Blood products include albumin, coagulation factors, fibrinogen concentrate and immunoglobins. This latter includes both normal immunoglobulins such as IVIG and hyperimmune (or specific) immunoglobulins such as those against tetanus, CMV, chickenpox or varicella-zoster, rabies and other pathogens. Additionally, they include antibodies such as those again the red cell RhD antigen used to prevent babies of pregnant women getting haemolytic disease of the fetus and newborn. These specific immunoglobulins are manufactured from plasma collected from immunised donors.

Current

683. NHSBT has only recently started collecting plasma for blood products again in 2021. I describe the processes and laboratories that are involved with manufacturing and testing blood components in general, as the processes as currently implemented for plasma are the same as for blood components. Some of these are not used for plasma donors and products but are included here for completeness. Also, some additional tests will also be required for plasma donations destined for fractionation and this is set out below.

NHSBT Manufacturing and Testing Sites

684. Following donation, whole blood, apheresis platelets and apheresis plasma are transported to one of the three NHSBT manufacturing sites (Manchester, Filton and Colindale) for processing into specific

components, red cells, pooled platelets, platelets collected by apheresis, FFP and cryoprecipitate. Plasma destined for fractionation is frozen and stored as we do not yet have a fractionator appointed.

685. Associated blood samples from each donation are sent to one of our two testing sites in Filton or Manchester where high throughput screening is carried out for primary blood grouping, and microbiology screening using both molecular and serology tests. Any donations found to be repeat reactive for markers of infection either using serology or molecular tests are removed from the inventory, a hold placed on the donor and remaining samples subjected to further microbiological testing at the Microbiology Services Laboratory in Colindale. In addition, all platelet donations will undergo bacterial screening as part of the manufacturing process.

Histocompatibility and Immunogenetics Laboratories

686. There are six laboratories in the H&I Function located at NHSBT Birmingham, Filton, Colindale, Tooting, Newcastle and Barnsley. The laboratories perform testing of patients and donors to support platelet transfusion, COVID-19 convalescent plasma collection, stem cell and solid organ transplantation and immunogenetic testing for disease association and drug hypersensitivity referrals. The H&I laboratory at Filton also provides specialist platelet immunology and granulocyte immunology services nationally. The H&I laboratory at Colindale carries out high throughput HLA (human leukocyte antigen) typing of apheresis platelet donors, NHSBT blood donors who have volunteered to join the BBMR stem cell donor registry and donated cord blood units collected by the NHS Cord Blood Bank (NHS-CBB). The H&I function supports the provision of HLA and HPA (human platelet antigens) selected platelets for patients who are immunologically refractory to random platelet transfusion by providing HLA and HPA testing of patients and donors and identifying suitable matched platelets for individual patients.

Laboratories involved in microbiological testing of donations

Microbiology Services Laboratory (MSL).

687. MSL carries out confirmatory testing on donations found to be repeat reactive on screening including tests for HIV, hepatitis B, C and E, HTLV, syphilis, West Nile Virus, Malaria and Treponemal (syphilis) antibodies. Any initial reactive bacterial screening samples are also sent to MSL for further culture and identification of bacteria where culture is positive. Sometimes, additional reference tests will be sourced from external laboratories in cases where it is proving difficult to interpret the test results or where the testing is not available in-house. External laboratories such as the Public Health England (PHE) laboratories may be used for investigation of potential transfusion transmitted infections where additional genotyping is required.

688. Plasma sent for fractionation will also need hepatitis A and parvovirus B19 testing. This will be agreed as part of the process of agreeing a fractionator. Currently NHSBT has frozen samples to facilitate this testing which will be done either by the fractionator, a third-party laboratory or NHSBT itself in future.

External laboratories and viral testing

689. We occasionally use various other external laboratories for viral testing and genotyping that goes beyond our routine screening or tests. This is usually for more specialised additional testing to resolve a specific case for example in the investigation of a potential transfusion transmitted infection:

- HIV, HCV, HEV (hepatitis e virus) and HIV avidity testing is done at PHE Colindale.
- Tropical virus screening tests for West Nile Virus antibody, and other tropical viruses (RNA and antibody) is carried out at PHE Porton Down.
- Malaria DNA and T. cruzi PCR is carried out at the London School of Hygiene and Tropical Medicine.

- Previously convalescent plasma donor testing for SARS-CoV-2 antibody undertaken at PHE Porton Down.
- SARS-CoV-2 neutralising Ab and SARS-CoV-2 RNA testing is undertaken at PHE Colindale.
- HTLV proviral DNA testing is carried out at the National Centre for Human Retrovirology (Imperial College Healthcare NHS Trust).
- Where required, EBV DNA, HIV pv DNA and Parvo B19 is carried out by the commercial company Micropathology.
- Where necessary mutual aid is provided by the SNBTS laboratory.

External laboratories and bacterial testing

690. This is provided as requested by our specialist scientists and microbiology consultants and again is not for routinely used tests but for investigation in specific cases; specifically bacterial 16S rRNA gene detection sequencing; pan-fungal 18S DNA gene detection and sequencing. Identification and susceptibility testing of organisms is carried out by a range of laboratories including:
    - Bacterial / yeast identification and MIC (minimum inhibitory concentration) testing at the John Radcliffe Hospital laboratory.
    - Identification and susceptibility testing of organisms , identification and MIC testing of anaerobic organisms by the Anaerobe Reference Laboratory, Cardiff.
    - Identification, typing and susceptibility testing of organisms bacterial / yeast / fungal identification and MIC testing and typing of specific bacteria (mainly *Staphylococcus aureus*) is carried out at the Antimicrobial Resistance and Healthcare Associated Infections Reference Unit (AMRHAI), Public Health England, Colindale.
    - Identification and susceptibility testing of organisms including MIC testing of fungal (including yeasts) is performed at the Mycology Reference Laboratory, Bristol.
    - Identification, typing and susceptibility testing of organisms and C testing and typing of gastrointestinal bacterial isolates is performed at Gastrointestinal Bacteria Reference Unit (GBRU) and similarly for respiratory bacterial isolates by Respiratory and Vaccine

Preventable Bacteria Reference Unit (RVPBRU), both PHE Colindale.

- Exclusion of Brucella species from cultures samples is performed at Animal and Plant Health Agency.
- Identification of Mycobacterium species performed at National Mycobacterial Reference Service South at PHE.

Public Health England

691. This body, soon to transition into the UK Health Security Agency (UKHSA), has a wide public health remit both at a local and national level. There are various laboratories **('PHLs')** around the country based within large NHS Trusts where specialist clinical departments require specialist, and often dedicated, medical microbiology support. PHLs provide:

- specialist advice and support, particularly for the investigation of outbreaks and incidents
- specialist referred tests - tests not performed in all laboratories, but which do not necessarily have to be sent to a reference laboratory (such as viral culture, other virology, mycology and serology tests, particularly if low volume)
- molecular diagnostic tests that are not widely available in other laboratories, such as nucleic acid amplification tests for HIV and hepatitis C
- emergency response to bioterrorist incidents, natural outbreaks, and serious epidemics, such as SARS and H5N1 influenza
- research and development - Public Health England's public health laboratories are at the forefront of research and development in medical microbiology and molecular diagnostics, providing our service partners with direct 'real-time' access to technological improvements and advancements
- additional work (identification or typing) where not done by a reference laboratory

- in addition, in its current form PHE has a range of specialist reference laboratories mainly based on the Colindale site but with specialist expertise e.g. tropical infections, based at other sites such as Porton Down. As already discussed NHSBT may request specialist typing and identification work from PHE but currently also supports a blood safety package of work within the Blood Borne Virus Unit at PHE.

692. From time-to-time NHSBT does have other relationships with laboratories and pharmaceuticals for example supplying or being supplied with products and services from PHE, the MHRA department National Institute of Biological Standards and Controls **('NIBSC')**, NHS England, reagent and biochemical assay producers as well as collaboration in research and development. Through our NCI route (addressed more in section 7) we provide samples to NIBSC as starter material for controls.

Other laboratories involved in specialist donation testing

693. These include the Biochemistry Department at the University Hospitals Birmingham NHS Foundation Trust which undertakes Total Protein Plasma testing for monitoring of donors who donate platelets and/or plasma. HbS (Sickle) testing is undertaken at University Hospitals Birmingham NHS Foundation Trust.

Other Laboratories in NHSBT

Red Cell Immunohaematology (RCI) Laboratories

694. There are seven laboratories providing RCI services at Barnsley, Colindale, Tooting, Filton, Birmingham, Liverpool, and Newcastle. This also includes a Reagents Department based in Liverpool. RCI ensure the safety and clinical efficacy of red cell transfusion therapy. The function also provides diagnostic support for a range of haemolytic conditions affecting fetuses, newborns and adults. RCI laboratories provide reference investigations of samples referred by external diagnostics laboratories for further investigation of serological

problems as well as antenatal screening services to meet the needs of patients and those who treat them. The Reagents Department supplies blood grouping reagents, red cells for ABO/D grouping, screening and identification of antibodies, control reagents and samples for quality assessment exercises for NHSBT in-house use, for sale to the NHS and other external customers. Most blood grouping reagents now supplied within Europe have to be CE marked, and the NHSBT Reagents Unit is accredited to ISO13485 for this purpose.

International Blood Group Reference Laboratory

695. NHSBT coordinates the IBGRL, which provides reference services related to blood transfusion. IBGRL is a designated collaborating centre for the WHO. IBGRL has the NHSBT National Frozen Blood Bank for rare units of blood which are used to fulfil requests of the NHS patients and rare patients abroad. It also:

- provides specialist clinical diagnostic services for NHSBT, providing expertise in red cell reference serology and blood group genotyping, including non-invasive fetal genotyping from maternal blood.
- maintains a database of donors with rare blood types which authorized laboratories can interrogate directly;
- performs research in blood transfusion science;
- generates a range of monoclonal antibodies, recombinant proteins and kits for the estimation of feto-maternal hemorrhage (FMH) which are available to researchers around the world.

The Component Development Laboratory (CDL)

696. This laboratory is part of NHSBT's internationally recognised research and development programme. Based at NHSBT Cambridge, CDL specialises in translational research that changes the way blood is processed, stored or tested. Through this, NHSBT improves the quality, safety and efficiency of the blood supply chain. CDL works with internal groups within NHS Blood and Transplant, as well as

academic and commercial partners. NHSBT collaborates with laboratories based at the Universities of Cambridge, Oxford and Bristol in an ongoing programme of research work relating to stem cells, culture of red blood cells, immunology and HIV biology

Hospital Laboratories

697. NHSBT engages with hospital laboratories to inform its demand forecast and influence hospital ordering behaviours. This is done by utilisation of a network of groups and forums, delivering education, information, communication, audit, support and advice to all transfusion laboratories and transfusion clinical teams. NHSBT Customer Service teams (including Patient Blood Management, Hospitals Customer services, Blood Stocks Management Scheme) provide the external facing contact for hospital transfusion teams not only for direct interaction with NHSBT but also to work with the NBTC and the Regional Transfusion Committees to support patient care and ensure blood supply.

698. For the sake of completeness, I shall add reference here to Non-Clinical Issue **("NCI")** by which NHSBT provides, under strict governance protocols, materials unsuitable for clinical use to external organisations for them to undertake a range of activities (eg R&D, education and training, laboratory EQA), some of which is work undertaken in collaboration with NHSBT. NCI is addressed further in section 7.

27. How have NHSBT's relationships with the various laboratories involved in manufacturing blood products for England changed over time? Specifically, please describe, as far as you, are able how NHSBT's relationships with the Bio Products Laboratory (formerly Blood Products Laboratory), Plasma Fractionation Laboratory (Oxford), Central Blood Laboratories Authority, Plasma Fractionation Centre (Scotland) have evolved.

699. The relationship between NHSBT (as it is now) and the locally managed laboratories and how this has changed overtime is dealt with in the *NHSBT Family Tree* provided as an exhibit in section 1. This document is exhibited as part of section 1 of this response. The issue is also commented on in the evidence available to the Inquiry from Dr Gunson, and in particular his report for the HIV litigation [DHSC0000142] and statement for the HCV litigation [NHBT0000025_001]. Considerable detail is provided about the service in *Fifty Years of Blood Transfusion* Volume 6 (1996) of Transfusion Medicine, which has what amounts to a history of the service to that date produced by Dr Gunson and Dr Helen Dodsworth [NHBT0000028]. Extensive history of the laboratories and NHSBT's relationships with them is also set out in Dr Lane's statement [CBLA0000005_002]. This answer has been written relying heavily on these documents.

700. I would like to make clear at the outset that BPL and the SNBTS who themselves are separate core participants will have a much better insight into the workings of their respective organisations, including their formation and history. I only repeat that history insofar as is needed to discuss the English blood service's relationship with those laboratories. The relationship between particularly BPL and the blood service is of importance, and I have commented on it variously in my answers to section 3, section 4 and section 8 (particularly in the context of the relationship between the two institutions concerning the sufficiency of supply of plasma).

701. By the 1960s, various laboratories had been formed and/or become part of the Lister Institute of Preventative Medicine. The laboratories include the BPL, the Plasma Fractionation Laboratory (PFL), the Blood Group Reference Laboratory (BGRL) and a Blood Group Research Unit.

702. I have discussed in section 3 the relationship between BPL and the blood transfusion service in these early years. While they were separate institutions, they were linked by the fact that the Consultant Advisor to the DHSS (Dr Maycock) both headed the Lister Institute (and later was director of BPL) and was chair of the RTD Committee meetings. In 1978 the position changed significantly on the retirement of Dr Maycock and the closure of the Lister Institute on the Elstree site. At that time Dr Tovey headed the RTD Committee meetings as the Consultant Advisor to the DHSS, and Dr Lane became director of BPL. From this point BPL and the BGRL were managed through a Joint Management Committee between the NW Thames Regional Health Authority and the DHSS.

703. Around December 1982, the Central Blood Laboratories Authority was established which took over the running of BPL, BGRL and PFL at Oxford. The CBLA was established by virtue of the CBLA (Establishment and Constitution) Order 1982 and it came into operation on 1 December 1982. It was responsible for the provision of laboratories for the manufacture of blood products and other purposes. This body was its own institution and the relevant top-level committees for the blood service (first the Advisory Committee on the NBTS; then the National Directorate of the NBTS) did not have executive authority over the CBLA. There do appear to have been significant links between the two institutions, however, as Dr Lane and Dr Gunson regularly attended various meetings for both institutions.

704. In 1991, BPL was renamed the Bio Products Laboratory to reflect the internal market in the National Health Service and in 1993 it became part of the National Blood Authority. BPL began cross-charging NHS hospitals for its products and limited competition in the international blood plasma market was permitted. Cross-charging is addressed in section 8 of this response.

705. The NBA was established in 1993 by Statutory Instrument 587 of 1993

(as amended by SI 589 of 1994). These SIs transferred the blood centres from individual RHAs and provided for the creation of a single national service. This transition was completed in April 2000. The functions of the NBA are set out in more detail in the NHSBT Family Tree. Importantly, for the purposes of this question, the following functions were provided for.

a. The provision of laboratories for the manufacture of blood products and for other purposes;

b. Collecting, screening and processing blood and its constituents and supplying blood, plasma and other blood products for the purposes of the health service;

c. The preparation of plasma fractions and other products for therapeutic, diagnostic and other purposes;

d. Research and development in plasma protein fractionation and for other purposes;

e. The manufacture of blood grouping reagents and other related reagents;

f. The supply of products prepared or manufactured for the above purposes of the health service;

706. For Scotland, these processes were undertaken by SNBTS at its specialist unit in Edinburgh, The Scottish Protein Fractionation Centre (PFC), which closed in 2008. I have seen reference to a paper which may be useful on this point although I have not seen the paper itself: *The manufacture of blood plasma products in Scotland: a brief history*, Foster PR, Scott Med J. 2015 Nov 26. I do not propose to set out the history of this institution as its connections with the blood service in England and Wales are relatively limited.

707. From the documents I have seen, I understand that the relationship between NBTS and the Plasma Fractionation Laboratory **('PFC')** was, historically, also relatively limited. The primary time that the relationship appears to have been raised was around the late 1970s and early 1980s, where it was thought that PFC might be able to fractionate some blood for the English and Welsh service.

708. Dr Lane deals with this issue at length in his statement for the HIV litigation [CBLA0000005], and I do not propose to repeat it here as the relationship was more an issue between BPL and PFC rather than the English and Welsh blood service and PFC. Indeed, it would appear from Dr Lane's statement that he was concerned that capacity at PFC would be preferred over expanding the capacity at BPL, and regarded PFC as overestimating their production capacity. It would appear that there were difficulties with the use of a shift pattern to cover 24 hours. In his statement, at para 353, Dr Lane explains that he produced a memorandum with Mr Angilley which marked the eventual dismissal of the option of England and Wales fractionating at PFC. Unfortunately, that paper does not appear to have been available to me.

709. Insofar as it assists to have a timeline, a brief summary of the events between the laboratories and the blood service is the following:

- 1954 - Agreement was reached between the government, MRC and the Lister Institute – BPL was established with funding from the Ministry of Health.

- PFL was the Plasma Fractionation Laboratory opened in 1967 in Oxford at the Churchill Hospital. It was established as BPL's pilot plant and to produce special products for the treatment of rare forms of haemophilia. It closed in 1992.

- 1978 – Lister Institute sold the Elstree site to the government. Running of BPL was transferred to Northwest Thames Regional Health Authority ("NWT") as an interim measure. Dr Lane replaced Dr Maycock to become Director in September 1978 and was responsible for the day to day management of BPL and the Plasma Fractionation Laboratory ("PFL") [CBLA0000005_002]

- 1982 – Central Blood Laboratories Authority (CBLA) created. CBLA administered BPL, PFL, Biomedical Services and IBGRL for approximately ten years.

- PFL developed the first heat treatment process for factors VIII and IX in the mid-1980s.

- Blood Product Laboratory Diagnostics (**'BPLD**') was set up in 1986. Its aim was to provide a service for blood grouping tests for the identification of correct blood groups of donors and patients and diagnostic units such a screening cells for various blood centres and hospitals. It closed in 1995 and operations were transferred to different centres.

- In 1990, following the establishment of the internal market within the NHS, BPL changed its name to Bio-Products Laboratory, although the BPL acronym remained. At the same time the government introduced a charging mechanism for BPL products to NHS customers.

- 1993: National Blood Authority (NBA) was formed and took responsibility for the National Blood Service, International Blood Group Reference Laboratory and Bio Products Laboratory ('BPL'), the latter two of which were formerly the Central Blood Laboratories Authority ('CBLA').

- 1998 – BPL began sourcing plasma from the US due to concerns over variant CJD in the UK.

- 2002 – DH formed DCI Biologicals Inc to purchase the US company Life Resources Inc to supply all BPL's plasma.

- 2005: NHS Blood and Transplant was formed, merging NBA and UK Transplant (UKT).

- October 2005 – BPL became an operating division within the new special health authority, NHS Blood and Transplant.

- 2008 - The Scottish Protein Fractionation Centre (PFC) closed.

- 31 December 2010 – BPL was vested into a limited company, Bioproducts Laboratory Ltd and ownership transferred to DHSC with BPL Limited and BCI Biologicals Inc being brought under the same DHSC holding company, Plasma Resources UK Ltd (PRUK).

- 18 July 2013 – Bain Capital bought 80% of PRUK from DHSC and it was renamed subsequently BPL Holdings.

- July 2016 – Bain Capital sold BPL Holdings to Creat – a Chinese company, as did DH.

28. Please outline the arrangements in place, if any, to enable cooperation between NHSBT and the various laboratories involved in manufacturing blood products for England, including any reporting lines or forums established to aid this cooperation.

710. Sections 3, 4 and 8 of my response are very relevant to this question. I do not propose to repeat that evidence, save by adding to it further. Here I provide a short chronology of various forms of cooperation which have existed between the blood transfusion service and the

blood laboratories and provide some selected additional examples of cooperation.

711. It is worth noting that, while the formal links are set out below, there were also a number of BPL (and other laboratories' representatives) on blood service committees, and vice versa. I do not propose to repeat the contents of the 'committees' paper which I considered in my answer to question 6 [BPLL0004826], however various examples are therein provided (particularly for working groups and standing committees).

712. From the documents provided to me, it would appear that the primary arrangements to enable cooperation between the blood service and the laboratories manufacturing blood products were by the various committees. As I noted in my last answer, in the early years of the blood service the primary link appears to have been through the Consultant Advisor to the DHSS being both the head of the Lister Institute/BPL and heading the RTD Committee Meetings.

713. From my reading for section 8 and the drive for higher plasma production in the 1970s, I can see how these arrangements worked. There were the regular meetings of the RTDs headed by Dr Maycock (and attended by the health services of the constituent parts of the UK) and, for a time, there were meetings of the Central Committee of the NBTS. There were also ad hoc meetings between representatives of the blood service and the blood laboratories, and various meetings with UKHCDO and the DHSS. It is worth noting that none of these links between the blood laboratories and the blood service had any formal nature. In sections 3 and 4 I discuss how the RTD Committee meetings had no statutory standing, nor any executive authority in respect of the blood laboratories or even the individual RTCs.

714. As was set out above, in 1978 Dr Lane became director of BPL and the management of the blood laboratories went to the Joint

Management Committee between North West Thames Regional Health Authority. I have been shown a document which provides the membership of the JMC in November 1978 [CBLA0000873]. It should be noted, for the avoidance of doubt, that the North West Thames RTC was not involved in this management committee; it was, instead, senior members of the RHA. Indeed, while the paper I have seen is headed "*National Blood Transfusion Service*", the only NBTS member appears to be Dr Tovey in his role as Consultant Advisor to the DHSS.

715. From 1 December 1982 the management of BPL, PFL and BGRL was vested in the newly created CBLA. Dr Lane reported to the Chief Executive (Mr. Bernard Crowley) and the Chairman (Mr Ronald Wing) of the Central Blood Laboratories Authority ("CBLA"), responsible for the operation and management of BPL and PFL since 1 December 1982 [CBLA0000005_002]. It would appear that both the blood service (through Dr Gunson) and the haemophilia centre directors (through Prof Bloom) were involved in this committee (see e.g. [CBLA0001680]).

716. I have discussed the Advisory Committee on the NBTS in my answer to section 3. Dr Lane for BPL was a member of that committee, and indeed led the single packs working party. I do not propose to repeat the detail of that work here (it is dealt with in s.8), but this was a committee aimed at changing from the use of 5 donation pooled packs to individual packs for better safety and ease of processing at BPL. Dr Lane began advancing this issue in 1978 when he became director, and the relevant kit at BPL appears to have come online and begun working in 1981/1982.

162. Another important committee which provided for communication and interaction between, among other bodies, the blood transfusion service and BPL was the NIBSC/UKBTS Liaison Group. The first meeting of this body was on 18 March 1987 and I have seen the meeting minutes [NHBT0000129_001]. The opening remarks of that

committee provide good detail of the work and cooperation undertaken by it:

The joint Liaison Group had been formed on the initiative of the UK Blood Transfusion Service seeking collaboration with NIBSC to formulate (scientific) guidelines for the standardization and safety of blood and blood products provided by that service. A commendable start to draft Quality assurance specifications had been made by committees within the BTS, chaired by Dr Wagstaff. Collaboration with NIBSC will aid and extend this endeavor with complementary scientific expertise and facilities.

The aims of the Liaison Group included: the formulation of Guidelines for the Manufacture of Biologicals for use in Transfusion Medicine; guidance on in-process control; final specifications for products made at the Blood Products laboratories in Elstree and Edinburgh for national use, and those made at Transfusion Centres for local use; the setting up of biological standard needed for production control or for diagnosis; and identification of topics arising from such work that required research. The proposal for the formation of this Liaison Group and its work, outlined in a letter (24.2.87) from Dr Schild, had been accepted and agreed enthusiastically by the membership listed.

717. While I have no personal knowledge, I understand from the papers that there were sometimes difficulties in the interactions between BPL and the RTCs. A number of these are addressed in my answer to section 8 and question 18. A notable example is the pushing back of plasma targets in 1986 as a result of the delays in the commissioning of the new BPL. To provide a selection of documents on the point, when answering question 40 I was shown the minutes of the Advisory Committee on the NBTS meeting on 17 June 1987 [NHBT0010811]. At that meeting there was a discussion of the setting back of plasma targets (which had been broadly resolved by that point). Dr Fraser commented on how RTDs felt about the situation: "*Dr Fraser said that RTDs had lost credibility because of the delays which had occurred at*

BPL; he thought there would now be more difficulty in obtaining funds from Regions and the future plasma supply would suffer".

718. This issue is made out in some papers that I have been shown from the Wessex RTC. I have seen an annual plan for the RTC for 1987-1988 [WITN0672053]. The plan includes the following comments concerning the slippage in the development of BPL and its plasma needs:

'INTRODUCTION

Our plans for 1986/87 received a major setback when we were informed of substantial slippage in the building programme for the new Blood Products Laboratory (BPL) at Elstree. As a result, the 1986/87 Plan was modified to produce a zero-change year.

The information that we now have suggests that the new plant will start to be commissioned in September/October 1987 and will be generating product in January 1988.

2. 1 There are several factors associated with the transition period leading to national self-sufficiency in blood and blood products which interact to produce problems in planning for both the short and long term. They are discussed below:

2.1.1 The definition of the level of production which represents self-sufficiency. This affects long term planning only; we have a target (9 tonnes of plasma per million population) to work toward over the next three years.

2. 1. 2 The building and commissioning programme for the new BPL. Already having fallen fall behind, it could fall further. Our dilemma is whether:

i) to assume that the new finish date is correct, propose an expensive development in plasma procurement and risk a long delay in reaping the rewards,

ii) delay the expansion until the new plant is fully commissioned and waste the major capital investment in BPL for at least one year, possibly two or,

iii) make a "guesstimate" which allows for the possibility of further delay an intermediate position between i) and ii) above.

It also explains the logistics and costs of increasing production to meet the increased targets eg:

2.3 Costs of Increasing Plasma Collection

Following the preferred option would result in a total plasma harvest for 1987/88 of 15410kg, made up of 6095kg in the period April-September 1987 and 9315kg October 1987-March 1988.

The change occurring from October 1987 is a 52% increase and can best be achieved by increasing the number of donations from which plasma is removed by 11000 in the half year. It will be necessary to collect these donations in multiple packs instead of single packs and the processing, which is labour-intensive, will involve staffing increases.'

719. In January 1989, the Central Blood Laboratories Authority ("CBLA")/NBTS Liaison Committee was set up to coordinate issues between the two bodies, including in relation to the plasma supply. CBLA reported to the Department of Health and to its Chairman Ron Wing and the NBTS reported to the Department of Health through Dr Gunson. The committee was the only means of having an effective

discussion and attempting to resolve issues between the CBLA / NBTS.

720. As has already been noted, in 1993 the blood laboratories were brought into the NBA. The following year the RTCs were also brought within the NBA. As bodies within the same institution, it would appear that the relationship was easier to manage; communication was easier; and, the executive control of the senior leadership of the NBA over both sets of bodies led to significant progress.

721. I would note, in passing, the parallel between the lack of executive authority that the senior leadership of the blood service had over its RTCs in the 1970s and 1980s, and the comparative lack of an executive authority over the blood service and the blood laboratories so as to ensure coordination and effective working practices between the institutions. It appears to me from the documents that I have read that the creation of the NBA and introduction of that executive authority over the blood services and laboratories was significant and effective from the perspective of coordination.

722. In my answers elsewhere I have focused on the cooperation between the laboratories and the top-level committees of the blood transfusion service. Below, I have now taken selected examples of cooperation and difficulty at the more individualized RTC level to provide further background information and historical context.

723. I have been provided with the minutes of a south east regional group meeting on 18 June 1980 [NHBT0108584_002]. At that meeting, there was a discussion about supply of Factor VIII and proportional provision of blood products.

'*Factor VIII supplies: Dr. Brookes and Dr. Williams commented that it is not clear when RTCs will be getting normal supplies of Factor VIII.*

Tooting did not get the normal quota in April. Dr. Davies added that the same applied to Edgware….

Dr. Rogers commented that Dr. Lane might be saying fairly quickly that he only wants FFP. Dr. Brookes is worried about a policy of not using time-expired plasma as this would bring problems with our staff and donors. Several members of the group agreed with Dr. Brookes….

PROPORTIONAL DISTRIBUTION OF BLOOD PRODUCTS: RTD(80)8 Dr. Rogers said that if Blood Products Laboratory are going to go ahead with this proposition, they should be more accountable. RTDs have not seen any updating on this subject on paper. We ought to stop the allocation of separate supplies to special departments from BPL. He added that Tooting is not getting a fair share of blood products. He is in favour of proportional distribution although it works to his disadvantage. The paper is not explicit enough, it does not tell us where the difficulties are going to be and how Dr. Lane is going to become accountable. Dr. Blagdon expressed that he is in principle in favour of proportional distribution. He added that Dr. Kernoff's prediction about the needs of Factor VIII is in the region of 13,000,000 units per year. Dr. Brookes commented on the fact that there are several specialised Centres and departments with large numbers of patients coming from abroad. The general opinion was that document RTD(80)8 does not give us sufficient detailed information in order to make a judgement. Figures are needed.

724. I have also been provided with the minutes of the eastern division consultants meeting for 5 July 1984 [NHBT0108586_002]. This is a clear example of the direct communication between the more regional aspects of the blood transfusion service and the CBLA/Dr Lane. In the minutes it is recorded:

3. D.D.A.V.P. - possibility of pilot study Dr. Contreras suggested a pilot study on Factor VIII yield following D.D.A.V.P. inhalation to be

conducted at a few Plasmapheresis Clinics. The meeting was in favour and it was suggested that Dr. Contreras should write to CBLA, with a copy to Dr. Lane, to ensure that BPL would be involved in providing Factor VIII yield data.

725. A significant issue in the early 1990s between BPL and the blood transfusion service was the introduction of ALT testing. This came up at a meeting of the eastern division of consultants on 18 January 1990. I have shown the minutes for this meeting [NHBT0118179]:

ALT tested plasma for production of IVIg Dr. Gunson reported that BPL are prepared to receive ALT tested plasma in a staggered fashion, but that all RTCs should comply by 2nd April 1990. Dr. Ouwehand expressed his dismay at BPL's decision to take an American licence requiring ALT testing and pointed out that the country will not be self-sufficient in IVIg from using only source plasma, that the Medicines Commission does not require ALT testing. The meeting strongly endorsed Dr Ouwehand's views and were saddened that a decision had been taken to spend scarce NHS resources on an American licence and testing~ which would have no effect whatsoever on product safety. Dr. Contreras would write to Dr. Lane, on behalf of the Division, to request a valid explanation and a sound financial and scientific justification for the choice of licence with its significant revenue consequences…..

10.2 Western Division It was reported that the Western Division would have appreciated some prior notice of the BPL recall of a batch of Factor 8. Members had been concerned to learn of this problem through the media. Dr. Moore advised the Committee that BPL had not alerted the Directorate of the recall and this matter would be taken up elsewhere'.

726. There are also occasions in the minutes I have been shown where difficulties of communication are expressly referenced, particularly at

the regional (rather than national management) level. I have been shown the minutes of a meeting of the eastern division of consultants held on 12 December 1990 [NHBT0097472_027]:

'8.3. Contracts with BPL 1991/92 There was unanimous dissatisfaction with the lack of communication between the NBTS and BPL and the ever increasing demands of the latter. Specifications were now outdated, since amendments had been introduced which were neither generally made known or being incorporated into a new specification. ….The Division was also of the opinion that BPL has no right, in the absence of a contract, to impose its latest demand for the receipt of Standard Operating Procedures for the release of plasma and was opposed to the continuously changing requirements of BPL. Consequently, it was proposed that a National contract should be negotiated between the NBTS and BPL, precluding deviation from a mutually acceptable specification and terms. Correspondence with colleagues in Europe and the States has confirmed that some of BPL's working practices are more restrictive than those of other fractionators. Negotiations should also include a review of plasma prices; plasmapheresis is difficult to make cost- effective with UK harness prices and a voluntary donor base, whereas a lower price for recovered plasma could be offset by raising the prices of cellular components. North London, with a high throughput of apheresis donors and plasma input, loses money on apheresis, which will be difficult to sustain with devolution. Hence, the Division was in favour of reducing the price of recovered plasma and increasing the price of apheresis plasma in an attempt to make BPL's product prices more competitive and also ensure that future targets for plasma could be met. It was recognised however that this would commit Districts to subsidise self-sufficiency in their purchase of cellular components. The Chairman agreed to write to the National Directorate, DoH and CBLA, on behalf of the Division, expressing the many concerns about BPL. It was also proposed that "Self-sufficiency" should be the topic of the next RTD Annual Meeting'.

727. I have been shown the minutes of a meeting of the eastern division on 6 June 1991 where communication difficulties again arose [NHBT00974763_001]:

'b. It was felt that when revising plasma specifications, BPL should consult with all the suppliers of plasma i.e. the Transfusion Centres, rather than the QUIN Committee.

c. Dr Snape was not able to provide forecasts of BPL's 1992/93 plasma requirements. It was hoped that some forecast would be provided as soon as possible when sales forecasts are available'.

728. Finally, I have been shown the minutes of the BTS executive committee dated 8 March 1993 [NHBT0041418] where a useful suggestion from BPL is raised:

'6.2 BPL Products Dr. Williamson reported on a suggestion raised by a BPL representative of the possibility of a joint purchasing agreement with North East Thames, which could result in lower prices for BPL products. It was agreed that this should be pursued if possible. Dr. Williamson undertook to write to Dr. Robin Thorpe at NIBSC re the source of plasma in some commercial fractionated products'.

729. From reading the papers and reading my answer here with that of section 8 and question 18, I think that it is important to get an understanding not only of how the leadership of the blood service cooperated with the laboratories, but also the individual RTCs and regional groups. I have tried to give a snapshot of this with the small number of documents I have considered here.

Section 7: Relationship of NHSBT to pharmaceutical companies

730.

731. For my answers in this section, I am providing information about NHSBT and its predecessors. Until they became part of the NBA in 1993, the blood laboratories were separate entities from the blood service, and I understand they will be covered by another core participant. In addressing this section on pharmaceutical companies, I have neither the knowledge nor the remit to comment on the blood laboratories and do not do so.

732. In relation to current and recent events, I have limited independent knowledge of the information I have provided here. Instead, I draw on correspondence with those within NHSBT who are currently responsible for relationships with pharmaceutical companies, and I have been shown relevant regulations, guidance, procedures and policies governing the relationship with pharmaceutical companies. I have also been provided with some of the details of NHSBT's contracting with pharmaceutical companies (see, in particular a copy of IBE, [WITN0672054]). As I have discussed elsewhere, I have no first-hand knowledge of the historic position and am working from documents that have been provided to me.

733. Also of general assistance is MPD148/13.1 [WITN0672055] which provides further relevant guidance notes on the procurement process itself.

Summary

734. My responses to the specific questions are below. However, the position generally seems to me to have been that any relationships, whether commercial or non-commercial, between NHSBT and pharmaceutical companies have historically been limited both in number and in scope given that NHSBT and its predecessors have not generally been responsible for the purchase and / or importation of blood products to meet clinical needs, nor for the prescribing of blood products or other medicines. This is largely because NHSBT and its

predecessor organisations did not have a therapeutic relationship with patients and is not responsible for NHS procurement.

735. Thus, historically, the extent of NHSBT's relationship was largely limited to supplies of certain blood components to pharmaceutical companies during the move towards self-sufficiency of blood products in the NHS. Plasma was also supplied to aid the development of testing methodologies, and historically for R&D collaboration. Based on the documents I have seen, any involvement in procuring factor concentrates, and the issuing of these products to hospitals, appears to have been limited to a small number of RTCs in the 1970s and early 1980s.

736. More recently NHSBT has supplied unused parts of blood donations that are either surplus to clinical requirement or unsuitable for therapeutic use to pharmaceutical companies either for R&D or to make into products used in the NHS for diagnostic purposes, through our non-clinical issue (NCI) route. These have a robust governance process around them to ensure their use benefits patients in the NHS by furthering knowledge or provision of a reagent that is used for diagnostic purposes and is thus an appropriate use of materials for both NHSBT and our donors. This has already been referred to in Section 6 above in the answer to Q26, and is expanded upon below in answer to Q29

29. Please explain NHSBT's relationship with any pharmaceutical companies involved in the production, manufacture, sale and/or importation of blood products. Has this changed over time? If so, please provide details.

737. This question concerns NHSBT's relationship with any pharmaceutical companies involved in some way with the production or importation, etc. of blood products. It is important therefore to start by stating that NHSBT and its predecessors have only had limited relationships with

pharmaceutical companies that are involved in the production, manufacture, sale or importation of blood products. Below I have listed a number of instances in which NHSBT appears to have been involved in a direct or indirect relationship with pharmaceutical companies that concerns the production, manufacture, sale and importation of such blood products. By 'indirect' relationships, I mean in this context those where other health service institutions had the direct relationships with pharmaceutical companies but NHSBT has also had some involvement as well. The list of relevant circumstances has been derived from the documents that I have seen following a review of relevant historical and contemporary materials.

738. A list of current NHSBT commercial relationships is attached, Copy of IBE, [WITN0672054] and a description of current commercial relationships is included in the answer to Question 30.

i. Purchase of Concentrates and Plasma

739. In general, from the documents that I have available to me, it would appear that RTCs were not generally involved in the purchase of factor concentrates. However, I have seen a number of documents which indicate that a small number of RTCs were involved in procurement, and issuing of products to hospitals, in the late 1970s and early 1980s.

740. From the late 1960s, it was recognised that Factor VIII and Factor IX were in very short supply and arrangements were made by the then Ministry of Health to obtain these products on a commercial basis [DHSC0100025_062]. Simultaneously, work began to accelerate the completion of the Elstree and Edinburgh laboratories with the ambition of treating the haemophiliac population in England, Wales and Scotland to expedite the domestic manufacture of these fractions. [HCDO0000394_044]. During this period, the ambition was for the blood services to become self-sufficient in supplies, however as a

consequence of insufficient materials produced, there was considerable pressure from practising clinicians for DH to obtain product licences for and negotiate with commercial suppliers. The blood services, in general, were not involved in any such commercial negotiations [OXUH0000662].

741. I have been provided correspondence between Dr Darnborough and Dr Maycock from August 1976 in which RTC provision of commercial concentrates was discussed. The risks of such procurement were clearly stated in a letter from NBTS director J. Darnborough "*I feel it would be quite wrong for the NBTS to have anything to do with the commercial preparations, and I am very surprised to learn that one Centre is acting as a middle-man in this respect."* [CBLA0000410].

742. The response to this suggestion from Dr Maycock in August 1976 presented the argument in favour of some NBTS involvement as follows: that "*I am sure that unless cryoprecipitate NHS Concentrate and commercial concentrate are issued through one organisation, we shall continue to be played off against the other as has indeed happened over the years. I know that a number of voluntary transfusion services take the view that if there is to be any dependence on commercial products the voluntary [sic] the voluntary service should organise the purchase and distribution."*

743. Dr Darnborough conceded in a later response stating: "*I think you have now persuaded me to change my mind and agree that 'dirty' though it is, we should organise the purchase and distribution of any commercial product that may be needed"* [CBLA0000431].

744. I have been shown a report from Dr Lane dated 28 February 1979 which appears to indicate that at least part of the reason for this view was that it was considered to be a necessary requirement for the assessment of the "*actual requirement of factor VIII concentrate"* [CBLA0000917]. As is noted in my answer to section 8, this issue

appears to have arisen alongside the government and blood service push towards self-sufficiency of the blood supply and the varying estimates of the needs of the country for concentrates.

745. I have been shown the minutes of the first meeting of the Advisory Committee on the NBTS from 1 December 1980 [DHSC0001391]. The issue of RTC supply of all concentrates, including commercial, appears to have come up again at that meeting:

On the question of monitoring usage, the Committee felt that there was some merit in the suggestion that all Factor VIII (including that purchased commercially) should be issued via RTC's. This arrangement already applied in some Regions. DHSS was to prepare a paper for RMOs and RTDs This would be circulated in draft to the Committee. Whilst there were arguments in favour of applying such an arrangement to all blood products, it was agreed that the paper should concentrate on obtaining agreement on the Factor VIII issue.

I confirm that this Centre holds regional stocks of commercial factor VIII concentrate purchased by the RHA on the basis of calculated regional requirements less what is expected from the BPL.

In practice this scheme works very well. Only Directors of Regional Haemophilia Centres are entitled to receive this material. In general each Director would prefer NHS material, if available, because users are charged by book transfer for such commercial factor VIII that they receive. The Transfusion Service arranges the direct purchase of commercial factor VIII in consultation with the RHA and its Treasurer.

This could easily be done by other Regions or it could be arranged by central purchase on the basis of information provided by regions. Personally I prefer the regional system.

746. I have been shown a short report that Mr Godfrey produced on 12 February 1981 [CBLA0001270]. In that report he commented on the concentrate issue:

Regional Transfusion Directors have suggested that it would be useful if all Factor VIII (including supplies purchased commercially) were to be held and issued by Regional Transfusion Centres. This would enable the use of Factor VIII to be monitored more closely and assist Directors in calculating the level of fresh-frozen plasma supplies needed to be sent to the Blood Products Laboratory, bearing in mind the proposed pro-rata supply of blood to Regions from 1 April 1981. This is already the practice in at least one Region (West Midlands). The Advisory Committee recognises that purchasing and distribution policy must remain a matter for local decision, but strongly commends this arrangement to RHAs for consideration.

747. There was a further meeting of the Advisory Committee on the NBTS on 23 February 1981 [CBLA0001287]. At that meeting, it was agreed that the proposal that all supplies of Factor VIII be held at RTCs would be put to representatives of the haemophilia centre directors.

748. I have also been shown the minutes of the RTD meeting on 17 March 1981 where this issue was discussed [NHBT0018341]. At that meeting the RTDs expressed favour for the Birmingham arrangement on commercial Factor VIII. Cost was discussed, and it was commented that the principle should be applied to all other commercial blood products. It was noted that, aside from Birmingham, this approach of distribution of Factor VIII from RTCs was already organised by Southampton, Cambridge and Manchester. Dr Jenkins and Dr Wagstaff noted opposition from their haemophilia centre directors for their regions in respect of this proposal.

749. There was a further meeting of the Advisory Committee on the NBTS on 22 June 1981 [CBLA0001388]. That meeting appears to have

followed a discussion with some of the haemophilia directors concerning the commercial Factor VIII supply issue. The minutes note:

Dr Walford reported that the suggestion that all supplies of Factor VIII should be held by RTCs had also been raised, but the Haemophilia Centre Directors' reactions had not been favourable. They feared that such an arrangement might mean that they would be unable to obtain commercial supplies of their choice, although it was explained that Haemophilia Centres' requirements for all forms of Factor VIII would indeed continue to be met at present.

Dr Bird and Dr Darnborough explained that central supply arrangements were working well in their Regions and there was always a full consultation with Haemophilia Centre Directors before supplies of Factor VIII were ordered. Members thought that in time Haemophilia Centre Directors would reconsider the matter and eventually, perhaps after NHSBT reorganisation, it might be appropriate for all blood products to be held and issued by RTCs. Meanwhile it was agreed that the Secretariat would draw up a list of those Regions already operating a central supply system for Factor VIII.

750. I have been shown a paper produced by Mrs Yuille of the Secretariat with document identification number AC(81)17 [CBLA0001456]. This would appear to be the list requested in the previous Advisory Committee meeting. The document provided information of which RTCs held Factor VIII and other products, whose budget such products were funded from, and any further comments. Of the 14 regions included, four indicated that they held Factor VIII product:

a. East Anglia: it indicated that it held Factor VIII product but no other blood products. It indicated that the Factor VIII was funded from the blood transfusion budget. In the comments it was noted "*[w]ould*

apply scheme to other products, but hardly any are purchased commercially".

b. Wessex: it indicated that it held Factor VIII product but no other blood products. It indicated that the Factor VIII was funded from the RHA budget separate from the RTCs. In the comments it was noted "*[e]ncountered difficulties in coping with Haemophilia Centre Directors' individual preferences for particular brands of Factor VIII and getting Haemophilia Centres to operate within their budgets*".

c. West Midlands: it indicated that it held Factor VIII product and that it intended to hold all blood products in due course. It indicated that the Factor VIII was funded from the blood transfusion budget in the first instance but was recharged on an AHA basis. In comments it was noted that no difficulty was encountered.

d. North Western: it indicated that it held Factor VIII product but no other blood products. It indicated that Factor VIII was funded from the blood transfusion laboratory budget but transferred to a separate RHA budget from April 1982. In comments it was noted that no difficulty was encountered.

751. On 15 September 1981 it would appear there was a joint meeting of the representatives of haemophilia doctors, blood transfusion service directors and the DHSS [DHSC0001311]. At that meeting, the purchase of Factor VIII through RTCs was discussed:

Dr Walford explained that it would be most helpful for the Department to have details of how Haemophilia Centres purchased their supply of Factor VIII. Haemophilia Centre Directors explained that each Centre operated its own system of purchase. Dr Hamilton said that in his Region (Northern), Factor VIII was purchased for all Centres through the Pharmaceutical Officer. Dr Kernoff explained that in North East Thames, a contract was made with the two commercial companies to

supply all Haemophilia Centres. Each Centre then paid for the Factor VIII it required. The contracted companies made regular returns to the Regional Supply Officer of the Factor VIII they had supplied.

Discussing the purchase of Factor VIII through Regional Transfusion Centres, Haemophilia Centre Directors were in general opposed to such a system because they felt that they might lose flexibility to choose the product they wanted. It was explained that clinicians would still retain the right to choose their products, and the RTC would only be responsible for ordering and delivery. Because of the pro rata distribution of BPL's Factor VIII, it was vital for Transfusion Directors to have up-to-date and regular information on the extent of commercial purchasing. After discussion it was agreed that Haemophilia Centre Directors would endeavour to keep Regional Transfusion Directors informed of commercial purchases by means of a monthly report. The Directors present agreed to inform their colleagues in other Haemophilia Centres and Haemophilia Reference Centres of this agreement.

752. There was a meeting of the Advisory Committee on the NBTS on 28 September 1981 [CBLA0001457]. At that meeting, the discussion with the haemophilia centre directors took place which was described as "*most constructive*". It was noted:

Haemophilia Centre Directors were aware of the need for close liaison with RTDs on the provision and usage of Factors VIII and accepted the need to provide accurate [sic] picture of the extent to which Factor VIII was being purchased within their Region. It had been agreed that Haemophilia Centre Directors would keep RTDs informed on commercial purchases, probably by means of a monthly return although details were left to Directors to work out locally.

753. I have not seen documents subsequent to this pushing the issue of RTCs purchasing commercial Factor VIII further. The documents

would appear to indicate that this was to remain in control of the haemophilia centre directors. I am unsure whether those centres which were purchasing commercial Factor VIII (as set out in [CBLA0001456]) continued to do so.

754. Supply of FFP is dealt with in my answer to section 8. It would appear from those documents that the blood service did not have relationships (until the NBA era and the vCJD issue dealt with in Q18 and see below) with pharmaceutical companies generally about supplying FFP. In regard to plasma derivates, my understanding of the extent of the blood services role, once it had been established that procurement was to sit with the Haemophilia Centres was therefore to identify where NBTS was unable to meet demands for particular blood products, and where any shortfall would need to be met from different sources [CBLA0000239]. An example of the blood services communicating the need for additional plasma supplies was in relation to fractionated plasma for Albumin [CBLA0002383] and [NHBT00118874_003]. This was to ensure that the demand for albumin was met overall by the NHS.

755. In respect of supply, from the 1970s, as far as I can see from a Memorandum and draft letter from Mr B Gidden to Mr J Smith, regarding "*Blood products production*", the risk of commercial supply from paid donors was paramount in NBTS's considerations. For example in relation to the necessity to establish self-sufficiency: "[a system of paid donors] *would constitute a most serious threat to the voluntary donor system upon which the NBTS is founded … The Department therefore regards it as of greatest importance, quite apart from the question of cost, that the NHS should become self-sufficient as soon as practicable.*" [CBLA0000224]

756. It appears, from Minutes of the meeting of the Eastern Division of Consultants in Blood Transfusion from 1989 which I have been shown, that the blood services' distance from procurement decisions was an

issue considered by some in the health services to be of "*great concern*" [NHBT0118858]. Specifically, the issue was that "*RTCs will have no control over the quantity of blood products hospitals will choose to use, nor where they would elect to buy from. If commercial products were cheaper, it is most likely that the hospitals would purchase those. In addition, even at the present time when BPL products are available free to the hospitals, certain hospitals preferred commercial products, e.g. Hammersmith and Great Ormond Street hospitals used commercial albumin for replacement during plasma exchange, St Thomas's hospital used commercial Factor VIII and the Royal Free Hospital used commercial CMV immunoglobulin. Furthermore, many hospitals have "special deals" with commercial firms for the purchase of albumin and Factor VIII, which are well below the commercial list prices.*"

757. The cross-charging approach to managing blood suppliers (details of which are set out in [NHBT0118859_002]) appear to have driven some hospitals' decisions to procure supplies commercially. Prices appear to have been "*picked by the Department of Health rather than derived and [it appears] that no real account had been taken of commercial prices, nor of the world glut of albumin. (The list price of some commercial albumin preparations is less than the BPL discounted price.)*" This rendered BPL "*vulnerable to commercial attack*". A further concern was that "*if RTCs did not purchase all the products manufactured by BPL then the BPL's requirements of plasma from the RTCs would also fall*" [NHBT0118858].

758. A further driver for involvement with pharmaceutical companies on the part of the blood services was public health. In 1998, in response to the emergence of the vCJD epidemic in the UK associated with the consumption of meat products from BSE-affected cattle, the Government introduced a ban on the use of UK human blood plasma for the manufacture of all plasma-derived medicinal products. During this period the UK purchased plasma and plasma derived products

from overseas sources due to the risks associated with plasma products made from UK donors, as far as I am aware this was not procured directly by the blood services. Where, in order to minimise vCJD risk, the Department of Health's (and subsequently NHS England's) procurement arms did purchase plasma for fractionation (for BPL) or plasma derived products (for the NHS), we believe that this was from the United States and Europe.

759. It appears from the documents that safety and quality were in general paramount considerations raised by the blood services where procurement of plasma derived products was taking place. For example, the 1992 contract negotiations between the CBLA and Octapharma [NHBT0017221] for virally inactivated plasma for therapeutic use identified factory standards, the need for additional pharmacological data and the protocol for the trial at three RTCs as matters requiring resolution.

760. Furthermore, the importation of plasma was also extended for paediatric transfusion of FFP, as part of the response to vCJD; this was to minimise the vCJD risk for children born after 1 January 1996 who hadn't been exposed to this risk through the food chain. This plasma was procured by NHSBT, initially from the US including the American Red Cross in Phoenix and Arizona, and subsequent to a later procurement exercise in 2010, from within the EU from Macopharma, Austria and Poland, and PAM Medical, Austria. This plasma was also pathogen reduced because of the higher rates of other viruses when compared to the UK. Supplies of plasma from the United States ceased from 2010 and from Europe in 2020. The contracts for these products are available on request.

761. More recently, as part of the new appointment of a fractionator for plasma collected today, this is being led by NHSE/I but NHSBT is involved in discussions and the procurement process through the work

on the DHSC/NHSE/I steering group for this work. This is following standard OJEU procurement processes.

i. Sale by NHSBT and its predecessors of unused blood components and other materials and which has historically included plasma.

762. As far as I can see from the documentary evidence, this is both a historic and current issue. As stated above, this is sometimes referred to as a non-clinical issue or NCI in the papers. NHSBT produces NCI products for research purposes. These products are *'non-clinical'* in the sense that they are surplus to and inappropriate for clinical purposes but nonetheless remain useful and where they can be used for the potential benefit of patients and processes in the NHS, we have considered this to be covered under our donor consent and that it is reasonable for them to be used. For that reason, and to the extent that it is appropriate, and given that they would otherwise be discarded, these materials are *issued* to non-NHS bodies both in academic and commercial settings.

763. NCI materials include components from blood and platelet donations such as expired components, waste products such as white cells following leucodepletion of components, excess plasma, together with some non-transfusion related NHSBT products from our cord blood bank, organ and tissue donation services and therapeutic apheresis services. The team within NHSBT with responsibility for NCI acts as an interface between the NHSBT departments that produce substances of human origin and those pharmaceutical companies in the UK that require access to human cells and blood components for their activities.

764. The types of activities for which these materials are used include R&D (for example through UK university departments), education and training (for example the UK National External Quality Assessment Scheme, NEQAS), the development and validation of diagnostic

reagents (including to the National Institute for Biological Standards and Control, NIBSC), the development and validation of new components, therapeutic products and processing methods and laboratory external quality assessment see: INF965, (Non-clinical Issue ("NCI") Customer Guide) [WITN0672056]. Some of this work may be undertaken in collaboration with NHSBT. NHSBT's current biggest contract for such materials is with Roche Diagnostic. NHSBT supply plasma to Roche to make diagnostic reagents.

765. Donated and patient material is only provided to approved laboratories and pharmaceutical companies. In order to ensure that the process is robust and transparent, NHSBT has a documented system of policy, process and procedures for NCI and guidelines for the use of donated material and contracts underpinning such relationships. Key conditions for the provision of materials for non-clinical issue include that it is released on an anonymised basis together with:

a. Generic Consent - Materials provided for non-clinical use are appropriately consented and supply complies with all statutory and regulatory obligations including (but not limited to) the Human Tissue Act (2004) and associated Codes of Practice and Standards;

b. Specific consent is required for any activity using animal models and genetic or other analysis or information that is requested alongside the sample (for example age) that could potentially establish a donor's identity;

c. NHSBT will not supply material via NCI which is to be used therapeutically. Material issued via NCI is not for use in establishing cell lines without specific authorisation;

766. Any costs incurred in making materials available are fully recovered and any surplus is retained by NHSBT to cover the cost for things

such as blood equipment, collection bags, staff, processing costs and other associated overheads, for the benefit of the wider Health Service. No charge is made by NHSBT for the donated materials themselves.[35]

767. Further guidelines for the use of donated material include the requirement for ethical approval of research using NCI material, and anonymisation processes. Cumulatively the blood service's NCI processes ensure that:

a. Materials provided for non-clinical use are appropriately consented and that supply complies with all statutory and regulatory obligations including (but not limited to) the Human Tissue Act (2004) and associated Codes of Practice;

b. NHSBT does not offer materials which may be administered to a person, used in a product which may be administered to a person and/or used as a supplement in a tissue culture medium;

c. Provision of materials is on a contractual basis which controls the supply, restrictions on use, treatment and handling of donations, payment and prohibition on "selling" of blood or blood components;

d. Requests for access to materials are scrutinised under an auditable process by appropriately trained NHSBT staff aware of the relevant regulatory, commercial and donor/public-facing considerations;

e. NHSBT balances support for valuable non-clinical work against the potential risk of damage to NHSBT's primary purpose;

[35] Also see: https://www.blood.co.uk/why-give-blood/how-blood-is-used/non-clinical-use/

f. As part of the UK Health Service infrastructure, NHSBT supports important research, development and other uses that will benefit patients and education now and, in the future;

g. No charge is made by NHSBT for the donated materials themselves and recipients are similarly prohibited from attaching a value to, or "selling", the donated materials. (POL273 [WITN0672057]).

768. The provision of materials for approved non-clinical purposes is a secondary purpose which, if donor or general public sentiment is withdrawn, has the potential to undermine NHSBT's primary purpose. Therefore, in addition to the legal, regulatory, ethical and donor-protection considerations outlined above, in assessing any request for access to materials for non-clinical purposes, NHSBT will also have due regard to whether that supply could potentially cause any risk to NHSBT's primary purpose and, if so, what mitigations can be put in place to minimise that risk.

769. The provision of materials for the clinical supply chain will always have primacy over the provision of materials for the non-clinical supply chain.

770. I provide MPD565 [WITN0672058] which is the relevant guidelines for the use of donated materials which sits alongside the NCI policy in POL273 [WITN0672057].

The Historical Position

771. As far as I can see from the historical record, the development of this use of NCI always prioritised the importance of materials for clinical use, and ethical issues were central to the development of NHSBT's NCI policies. These are set out below.

772. From the early 1980s it was noted that a large part of the thrombin at BPL was being used for hospital bench laboratory testing but not for clinical purposes [CBLA0001190]. This led to questions from the NBTS Joint Management Committee about the Central Blood Laboratories' charging policies including whether CBL should provide diagnostic material on a commercial basis in competition with commercial firms.

773. I have been shown the minutes of an RTD meeting on 25 June 1980 [SBTS0000290_004]. At that meeting Dr Lane "*thought that it made economic sense to sell excess immunoglobulins that might otherwise be destroyed*". Dr Tovey went on to note:

…he thought that if excess products were to be sold they should be sold to international organisations like the Red Cross and the World Health Organisation. He said that he would discuss the question with Dr Hantchef, Medical Officer to the International Red Cross, when he met him in August.

774. I have also been shown the minutes of the RTD meeting on 15 October 1980 [DHSC0002365_021]. At that meeting the following was set out in respect of the sale of excess blood products:

The Chairman had discussed the sale of excess blood products to overseas voluntary transfusion services with Dr Hantchef of the International Red Cross who said that there was already a surplus of iummunoglobulins and referred him to the Swiss Red Cross Transfusion Service who might be interested in purchasing from the NBTS.

Several members thought that excess blood product might be made available at a reasonable price to countries which could not readily afford to pay the commercial rate, or to international organisations like Oxfam. The Chairman felt that there were difficulties selling blood

abroad. For example, there was the question of who would pay for the packing and export, what export regulations applied, and what would donor opinion be about selling abroad. He felt that the time was not right to pursue the matter with the Department but that in due course it might be appropriate to put the matter to the new Advisory Committee.

775. In 1981 under Dr Lane, BPL considered the trading of excess blood products to establish the most economical practice in overall fractionation schedules [CBLA0001379]. It was noted that "*sale of excess products and intermediates is clearly relevant to the extension of activities in plasma fractionation to provide NHS self-sufficiency since a considerable volume of unwanted bulk intermediates will result*". Discussions at BPL noted that "*there are no other laboratories with the equivalent expertise or resources to provide these intermediates*".

776. In September 1981, Ministers took the decision to allow for the sale of surplus material derived from blood. The nature of such consent was only to the "*disposal of 'surplus' materials which would otherwise be destroyed and there could be no question of selling products for which the NHS has a need"* [CBLA0001448]. In November 1981 Ministers asked officials to consult the NHS and private sector about handling and processing charges for blood products supplied to private clinics and hospitals [CBLA0001457]. The Advisory Committee for NBTS agreed that any charges for such products should be calculated nationally. The Minutes of the 183rd Regional Transfusion Directors' meeting, held on 7th October 1981, show that commercial approaches to RTCs for the purchase of blood and blood products were not considered possible " *until the DHSS had given advice to regional health authorities regarding the arrangements under which such transactions could take place*" [NHBT0018339]. This may have been related to the significant political dynamics surrounding the provision of blood and blood products to the private sector [CBLA0001551].

777. The documentary record shows ongoing discussions during the early 1980s about the development of a proposed service for the sale of products [CBLA0001797]. The RTDs during this period remained "*divided*" about the proposed service charge for blood to the private sector, and it was agreed during a 1984 meeting of RTDs to write to the Deputy CMO at DHSS highlighting the following points: "*1. There should be some legislation to prevent the formation of both small and large private blood banks. 2. An investigation should be carried out regarding the legality of importing blood for private use. 3. An overall blanket service charge should be made to the private hospital or clinic. The charge would be spread across all patients to cover those who are unable to give blood themselves. The charge would be based on an average usage rate. 4. It would seem desirable to pursue again the idea of an 'across the board' charge to all NHS hospitals 5. To reiterate that the private sector should, at present, purchase specific blood products that are available commercially.*"

i. Immunoglobins

778. Obtaining sufficient immunoglobins to meet domestic clinical demand has been a long-running issue. It is unclear to me, however, from my review of the papers the volume of immunoglobin that was purchased and stored from the 1970s onwards. Meeting minutes from 1986 show that while there had been a long-term ambition for BTS to become self-sufficient for immunoglobulin – it would appear that this had proved difficult because there was no money set aside for this purpose in some regions. From 1986 [CBLA0002312], work was undertaken by the RTDs to identify the demand for specific immunoglobulins, in particular for anti-D and anti-Tetanus hyperimmune immunoglobins. The evidence suggests that supply of specific immunoglobins was a constant problem throughout the 1980s. For example, the choice of pharmaceutic companies in the provision of anti-D immunoglobin was driven by the demand for immunoglobins [CBLA0002358], and the difficulties of enabling a major increase in production at short notice [CBLA0002383].

779. Over the course of the late 1980s and 1990 the blood services began to produce additional immunoglobulins, for example IVIg (intravenous immunoglobulin) began to be produced in 1988, as purchase of IVIg from the Commercial Sector represented a major DH expense. The levels produced at different RTCs appear, from my review of materials, to differ across sectors with some that "*have a surplus and some [that have] deficiencies on pro-rata return*" [NHBT0118874_003]. During this period, however, the blood services do not appear to have had control over which products were used by hospitals, and even in cases where BPL products were available free, certain hospitals appear to have preferred commercial products and purchased those [NHBT0118858].

780. A ban was introduced in 1998 on the use of UK plasma to manufacture immunoglobulins due to the risk of vCJD transmissions. Since the introduction of the ban, plasma for the production of immunoglobulins means that products used in the UK have been made from plasma collected from donors outside the UK and/or products have been imported and the primary source for these is the USA.[36] The introduction of this ban is dealt with more fully in answer to Q18.

781. Currently, NHSBT stocks some doses of very high dose Anti-D immunoglobulin. This is to cover any patients that require this product in an emergency as the lead time for ordering is over 24 hrs, supplied by CSL Behring UK LTD. NHSBT do not regularly issue this product as the need for it is very limited, but have agreed for many years now to keep it as a 'cover' product.

Other Relationships

782. The above aside, NHSBT's relationships with pharmaceutical companies, such as they are, concerned matters of a different, more

[36] [RLIT0001560]

specific, and more limited nature. They arose, for example, in relation to the development of testing methodologies (such as for HIV, HCV, HTLV1), the development of plasmapheresis and related techniques and technology, or, more simply, for the supply of products required for NHSBT operations. Examples include:

a. Relationships with pharmaceutical companies producing HIV tests, in particular in the mid-1980s where many companies were approaching RTDs to offer HTLV-3 (now HIV) tests, although this also included HIV-1 and HIV-2 tests. When considering the relationships with pharmaceutical companies as a result of these tests the Regional Transfusion Directors were aware of the risk for potential conflict stating that they should not "*be pressured by commercial sources to accept a test which is not ideal for our purposes and that we [the RTDs] should act together*" [CBLA0001995].

b. The purchase of reagents from the Blood Group Reference Laboratory as commercial supplies were running out [NHBT0018200];

c. The development of certain HBsAg (Hepatitis B surface antigen) RIA tests – in 1981 Burroughs Wellcome offered a free trial of tests to RTC representatives [CBLA0007637]. However, BPL were concerned that the free provision of such a test by a pharmaceutical company would obstruct evaluation by BPL of its RIA (radioimmunoassay) test. BPL contacted DH to ensure that the RTCs would be able to have the BPL RIA test on desirable terms at the earliest possible opportunity [CBLA0008875].

d. Products and technologies such as bags for plasma processing. For example, RTDs were keen to ensure in the 1980s that, rather than allowing the supplies council to do the purchasing, they could avoid a manufacturing monopoly while having direct control over

the mixing and matching of packs by dealing with the manufacturer direct [CBLA0001742]. Meeting minutes show that RTDs were aware of the risk of monopoly suppliers and engaged with procurement professionals to help resolve the situation [CBLA0002409]. Other meetings where this issue was raised include:

i. Minutes of the 204th Regional Transfusion Directors meeting, held on 15th July 1987 [CBLA0002383], confirmed that the proposals for central purchasing came "*to nothing, at least for the moment*".

ii. Minutes of the 188th Meeting of Regional Transfusion Directors, held 18 May 1983 [CBLA0001707] during which it was decided that "*RTDs should ascertain proportions of packs used at present and the intended usage over the next few years*";

iii. Agenda and Minutes for the 190th meeting of Regional Transfusion Directors on 25th January 1984 [CBLA0001797] during which it was agreed that the main commercial concerns "*would not object to the bulk ordering of blood packs from two or more regions*"

iv. Minutes of the 207th Regional Transfusion Directors Meeting, held on 13 April 1988 [CBLA0002409], which concluded with the need for a letter from the RTDs to the Director of Procurement on the monopoly situation. It is not clear to me from the evidence available whether this situation was ever resolved.

e. Products and technology used for collecting blood for example machinery that used for apheresis collection, over the years this would have included Autopheresis-C machines from Baxter Healthcare, machinery from Haemonetics supplied under contract,

together with more recent contracts with Terumo who provide the Trima machines used today, other supplies such as Scinomed, Fresenius-Kabi and others will have been part of validations and procurement processes.

f. Insofar as is relevant here, testing and red cell typing today is done as part of my answer to section 6.

783. There are a number of further areas in which NHSBT and its predecessors have had relationships with such pharmaceutical companies although this does not directly involve the sale and / or importation of blood products or supplies. I understand that these include the following:

a. Indirect relationships with pharmaceutical companies through supplying, or being supplied with products and services from Public Health England, NHS England and Reagent and biochemical assay products;

b. In the context of collaboration for research and development. Such research partnerships appear to me, from those documents that I have seen, to have been conducted in a manner that showed awareness of the risks associated with commercial involvement. For example, in the 1980s the NBTS's Scientific and Technical Committee for the Central Blood Laboratories discussed and shared information about new chromatographic techniques and innovations in centrifugation in anticipation for an NHS/industrial partnership in plasma fractionation [CBLA0001171]. During the discussions in preparation for engagement with Ministers on this topic members of the NBTS's scientific and technical committee expressed concerns about a commercial company taking over BPL: "*they explained some of the serious problems such a take-over would pose, including the possibility of increasing the hepatitis*

risk from UK blood products and the likelihood of damage to the voluntary blood donor system."

c. Currently we have relationships with a number of commercial companies with whom we are developing potential innovations in blood components or diagnostic testing, as described below.

d. A final set of relationships included those established by the movement of personnel between the blood services, academia and pharmaceutical companies, particularly in the development of new technologies such as plasmapheresis and in particular apheresis harnesses. Such relationships would have been, as set out in response to Question 33, transparent and fully declared.

784. Commercial firms were not, as far as I can see, provided with regular updates on HIV / HCV [NHBT00097469_014] as the Management Committee of NBTS were concerned that circulating such information to commercial companies may lead some RTCs to "*refuse to send data if this were to take place*".

785. Therefore, while NHSBT has had relationships with pharmaceutical companies, any such contracts as there may have been have been concerned mostly with the limited and specific matters referred to above. Further, it seems notable to me that the number and variety of such purchases from fractionators has reduced significantly over time as the blood services have moved towards self-sufficiency.

30. Does NHSBT contract directly with pharmaceutical companies involved in the production, manufacture, sale and/or importation of blood products? Has this changed over time? If so, please provide details.

786. As set out above:

a. In respect of NCI products, NHSBT has a standard form contract for non-clinical material transfer. Further information on the form of such contracts can be provided on request.

b. The UK has purchased plasma as described from the United States and Europe both to make into plasma derived products and to supply paediatric recipients with FFP for transfusion. Robust contracts were placed around the purchase of such plasma, the aim of which was to ensure the continuity of supplies to the NHS, and minimise risk – for example that of vCJD.

c. The strategic goods team at NHSBT procures a range of products purchased for NHSBT's activities. This includes among other items blood bags, testing equipment and consumables for NHSBT's manufacturing centres. The supply of these products includes global pharmaceutical companies such as Roche, Abbott and Grifols.

787. A list of some of the current NHSBT commercial relationships (primarily related to testing) is attached at [IBE, WITN0672054]. Current contractual relationships with pharmaceutical companies broadly fall into three groups:

a. Those providing goods and services needed to collect, manufacture, test and issue blood components including IT platforms and those required to employ a workforce. Those involved in the collection, manufacturing and testing of blood are pharmaceutical companies.
b. Those where we are developing new processes eg R&D
c. Those where we supply human material as described as NCI above

788. Examples of relationships for R&D include:

a. Macopharma – NHSBT has a joint project funded by NIHR on universal plasma and has also been doing some work on removing red cells from platelets – contracts are in place that cover these relationships and these have been declared on interest register; NIRI Nonwovens Innovation is also a party to this contract;

b. Zimmer-Biomet – NHSBT previously had a contract in place to look at the rejuvenation of red cells, but this has subsequently been terminated.

c. Cerus – NHSBT previously had a contract to validate and supply pathogen inactivation to red cells that has recently been terminated.

d. We have contracts with a number of suppliers who provide goods and services for our ongoing manufactured red cells project and clinical trial RESTORE;

e. Terumo – NHSBT in the process of developing a relationship with Terumo on a whole blood project and R&D on cryoprecipitate. No contracts for either are currently in place as the nature of the projects have not yet been fully specified;

789. In addition, a number of further CDAs are in place to keep a watching brief for projects, but these are without contracts in place at the present time.

790. In respect of the historical changes in the control and management of contractual relationships, the minutes of the National Directorate of NBTS [NHBT0071804] from 1 February 1991 at 13.6 show that proactive steps were taken to formalise relationships, where these existed, between RTCs and commercial companies to which the RTCs provided samples and reference materials from human blood by establishing a register for commercial involvement. The ambition of

such a register was to ensure that any such transaction was both ethical and sanctioned by the RTD.

31. Has NHSBT ever received any financial or non-financial incentives from pharmaceutical companies to use certain blood products? If so, please provide details.

791. Save for where companies have offered normal commercial discounts on their products (an example of which is included below), so far as I am aware, no. NHSBT does not, in general, use blood products. It produces blood and blood components. NHSBT has obtained FFP, but this was not 'used' in any clinical sense save as to process it and supply it to hospitals.

792. All NHS bodies are subject to the Nolan Principles, also known as the 'Seven Principles of Public Life' that establish the ethical standards to which those working in the public sector are expected to adhere. These, materially, include: '1.1 – Integrity' – which requires holders of public office to avoid placing themselves under any obligation to people or organisations that might try inappropriately to influence them in their work, and prevents them from acting or taking decisions in order to gain financial or other material benefits.[37]

793. NHSBT has its own guidance requiring that NHSBT employees must declare any interest, gift or hospitality that might influence their decision making.[38] Some employees (the majority are consultants) may act as advisors for commercial companies and these must be declared. At the end of each year NHSBT completes a 'declarations of interest' exercise which lists any donations, gifts, hospitality, loyalty interest, outside employment, patents and sponsorship interests amongst others.

[37] https://www.gov.uk/government/publications/the-7-principles-of-public-life
[38] https://peoplefirst.nhsbt.nhs.uk/Pay-Benefits-and-Pensions/declaration-of-interests.htm

794. Any such financial / non-financial incentives must therefore be declared in accordance with NHSBT principles. I have made enquiries within NHSBT, but I am not aware of any use by pharmaceutical companies of blood products, save for those that are contained within clear contractual agreements, as described in the previous section, or those supplied pursuant to NHSBT's NCI programme with its associated governance and policies.

795. Historically, there have been instances where the blood services have been approached by pharmaceutical companies on a number of occasions for example in 1986 by Axon Health Care, Speywood Porton and Amersham International, although in all such instances the directors of the blood services were concerned about the ethical and financial implications and the real objectives of the commercial approach: "*This company has approached a number of RTD's. They apparently wish to produce monoclonal antibodies to a range of blood group antigens. A meeting was held […] but concern was expressed by all over ethics, finance and the real objectives of Axon. […] The Chairman has been approached by (Speywood) Porton International for 50 ml/ blood samples. Amersham International have also asked for plasma to help in production of anti HTLV III reagents. If the NBTS cannot produce the materials importation will be necessary. […] The meeting felt that if such considerations would improve patient care a concerted approach from the NBTS would be best. Such materials could be produced in the NHS. The meeting felt that a well-structured response was required to all such requests. It was proposed that perhaps an ethical sub-committee with a special interest in monoclonal antibodies could consider the need and give legal advice.*" [NHBT0018200].

796. I have been shown one instance of discounts being offered for test kits for Hepatitis B and HIV, however this discount appears to be attached to the contract duration with an 8% discount for a twelve-month order, and a 5.5% discount for a six-month order [NHBT0041283_002].

32. Has NHSBT ever received any funding to prescribe, supply, administer, recommend, buy or sell any blood product from a pharmaceutical company? If so, please provide details.

797. The simple and necessarily short answer to this is no, not so far as I am aware. I would be surprised if this was the case. As described above, NHSBT and its predecessors have not prescribed, and not generally bought or sold blood products from pharmaceutical companies.

798. Our clinical studies/trials that we are engaged with or sponsor have tested the efficacy of different blood components and medicines. Where this relates to the efficacy of blood components, these are supplied by us, not a separate pharmaceutical company. Where these relate to medicines these have also been supplied by us. The only case involving a blood product that I am aware of is a small trial of fibrinogen concentrate that we did which was provided by a company, but this was done without any direct involvement from the company and without any incentive to use this product. Additionally, we did not provide them with the results other than those in the final public publication.

33. What regulations, requirements or guidelines are in place at NHSBT concerning declaratory procedures for involvement with a pharmaceutical company?

799. As set out above all NHS bodies are subject to the Nolan Principles. NHSBT also has its own guidance requiring that NHSBT employees must declare any interest, gift or hospitality that might influence their decision making. NHSBT employees are required to declare these interests in NHSBT's online system '*My ESR*'[39]. Any such declarations of interests are informed by NHSBT's Anti-Bribery and Corruption

[39] https://peoplefirst.nhsbt.nhs.uk/Pay-Benefits-and-Pensions/declaration-of-interests.htm

policy that specifies that declarations of material interests should be at the earliest opportunity, and in any event within 28 days, and the associated Anti-Bribery and Corruption FAQs.

800. In the context of any purchase from pharmaceutical companies by NHSBT, the NHSBT Procurement Procedures Manual 1.1 Procurement Policy, [WITN0672059] mandates procurement professionals to follow good practice. As per the NHSBT guidance, good practice includes full declarations of interests for procurements professionals and staff involved in the procurement process, strict compliance with the Public Contracts Regulations (2015) the main principles of which are transparency, equal treatment, non-discrimination and proportionality.[40] The role of procurement, as set out in the procurement policy is to "*enable the NHSBT to obtain the maximum possible benefit from the money it spends on the goods and services constantly seeking best value for money, reliability, responsiveness and innovation.*"

801. Other relevant procurement practices include clear specifications for procurement, and requirements that procurement professionals adhere to process flow. For example, ensuring both that the customer is responsible for producing the specification and that any procurement decision is subsequently reviewed by quality assurance. Further, procurement will source its supplies from pre-vetted quality suppliers and predetermined contractual arrangements, and all procurement will be done in compliance with "*NHSBT SO's and SFI's, public sector procurement policies, relevant UK law and PCR (Public Contract Regulations).*"

802. In addition to the procurement regulations and requirements, the majority of procurement professionals employed by NHSBT are members of, or studying towards qualifications, with the Membership

[40] https://www.legislation.gov.uk/uksi/2015/102/contents

of the Chartered Institute of Procurement and Supply ("**CIPS**"), and are required to comply with the CIPS code of conduct.[41]

803. In respect of individual staff involvement with pharmaceutical companies, the approach that prioritised transparency was also adopted at the hospital and NHS Trust level, with the Trust developing individual frameworks in determining when commercial sponsorship or a joint working agreement is appropriate. Hospitals required any employees in receipt of funding to declare this fully. Further, where projects are classed as research, they will require approval by the Health Research Authority ("**HRA**") or from a Research Ethics Committee.

34. Does NHSBT provide any pharmaceutical companies with results from medical research studies undertaken? If so, please provide details.

804. No, NHSBT does not provide results from research studies to pharmaceutical companies supplying medicines undertaken in any privileged manner that I am aware of. Of course, where the research results are publicly available pharmaceutical companies will be able to access the results.

805. As described above, NHSBT engages in R&D activities with pharmaceutical companies, these are related to goods and services provided by these companies such as elements used in blood manufacturing or in potential new developments for manufacturing blood components, they are not concerned with blood product use or other medicines. Where such collaborations are taking place, contractual arrangements will govern any information sharing between NHSBT and pharmaceutical companies.

806. I understand that the contracts register has been reviewed and filtered for all contracts which were entered into with commercial /

[41] [RLIT0001561]

pharmaceutical companies and there are many. It would take a considerable amount of time to review them all and to speak to all the individual research leads who requested these contracts. I hope the review we provide is sufficiently comprehensive and proportionate and that the general position as described is sufficient to respond to the question. NHSBT Research & Development does not share any donor data with pharmaceutical or commercial companies. We do work with researchers embedded within universities. I believe the answer for NHSBT directly to be, no.

Section 8: Sufficiency of modern blood supply

One of NHSBT's responsibilities is "to optimise the… supply of blood, organs, stem cells and tissues and match them to patients".

35. How does NHSBT understand its responsibility to ensure a sufficient supply of blood in England? Has this responsibility changed over time in nature and / or extent? If so, please provide details.

Current Position

807. NHSBT is a national organisation operating across England. One of its responsibilities is to provide a safe and consistent supply of blood components to NHS and private hospitals for use in patient treatment. The Blood Supply Division describes its strategic objectives as: *"to ensure for all patients, including patients with complex needs, that the right blood components are available at the right time, and are supplied via an integrated, cost efficient and best-in-class supply chain and service." [WITN0672060]*[42]

808. This requires a combination of high-quality donor recruitment and selection, infection screening, serological testing and blood component production (followed by evidence based clinical use). NHSBT is also responsible for transporting blood between collection and processing

[42] NHSBT Annual Report 2019 – 2020, pg. 22 [WITN0672060]

environments and to hospitals. NHSBT recovers its costs of producing blood products by charging a price (based on full cost without profit). Hospital trusts pay for the blood they use [WITN0672060].[43]

809. The maintenance of a sufficient supply of blood is part of our key structure and features in our reporting to our Board our key performance indicators in senior management meetings of the Blood Supply Directorate.

810. A specific trans-directorate meeting termed BOLT, the Blood Operations Leadership Team, is led by our Assistant Director of Planning, Performance and Stock Management and includes a representative from the Donor Experience, Blood Supply and Clinical Services Directorates. This group meets monthly (or more frequently when needed, as during the pandemic). It takes inputs from our actual and predicted stock levels, our performance and planning team and hospital (demand) intelligence and makes decisions on the number of appointments and other actions to ensure sufficient stocks and hence supply of all blood components.

811. This output is monitored on a monthly basis by our Board in the performance report and described as OTIF that is the delivery of blood components ordered on time and in full, this is described in my answer to question 37

812. On 5 July 2021, we published our 2021/22 Business Plan [WITN0672062]. Our priorities were set out in four pillars, three of which are relevant to the sufficiency of the blood supply (emphasis in original):

Diversify and Strengthen our donor base

Our priorities for 2021/22:

- *reduce the Ro Kell Neg Gap in blood donation*

[43] NHSBT Annual Report 2019 – 2020, pg. 36. This is true of all of the operating units except Organ Donation, CBB and BBMR which are funded by DHSC and the other UK Health Authorities. [WITN0672060]

- *improve our donors' experience by upgrading our digital services*
- *grow the foundation of a new plasma donor base*

Modernise and extend our established services

Our priorities for 2021/22:

- *Modernise supply chains to protect and sustain a safe supply of blood*
- *Increase organ donors and transplants through opt-out and utilisation*
- *Modernise our Pathology Services*

Develop and grow new and high-potential services

Our priorities for 2021/22:

- *Build capacity in the UK cellular therapies supply chain*
- *Expand our tissue and eye service offering to patients*
- *Support the Government ambition for a domestic supply of plasma for medicines*

813. Within the Business Plan, there are targets and milestones in relation to each priority, with key activities set out to reach these milestones.

814. Furthermore, the National Blood Transfusion Committee has documented national shortage plans for red cells [WITN0672063] and platelets [WITN0672064]. These plans describe how hospitals and NHSBT should work together to reduce the risk of red cell or platelet shortages through the management of both the supply and demand for blood should a shortage occur. Hospitals are required to have Emergency Blood Management Arrangements in order to respond to notifications from NHSBT. Since the COVID pandemic NHSBT has published its stocks of components daily on its website.[44] NHSBT aims to hold six days of red cell stocks and a minimum of one day of platelet stocks. Hospitals usually hold a similar level of stocks in addition. Occasionally, NHSBT may write to hospitals to let them know that our stocks are below our target but not yet at the level that would trigger the shortage plan (three days of red cell stock) and ask them

[44] https://hospital.blood.co.uk/business-continuity/coronavirus-covid-19/

not to order more units than they require. This is typically accompanied by a number of actions within NHSBT to bring more donors in and increase the number of appointments available.

815. Red cell shortages are rare in the UK, and patients would not be affected until red cell stocks in NHSBT fell below two days of stock and the 'amber' plan was activated. NHSBT defines targets for each blood and platelet group and monitors and publishes these on a daily basis. They are discussed frequently in senior management team meetings. Occasionally, there has been a seasonal reduction in the stock of red cells units of a specific blood group, for example Group O D negative. In these instances, NHSBT would disseminate specific marketing for donors of this group and notify hospitals of this specific group. In preparing this statement, I have searched for information on shortages dating back to April 2010. Although red cell levels have at times fallen below the overall target, there have been no red cell shortages requiring an Amber trigger level since at least April 2010.

816. In this period, there have only been two stock shortages capable of triggering our current Amber plan, both with platelet stocks.

a. From 5th March 2018 to 8th March 2018, NHSBT announced an Amber shortage of Group A platelets in the immediate wake of the extreme weather conditions known colloquially as the 'Beast from the East' (Anticyclone Hartmut 24th February to 4th March 2018). This severely impacted on our ability to collect, and donors' ability to donate, blood and platelets.

b. I would also like to note an incident on 9 October 2012, in which NHSBT took action to improve platelet stocks: in particular, this included restricting supplies to named patients for a short period of time. My understanding is that at this time, we did not have a platelet shortage plan in place, but that if the current plan was

applied, this incident would also have triggered an amber stock alert (paragraph 5.2.3).

Historic Position

817. I have addressed the history of NHSBT and its predecessors in section 1 to my answer. There is also the *NHSBT Family Tree* which has been provided as an exhibit [WITN0672007] previously. The documents explain the fragmented nature of the service in England and Wales between 1948 and 1993/94. Over that period the RTDs were responsible to their RHAs and operated RTCs somewhat like independent institutions. This makes it hard to attribute a corporate understanding to the blood service in those circumstances. In particular, it is not clear that, prior to the establishment of the NBA in 1993/94, there was a coordinated way of ensuring sufficiency of blood supply, beyond RTCs reaching out to one another.

818. However, I have been shown the terms of reference and aims of the various forms the blood service took prior to NHSBT. See, for example, (1) the NBA aims set out in section 1; (2) the terms of the reference of the Advisory Committee of the NBTS in section 3; and, (3) the "*Responsibilities of a Regional Blood Transfusion Centre*" in table 2.4 in *Fifty Years of Blood Transfusion* [NHBT0000028]. While I cannot speak to what individual RTCs and RTDs understood the position to be, it would appear that the understanding now held by NHSBT has not changed much over the years.

819. I have explained how NHSBT and its predecessors' obligations in respect of different areas of the UK changed in my answer to the questions in section 3 and do not repeat that here. This will necessarily have affected the blood services' understanding of its responsibilities.

820. I would highlight that historically, as I understand it, the provision of plasma for fractionation until 1998 – especially where it was primarily

provided via recovered plasma from whole blood donations – meant that shortages of other blood components were rare.

821. I understand from colleagues that even in the early days of NHSBT it was much more common to have supply shortages and that medical leads in each of the zones were frequently in contact to move supplies around the country. Also letters to hospitals were frequent to announce shortages, particularly of platelets. This has reduced substantially in the last ten years, firstly after the Blood Donation and Patient Services directorates were amalgamated to form a Blood Supply directorate and more recently with increased management oversight and new processes as described elsewhere in this section such as the integrated supply planning processes and the committee to oversee this (BOLT). I believe evidence is going to be given by Dr Williamson to the Inquiry and I believe she was involved in these discussions. Lacking documentary evidence to inform my own knowledge, which is necessarily second-hand, I will not expand on this issue further and leave it to those clinicians who were present at the time to comment on, should this be necessary.

36. Does NHSBT share its responsibility to ensure the sufficiency of the blood supply in England with other stakeholders (for example, government departments or other medical/public health organisations)? If so, please provide details.

822. A full description of NHSBT's relationships with other bodies is provided in Annex D to the Framework Agreement between the English Department of Health and NHSBT [WITN0672065].

823. **English Health Department:** The English Health Department has overall responsibility for care of patients in England. NHSBT is accountable to the Health Department (as the sponsoring department)

for providing a blood service in England [WITN0672060].[45] I set out the nature of this accountability in detail in my answer to Question 24. In this answer, I would highlight that all information on blood stocks is shared with the DHSC Sponsor team through our Board performance reports, and any issues relating to a potential for shortage are shared, together with the mitigating actions. During the last prolonged issue with red cell collection, a *'Back to Green'* plan was shared with the board and was scrutinised in detail by ARGC.

824. **Other Blood Services:** NHSBT is also a member of the UK Forum of Blood Services and shares a memorandum of understanding with blood operators in the devolved UK nations to provide mutual aid in the event of supply challenges.

825. **NHS England and the National Blood Transfusion Committee**: NHSBT collaborates with the National Blood Transfusion Committee which provides a forum for the Royal Colleges, Specialist Societies and NHSE/I (NHS England and Improvement), to facilitate guideline development, quality standards and evidence-based practice. Reporting to NHS England/Improvement, the NBTC provides national advice on initiatives to optimise the prescribing and safe delivery of blood components. Additionally, appropriate use of blood components and the minimisation of wastage of components is also within the remit of this body. The NBTC and its Regional Transfusion Committees comprise a structure that provides education, audit and advice to hospitals and their transfusion committees on best transfusion practice. NHSBT provides data and resources to enable this work to be carried out, and for hospitals to act on NBTC's advice.

826. Specifically related to sufficiency, the NBTC owns the national shortage plans in conjunction with NHSBT and there is agreement on the actions required if stock levels of components are low.

[45] NHSBT Annual Report 2019 – 2020, pg. 20 [WITN0672060]

827. In addition, the changing health care system may result in changes to commissioning arrangements, led by NHS England, and NHSBT will work with them to implement any changes that are proposed. NHSBT also works with NHS England to ensure business continuity processes are in place to manage supply of blood components during planned and unplanned major events.[46]

828. **NHS foundation trusts, NHS trusts and other health providers:** NHSBT's core function is to provide critical products and services directly to NHS hospitals, and to support them in using blood, stem cells and tissues appropriately and effectively. NHS Trusts help provide knowledge on blood stocks through the NHSBT Blood Stocks Management Scheme and these are regularly reported. NHSBT and hospital trusts work together to ensure that the right blood is always available for patients. The communications we send to hospitals if our stocks are low are dealt with above. We also work closely with NBTC on shortage plans as detailed above. As part of this NHSBT will work collaboratively with NHS hospitals and seek to minimise wastage of blood from donor through to patient.

829. **Independent and third sector health providers:** NHSBT works in partnership with independent and third sector providers where appropriate to improve the availability, safety and quality of the products and services it provides to NHS patients. An example of this is where we work collaboratively with charities to encourage people to donate their blood, tissues, stem cells or organs.

830. **NHS England**: NHSBT is a provider of specialist products and associated services. The changing health care system may result in changes to commissioning arrangements, led by NHS England, and NHSBT will work with them to implement any changes that are proposed. NHSBT also works with NHS England to ensure business

[46] See: https://hospital.blood.co.uk/business-continuity/

continuity processes are in place to manage the supply of blood components during planned and unplanned major events.

831. **The Medicines and Healthcare products Regulatory Agency**: The MHRA is the appointed Competent Authority that regulates NHSBT's compliance with the Blood Safety and Quality Regulations, which take into account the requirements of relevant European Directives (insofar as they remain applicable). Whilst NHSBT works with the MHRA to identify and mitigate against the potential impact of any emerging threats to the safety of blood, it is also concerned with patient safety which will include the safe, sufficient, and efficient supply of blood to the patient.

832. **Care Quality Commission**: NHSBT is regulated in England by the CQC under the Health and Social Care Act 2008. The CQC will perform a 'Well Led' inspection of NHSBT to assure that the leadership and governance of NHSBT allows it to perform its functions effectively.

833. **NIHR (DHSC)**: the National Institute for Health Research funds four Blood and Transplant Research Units. NHSBT works in partnership with them to deliver research in various areas of our business. One BTRU performs research on Blood Donor Health and Genomics, and they have a remit to conduct research which will translate into improvements in the sufficiency of the blood supply

37. To what extent does NHSBT ensure the sufficiency of the blood supply through its management and oversight of its transfusion centres?

834. I have commented on the term "transfusion centre" in my answer to Q18 above. I have addressed this question as part of my broader answer to Q39 below.

835. NHSBT plans the supply of blood in England from voluntary donation to hospital receipt. This includes responsibility for Stock Holding Units **('distribution centres')**. NHSBT does not manage hospital blood banks, which are managed by the receiving hospitals.

836. NHSBT ensures sufficiency of blood supply through an integrated supply planning process[47], which is monitored by BOLT, as described in my answer to question 36. This integrated supply planning process entails:

a. forecasting blood component demand based on historical usage and commercial/clinical insight. NHSBT publishes a short-term (next 12 months) and longer-term (up to 5 years) demand forecast which is subject to regular review;
b. planning sufficient donors, donations and collection/production capacity to meet this forecast demand;
c. holding blood component stocks in the right quantities in each of its 14 distribution centres to meet demand from the local hospitals which each of these sites serves.

837. NHSBT measures its ability to provide a sufficient supply to hospitals through an industry standard measure of "On Time, In Full" ("OTIF") performance. Over 2020/21, NHSBT achieved OTIF performance of 98.6%. Where NHSBT was unable to fulfil demand "in full", a clinically suitable alternative product was provided. This is described further in my answer to question 40.

38. To what extent does NHSBT ensure the sufficiency of the blood supply through its engagement with laboratories?

838. I have found this question difficult to answer as I am not sure what link there is between ensuring that we obtain sufficient blood and our relationship with laboratories. I have tried my best here to detail what I think could be relevant.

[47] NHSBT Annual Report 2019 – 2020, pg. 25 [WITN0672060]

839. CDL is part of NHSBT's internationally recognised research and development programme. CDL specialises in translational research that changes the way blood is processed, stored or tested. Through this, NHSBT improves the quality, safety and efficiency of the blood supply chain. CDL works with internal groups within NHS Blood and Transplant, as well as academic and commercial partners[48].

840. Further, NHSBT engages with hospital laboratories to inform its demand forecast and influence hospital ordering behaviours. This is done by utilising a network of groups and forums, delivering education, information, communication, audit, support and advice to all transfusion laboratories and transfusion clinical teams. NHSBT Customer Service teams (including Patient Blood Management, Hospitals Customer services, Blood Stocks Management Scheme) provide the external facing contact for hospital transfusion teams not only for direct interaction with NHSBT but also to work with the NBTC and the Regional Transfusion Committees to support patient care and ensure blood supply.

841. NHSBT provides the central nucleus for the transfusion community within England and utilises the links above to collaborate with laboratories; optimising and promoting the appropriate use of blood components through the production and support of education and reference material (including the contribution to guidelines) or by direct contact where necessary. This 2-way mechanism ensures that there is regular and transparent dialogue with specific focus through working groups and targeted actions where concentrated effort is required.

842. NHSBT collects and monitors component issue and wastage data and provides regular information to hospitals, benchmarking against other users to identify outliers where support might be required. The use of

[48] https://www.nhsbt.nhs.uk/component-development-laboratory/

specific component key performance indicators ensures priority components are maintained in conversation and focus.

843. Finally, NHSBT coordinates with the IBGRL[49], which provides reference services related to blood transfusion. I have commented on IBGRL in my answer to question 26

844. I have provided further detail on NHSBT's relationship with laboratories in the answer I have provided to section 6.

39. Please explain how NHSBT's functions and practices contribute to maintaining the sufficiency of the blood supply in England. For example, you may wish to comment on the NHSBT's policies, guidance or practices that relate to:

a. public information campaigns to recruit donors;

b. maintaining adequate infrastructure, including ensuring appropriate geographical coverage of transfusion centres and/or increasing the number of transfusion centres;

c. maintaining adequate logistical arrangements to ensure the appropriate storage and distribution of blood and blood products;

d. methods to maximise the yield of blood products from donated blood; and

e. the setting and reviewing of targets for the amount of plasma required to be collected by each transfusion centre under NHSBT's remit.

[49] NHSBT Annual Report 2019 – 2020, pg. 96 [WITN0672060]

845. My answer to this question builds on the discussion on plasma targets in Question 18 above. I do not repeat the information provided there, which should be read alongside this answer.

846. It might assist to note that, "blood supply" could cover the following items that NHSBT provides and terms 'blood components' (and its predecessors provided in the past): whole blood, red cell concentrates, FFP, platelets, cryoprecipitate, specialist plasmas, and other specialist components. This is not an attempt to provide a complete list but just detail the range of items that the blood service is involved in providing.

847. In my answer, particularly for the historic section, I have concentrated on the provision of plasma for fractionation of blood products, as that appears from the documents to have been critical, until we ceased to collect in the late 1990s.

848. As with other sections in my rule 9 response, I have been shown the following documents which deal with this matter in some detail. I have relied on them significantly in the drafting of my answer to this question.

a. *Fifty Years of Blood Transfusion* in (1996) 6 Transfusion Medicine by Dr Gunson and Dr Dodsworth [NHBT0000028].
b. Dr Gunson's First Preliminary Report for the HIV litigation [DHSC0000142].
c. Dr Gunson's statement for the HCV litigation [NHBT0000026_009].
d. Dr Lane's draft statement for the HIV litigation [CBLA0000005_002].

849. I note again the nature of the RTCs as a loose federation of institutions accountable to and funded by the RHAs for most of their existence. As a result of this, it is hard for me to identify steps that individual RTCs might have taken to secure the sufficiency of the blood supply with respect to plasma collection. This is exacerbated by the fact that I

have no first-hand knowledge of the majority of the events I discuss, and I am primarily working from the papers provided by those assisting me.

850. As I am working primarily from documents, and I have no first-hand knowledge, and the period covers decades, I have not attempted to identify every step that the blood service took to secure the sufficiency of the blood supply. I have tried to identify particular events over the years which, it seems to me, are particularly relevant.

Modern position

851. Until 2021 NHSBT has only been required to supply blood components to hospitals since 1998 when collection of plasma for fractionation stopped in the UK. I am aware from speaking to colleagues that shortages of blood components between the zones was more commonplace and that there were frequent needs to move supplies around the country in order to meet orders from hospitals. I am not aware that this provided significant problems for hospitals, but I am aware that NHSBT did have more communications with hospitals around stock during the period from 1998 to 2010.

852. I address the period beyond 2010 in my answer to question 35 where, largely, the sufficiency of the supply of blood components has not been a significant concern. Although red cell levels have at times fallen below the overall target, there have been no red cell shortages requiring an Amber trigger level in the NBTC shortage plan since 2010. There have been two short-lived incidents of platelet shortages during this time.

The next paragraphs describe the measure taken today to ensure the sufficiency of the supply of blood components. As noted in my answer to the previous question, the need for self-sufficiency in plasma historically was the biggest driver of blood collection. This meant there was no shortage of red cells and efforts were made to educate

clinicians to use concentrated red cells to maximise the amount of plasma available for fractionation.

853. NHSBT runs ongoing donor recruitment campaigns to explain the benefits of donation and relies on the support of a wide range of charity partners to help promote all forms of donation. It has established blood forums to bring its partners together to share campaigning ideas and best practice.[50]

854. NHSBT public marketing campaigns require agreement from both the DHSC and Cabinet office in order to spend money for this purpose.

855. As described in the response to question 3, NHSBT is also directed by the Directions. Section 2(2) of the Directions sets out a number of functions in relation to blood:

a. to provide a collection, storage and delivery service for blood;
b. to provide a screening, testing and processing service for the preparation of blood;
c. to conduct or commission research into the uses of and development of blood;
d. to provide diagnostic and other services in connection with the collection and use of blood and treatments depending on or requiring their use (including, for example, reagent preparation and provision, patient pathology and therapeutic services, histocompatibility and immunogenetic services, platelet and granulocyte immunology);
e. to promote, by advertising, marketing and otherwise, the donation of blood, with a view in particular to maintaining an adequate supply of blood;
f. to prepare, store and distribute plasma fractions and other products for therapeutic, diagnostic and other purposes;

[50] NHSBT Annual Report 2019 – 2020, pg. 21 [WITN0672060]

g. to promote, through advice and guidance, the appropriate use of blood, (having regard in particular to the need to promote the effective use of blood) and, as it considers appropriate, to provide a reference laboratory for donors and patients; and
h. to establish and manage a register of blood and any associated services necessary for the effective treatment of patients.

856. NHSBT's Central Planning Team **('CPT')**, which is part of the Blood Supply Directorate, are responsible for coordinating the end-to-end blood supply chain at NHSBT. This includes forecasting blood component demand and coordinating supply plans across a number of functions to ensure forecast demand is met. The Integrated Supply Planning process is led by the CPT and aims to ensure the Supply Plan and operational activity is coordinated to meet the demand forecast. The following departments participate in the integrated supply planning process:

a. The Donor Experience Team **('DET')** ensures that NHSBT collects blood to plan, with the appropriate number of active donors in order to meet patient demand including by donation type, blood group mix and a need for a sufficient quantity of priority donors whose donations support specialist treatments. The DET is also responsible for the end-to-end donor experience journey and accountable for the management of the blood donor base, including recruitment of new donors, retention of existing donors and reactivation of lapsed donors. The DET runs recruitment and awareness campaigns both nationally and at local level (e.g. local radio broadcast, TV, Social Media channels) and coordinate activity to ensure known donors book donation appointments when we need them, including through the National Call Centre and an online appointment booking platform. They formulate all

communication strategies and research methodologies into donors' behaviours, triggers and complaints.[51]

b. The Session Planning Team create donation appointment grids up to c.20 weeks in advance, ensuring sufficient appointments are planned to meet the supply plan. Approximately 75% of whole blood donations are collected at community venues (e.g. church halls, leisure centres). The Session Planning team also book these venues, ensuring that the location of booked venues is aligned to the size of the active donor base.

c. The Blood Donation Operations Team deploys staffing resources and equipment to blood collection locations, including permanent fixed locations and community venues, taking donations from donors who attend these sessions. The team are responsible for giving donors a safe and positive donation experience and ensuring that the blood collected is safe for transfusion.

d. The Manufacturing Team process each blood donation into the required product to meet the supply plan. The Testing team perform routine and (where required) discretionary tests on each donation to ensure they are safe for transfusion. Products are only validated for issue to hospitals once test results are confirmed satisfactory.

e. The Hospital Services Team receive orders from Hospitals using an online blood ordering system and then pick and package orders ready for dispatch.

f. The Customer Services Team manage the relationship between NHSBT and hospital customers.

[51] NHSBT Annual Report 2019 – 2020, pg. 16 [WITN0672060]

g. The Logistics Team collect donations from centres and mobile sessions and dispatch and deliver orders to hospitals 24/7 using a combination of NHSBT drivers and third-party providers. Hospitals receive routine deliveries on predetermined schedules, but ad-hoc deliveries can also be dispatched, including emergency "blue-light" deliveries if required. Hospitals can also organise collection of their own orders if preferred, using hospital logistics networks or volunteer services (e.g. bloodbikes). Stocks are balanced across the 14 stockholding centres using the BMV transport network (trunking) to meet demand from the local hospitals which each of these sites serves. Warehouses receive and distribute consumables required in each of our 14 distribution centres and blood donation teams to meet demand to collect blood.

Modern position – plasma

857. As previously documented, early in 2021, NHSBT were instructed by the DHSC to start collecting plasma for fractionation following the building of significant infrastructure during the COVID-19 Convalescent Plasma programme.

858. The DHSC has written, and had approved, a business plan to get to 30% self-sufficiency for intravenous immunoglobulin over the next five years. This is for domestic supply to the UK.

859. The responsibilities of parties to deliver against this plan were agreed in June this year in a Memorandum of Understanding, between the signatories who are

a. The Secretary of State for Health and Social Care (DHSC);
b. NHS England and NHS Improvement – Commercial Medicines Unit (NHSEI);
c. NHS Blood and Transplant.

860. The activities to be performed by each party are described in the annex to this document, but in summary

a. NHSEI will appoint a supplier of immunoglobulins (fractionator) and set up the commercial arrangements.
b. NHSEI will agree the volumes of plasma and Immunoglobulins for a domestic supply with DHSC and NHSBT, including estimates of future annual requirements.
c. DHSC will determine the list of plasma derived medicines, determine the size of the supply beyond plasma collected from whole blood and reimburse NHSBT for the collection of plasma.

861. The measures taken to ensure the sufficiency of supply of plasma within NHSBT will follow the processes described above for the supply of blood components

Historic – Headline Points

862. As I noted in my answer previously, collection of plasma to supply volumes of Factor VIII between the 1970s and 1998 was the biggest driver of blood collection as I understand it.

863. I have seen a couple of references to short-term issues for the supply of red cells in some regions but I am not aware that these were of any consequence for hospitals or patients as these were managed by coordination between regions.

864. In this answer I am therefore primarily addressing the steps taken by the blood service to attempt to meet the plasma targets prior to 1993 when, due to the impending introduction of recombinant factor VIII, RTCs were asked to reduce their plasma supply.

865. This is a separate question from that answered in question 18 (which concerns the setting of those targets) and question 40 (which concerns whether the targets were in fact met). As I understand it, the blood service took a number of steps consistently over the years to secure the sufficiency of the blood supply. I have not identified every occurrence of these recurring steps. They include:

a. Regular advertisements encouraging people in England and Wales to give blood. Various such adverts are provided in *Fifty Years of Blood Transfusion* [NHBT0000028], beginning in World War II up to the NBA. Various television advertisements have also been produced over the years, a number of which are currently available on Youtube[52] [53] [54] [55]. Often these would be timed to meet periods in the year where there was an additional need or historically low donation levels (e.g. Christmas). Advertising and donor recruitment was a regular feature of the RTD meeting minutes that I have been provided. See, for example, the discussion of recruitment pamphlets in [NHBT0016485], which are meeting minutes I have been provided for 30 April 1975.

b. Encouraging individuals in the public eye to give blood. I am aware that in the 1980s the North London RTC succeeded in having Prince Charles give blood[56]. While it is a historic example, *Fifty Years of Blood Transfusion* [NHBT0000028] at p.66 identifies Guy Gibson VC giving blood.

c. Increasing the size of the service. This covers increasing the numbers of RTCs, increasing the number of specialist plasmapheresis centres, increasing the amount of equipment, or increasing the number of staff working in the organisation. These changes are apparent over time throughout the documents I have been provided to review. It would appear from the documents I have been shown that the blood service and DHSS was consistently trying to convince RHAs to provide more money and provide for increased production of blood and particularly plasma.

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[52] https://www.youtube.com/watch?v=_CsOxvy_IIo (accessed 30 July 2021)
[53] https://www.youtube.com/watch?v=tFG1ktssZSg (accessed 30 July 2021).
[54] https://www.youtube.com/watch?v=4THaCZmzMQk&list=PL8qco88W24NfXKELODRUiOu_ex0eXpmtE (accessed 30 July 2021).
[55] https://www.youtube.com/watch?v=CH1p2_NfzJQ&list=PL8qco88W24NfXKELODRUiOu_ex0eXpmtE&index=5 (accessed 30 July 2021).
[56] http://content.time.com/time/subscriber/article/0,33009,963393,00.html (accessed 30 July 2021).

d. At various points there were discussions about whether to centralise the NBTS. Such centralisation, as it was achieved over time with the move from the Advisory Committee to the National Directorate, and then eventually the NBA (and now NHSBT) provided more central coordination which was relevant to the coordination of blood donation and plasma production.

e. Various steps changing donor rules such as to allow donors to take shorter breaks between donations, reintroduce temporarily deferred donors, or to allow older or younger donors to donate. Such steps are discussed elsewhere in my answer in respect of safety and management of RTCs and are not set out in detail for this question.

866. Aside from these general points, there were specific developments which were aimed at improving the amount of plasma available (and hence meeting the targets) that I would like to highlight here before dealing with the time period in more detail. The documents I have been shown deal with such matters as those described below in order to increase the availability of plasma for fractionation:

a. *Changes in anti-coagulant*: this improved the longevity of the blood and the amount of plasma that could be extracted in the production of red cell concentrates. This includes the move from acid-citrate-dextrose to citrate-phosphate-dextrose around 1957; the changes introducing CPD (A) around 1981; and, the change to SAG (M) around 1983 which had a significant impact on plasma extraction.

b. *Single packs:* this change appears to have been spearheaded by Dr Lane from 1978 with significant success achieved by 1981 and 1982 when the relevant hardware at BPL came online.

c. *Red cell concentrates*: from 1975 there was a move to increase clinicians accepting red cell concentrates and thereby allowing for more whole blood donations to be processed to provide plasma.

d. £0.5 million from DHSS in 1975: the provision of this sum of money in 1975 allowed NBTS (and BPL) to significantly increase production by spending money expanding the service.

e. Move to pro-rata distribution of blood products: Around 1980/81 this change was made by BPL and NBTS so that the amount of plasma that was produced by a region was proportional to the amount of product that was provided to them at the end of processing. This was to provide an incentive for RHAs to fund the production of more plasma.

f. Plasmapheresis: the move to provide more than specific plasmas by plasmapheresis was initially seen as a possibility from 1978. Dr Gunson appears to have been a proponent of plasmapheresis in the early 1980s as a way of meeting the need for plasma. This seems to have had some success from 1982. For further detail see the answer to Q50.

g. Inter-regional distribution of blood: there appear to have been early steps to achieve this in 1975 by Dr Darnborough and 1983 for red cell distribution from Cardiff. Provision of blood through inter-regional distribution to meet shortfalls was a service particularly advanced and orchestrated by the central management available through the National Directorate of the NBTS.

h. Cross-charging: this was raised in the early 1980s but was initially met with significant resistance from clinicians and RHAs. It was introduced from 1 April 1989 and provided further incentive and need to produce plasma and appears to have been a significant

factor in the provision of blood and plasma in the late 1980s and early 1990s.

867. At this point I would make the following observations. The steps described in the above two paragraphs were appropriate to try and meet the agreed targets for plasma. However, I would say that there were certain other points that were also pertinent.

a. Meeting rising targets would have required additional funding and this is covered in my answer to question 23.
b. The collection of plasma by plasmapheresis. There were clearly many discussions on collection of more plasma by apheresis. This is noted in documents from 1978 when largely single packs appear to have been prioritised. Then in the first four meetings of the Advisory Committee to NBTS this is discussed and reference to a DHSS paper on this is made, which I haven't seen. Whilst there was some action in 1982 when some new centres were set up there were further discussions in 1988 at CBLA. Despite these, in a document (NHBT0017098) which I have seen, there is a table headed "*Supply of fresh frozen plasma from RTCs 1975-1985*" which references 8.4% of total plasma being collected by plasmapheresis in 1985 and 16% by 1989. If it had been collected this way, it would have been likely to have had most impact during the period 1977-84. The reasons, as I understand them, for not adopting this approach were based on cost grounds, as plasma collected by apheresis is significantly more expensive than recovered plasma; plasmapheresis requires expensive static centres, machines and consumables. It appears that RTDs could not persuade DHSS, BPL or RHAs on the case for this. Given that two to three times as much plasma can be collected from each donor on a single visit compared to a whole blood donation and that donations can be significantly more frequent (nowadays every fortnight rather than every three months), the capacity to collect significantly more plasma to meet the demand required for self-

sufficiency could have been approached differently. Whilst it may have been properly considered (in documents that I have not had access to), in any event it was not realised. If the agreed aim of all parties was to collect enough plasma to achieve self-sufficiency it might have been possible with a different approach.

c. However, hitting the targets for collection of plasma and providing this to the fractionator was not the whole answer; the ability to effectively fractionate was also required. In many discussions the ability of BPL to do this and the timing of the upgrade being ready was important. I can see from the documents that this became a particular issue in the mid-to-late-1980s when there were delays to the commissioning of the new BPL.

d. As has been noted before, the organisational structures and decision-making framework, did not help to achieve efficient or effective decision making, either in terms of getting agreement, or in terms of negotiating or collaborating between regions. There was therefore a lack of what might be termed a systematic approach to firstly setting targets but also more broadly to the issue of how to achieve self sufficiency

e. Finally, today on a project of this size we take for granted the communication methods, spreadsheets and other 'project management' tools that we now use. Without these and in the context of a lack of an effective decision-making system, a lack of significant planning and coordination and cost constraints, I can see how hitting a continually increasing target would have been extremely difficult.

868. For ease of cross-referencing I have used the same periods identified in Q18 although, as is noted there, in reality this was one continuous run of events. As with Q18 I have focused on the production of general plasma and whole blood. There are specific details in the documents cited that deal with other items such as albumin and specific plasmas.

Early Years

869. As events prior to 1970 are such a long period of time ago, I have found it difficult to produce much information for this period. From the documents I have been shown, I would like to highlight the following events.

870. I understand from p.17 of *Fifty Years of Blood Transfusion* [NHBT0000028] that the number of RTCs was increased in the 1950s and 1960s. Brentwood was constructed in 1955, a centre (albeit not an RTC) was established in 1964 in two wards at Lancaster Moor Psychiatric Hospital, and Southampton RTC was established before 1970.

871. I also understand from p.27 of *Fifty Years of Blood Transfusion* [NHBT0000028] that in 1957 the standard anticoagulant for blood was changed from acid-citrate-dextrose to citrate-phosphate-dextrose. I understand from p.22 of that document that using citrate-phosphate-dextrose had the effect of lengthening the amount of time that red cells could be stored to 28 days.

872. I also understand from pp.27-28 of *Fifty Years of Blood Transfusion* [NHBT0000028] that there were some production benefits to the introduction of one-piece plastic blood packs (replacing glass equipment). The primary benefit appears to be safety, but this document indicates some other benefits also (for example, in separating plasma). I understand from p.28 that the introduction of plastic packs was slow in England and Wales as a result of both the expense and supply complications. It would appear the change-over was not complete until 1975. I have been provided with document [CBLA0000255] (discussed below) which indicates that on 19 February 1975 Newcastle, Leeds, Sheffield, Cambridge, Tooting and Liverpool were still issuing between one third and one half of their blood in bottles.

Period 1973-1977

873. As I have explained in my answer to Q18, the 1970s saw significant demands for plasma from the NBTS. As is also set out in Q18, these demands consistently increased over the decade. Save where necessary, I will not repeat the information regarding plasma targets here. I should note that the relevant meetings and initial estimates for 1973 are included in the answer to Q18.

874. I have been provided a letter from Mr Gidden of the DHSS to Regional Administrators of RHAs dated 24 December 1974 [CBLA0000239]. Aside from discussing targets, the following information regarding the recently announced £0.5 million in funding is set out:

4. To achieve a 40% use of concentrated red cells will require the full co operation of clinicians. Clearly no steps can be taken towards this objective unless parallel action is taken to ensure that RTCs have sufficient facilities to separate more plasma from whole blood and thus to meet the increased usage of concentrated red cells. For this purpose the cost of providing the necessary facilities such as additional equipment and staff might be up to £0.5 million in England and Wales, part of it recurring (the cost of collecting 400,000 additional donations annually might be of the order to a further £1.0 to 1.5 million). The extent to which the capacity of RTCs to produce plasma can be increased will vary from Centre to Centre.

5. It would clearly be considerably cheaper to produce these blood products within the NHS than to buy them from commercial sources.

6. If the normal procedure for the financing of health services were to be followed, Authorities would need to agree, collectively, to accord blood transfusion priority for additional resources over a period of several years, within a co-ordinated programme of expansion. However, additional expenditure is bound to be somewhat disproportionate as between Regions if realistic targets are adopted with the aim of making NHS production sufficient to meet clinical

needs. It has therefore been decided that since the Department would in any case have to co-ordinate the programme for the increased production of blood products earmarked finance of up to £ .5 million should exceptionally be provided for this purpose. The department proposes to invite estimates of requirements in RTCs for the increased production of plasma, with the primary aim of making the NHS self-sufficient in AHG concentrate in 2 to 3 years.

875. I have been provided the minutes of a special meeting of the RTCs on 19 February 1975 [CBLA0000255]. At this meeting the use of the £0.5m to meet the 275,000 donation target for the preparation of Factor VIII was discussed. I have also been shown a draft appendix 1 to RTD (75)1 which provides details of the current and targeted number of donations to meet the overall target of 275,000 [NHBT0017090]. There are manuscript notes for numbers of cryoprecipitate, which the minutes explain were not included in the draft. It was noted that the table would be revised to reflect the amount of plasma that might be expected to become available when production of cryoprecipitate declined (the minutes estimate a number equivalent to 100,000 donations).

876. The directors appear to have then discussed how the targets in appendix 1 can be achieved. There was some limited discussion of the life of red cells after centrifugation. The primary discussion concerned the use of concentrated red cells:

The rate at which the target of plasma derived from 275,000 donations was attained, would largely depend on the ease with which hospital clinicians would accept concentrated red cells.

To overcome this difficulty, Dr Cleghorn proposed that a smaller amount of plasma should be taken from a greater number of donations, so that the clinician would be presented with containers of blood more closely resembling whole blood than concentrated red

cells. He suggested that haematocrit might be adjusted to 55 per cent. In his opinion such a scheme should be operated with little additional staff or equipment and might have to embrace all centres.

It was agreed that Dr Cleghorn and Dr Jenkins should consider this proposal and then meet Dr Maycock, Mr Vallet, Dr Waiter and Mr Jackson.

877. The directors then went on to consider the other appendices to RTD (75)1. I have been provided these at [OXUH0003566_006]. Appendix 2 provides guidance on taking blood and plasma. Appendix 3 appears to be a form providing for estimates of the relevant expenses for increasing plasma production. Appendix 4 appears to be provided for RTCs that might exceed their Appendix 1 targets.

878. I have been shown the minutes for the next RTD meeting on 30 April 1975 [NHBT0016485]. There was a discussion of the Appendix 3 estimates that had been provided. I have not been provided with RTD (75)10. As Dr Maycock asked the RTDs to reconsider their estimates, I will not dwell on these minutes further. Independent of this, Dr Darnborough explained that he had provided some *ad hoc* inter-regional distribution of blood. There was a suggestion that assistance might be placed on a formal footing but matters were left as they were.

879. The next RTD meeting was on 2 July 1975 [NHBT0016482]. At that meeting a new table of expenses arising out of the Appendix 3 returns was provided as RTD (75)11. I have been provided that document at [DHSC0002369_004]. That document provided for an overall total cost for the works to increase plasma supply of £805,946. This was made up of £310,898 capital costs, £12,972 non-recurring revenue costs, and £482,076 recurring revenue costs. The document also provides a cost per donation calculation: the lowest was the South Western RTC at £1.48 per donation; the most expensive was Oxford at £5.40 per donation. In respect of this Mr Jackson from the DHSS said:

Mr Jackson explained that paper RTD (75)11 summarised replies to letter DS117/75 of 21 March 1975 and replaced Tables 1-3 of RTD (75)10. He was asked as to what the position would be if one Centre could spend more money in 1975-76 than had been allowed for revenue? He replied that the Dept. would try to make adjustments in those regions which were likely to underspend in 1975-76. He said that replies had not yet been received from RHAs Newcastle, Leeds, Cambridge, Oxford and Liverpool to the letter (copy sent to Directors), explaining allocations; Mr Jackson asked if RTDs would ask RHAs to send these as soon as possible.

880. I have been shown the minutes of the RTD meeting on 8 October 1975 [DHSC0105496_024]. In that meeting paper RTD 75(21) was produced which included details of the schedule for each RTC reaching its target. It provided for a target of 347,000 donations to be reached within 18 months. I have not been provided this paper, and do not comment further as a replacement was subsequently issued.

881. Two further matters did arise at this meeting. The minutes I have been shown record that it was agreed that the amount of plasma to be removed when creating red cell concentrates was 180ml. In addition, Dr Darnborough reported that about 240L of plasma had been returned from local hospitals to Cambridge RTC as part of a scheme to recover plasma from red cell concentrates made at hospitals. Dr Maycock asked that other RTDs consider making these arrangements.

882. I have been shown the minutes of the next meeting of the RTDs on 21 January 1976 [NHBT0016480]. An updating paper on the provision of plasma, RTD (75)26, was provided [CBLA0000336]. I have also been supplied this paper. This paper primarily deals with plasma targets and has been discussed in my answer to Q18. In the minutes to this meeting Dr Maycock reported that the modifications to BPL to allow it

to fractionate the proposed amount of fresh plasma would be finished in January or February 1976.

883. I have been provided the minutes of the RTD meeting on 17 March 1976 [NHBT0016478]. At this meeting there was a discussion of the increased use of red cell concentrates. Some hospitals were reported as using 60% red cell concentrates. Dr Cleghorn and Dr Jenkins proposed that 120mL of plasma should be removed from all donations, as "plasma-depleted" blood seemed widely acceptable. Edgware, Brentwood and Cardiff were already doing this for about half of their donations. Dr Cleghorn and Jenkins were asked to produce a paper. Financial and staffing limitations of adopting this approach were noted.

884. I understand there was an RTD meeting on 2 March 1977 for which I have been provided the minutes [NHBT0016473]. There was a discussion of the use of red cell concentrates. Dr Cleghorn pointed out that "*it might be necessary to put more money into the NBTS if substantially more plasma was to be available*". The minutes provide details about the percentage use, and capacity for further use, of red cell concentrates in each region.

Period 1977-1984

885. As explained in Question 18, there was a paper delivered by the DHSS Working Group on Trends in the Demand for Blood Products. I have discussed that paper, and the targets that were issued as a result of it, in my answer to Q18. In respect of next steps for the NBTS in meeting those targets, I have first been provided with the minutes of the RTD meeting from 3 May 1978 [BPLL0007406]. In that meeting it was noted that the DHSS was currently considering the most effective methods of meeting the requirements in the report.

886. I have been provided with the minutes of an RTD meeting 5 July 1978 [CBLA0000802]. At that meeting paper RTD (78)20 was produced, which I have been provided [CBLA0000743] - this document discloses

the details of a request made to RTCs to further increase their supply of plasma to the BPL. At least six offered the possibility of some increase if single packs were accepted or further funding provided. Dr Maycock then said:

Sir William reminded Directors that the use of plasmapheresis to obtain plasma for fractionation had up to now been confined to donors with special antibodies and any extension of the plasmapheresis programme to increase the routine production of plasma should be fully discussed.

Directors decided that the development of plasmapheresis as a means of providing additional plasma should be urgently considered at each of the 3 regional RTD groups meetings; each group was asked to provide a short discussion paper for the next RTD meeting.

887. Dr Lane also proposed that a working party be established to consider new methods of harvesting plasma, including the use of single donor packs. The Directors agreed to convene such a working party. Dr Waiter, from the DHSS, was also asked to attend. Mr Parrott from the DHSS noted:

Mr Parrott said that the decision of Directors to carry out a feasibility study to examine new methods of harvesting fresh frozen plasma was welcome. He reminded members, however, that there were aspects other than the purely technical ones which would have to be taken into account and both the Regions and the Department would be interested in the possible financial consequences of any charge.

888. I have also been provided the minutes of the RTD meeting on 4 October 1978 [DHSC0002367_005]. At this meeting Dr Lane's working party was named the "S *ingle P acks C ommittee*". It was also noted that Brentwood RTC "*could probably be expanded sufficiently by the time the Army withdraw its facilities (in 1981)*" at the Army Blood

Supply Depot, to meet the needs of London. It was thought the Bristol RTC could meet the needs of the Wessex Region.

889. As is noted above, I have not provided every reference to donor recruitment in the RTD minutes as it appears in nearly every set of minutes. However, I have been provided the meeting minutes for 7 February 1979 [SBTS0000089_101]. At this meeting Mr Dutton said that NBTS needed to be "*geared up to meet the recommendations of the Trends Working Party's report*". He explained steps would be needed to recruit more donors and retain old donors. He proposed that recruitment arrangements be reconsidered. The following was then noted:

He reported that the British Safety Council now seemed ready to start its campaign to recruit 21,000 new donors for the NBTS, and it was a question of deciding where the Council should begin campaigning. Directors agreed that the matter should be referred to the Regional Donor Organisers' meeting.

Some directors asked whether it might be possible to bleed donors in the London area at more frequent intervals than at present, but it was agreed that because of regional variations in the competence of the donor panel this topic would be better discussed at a meeting of the Regional groups.

It was also thought that the film "A little goes a long way" if shown on TV might be an excellent recruiting aid.

890. I have been shown the minutes of an ad hoc meeting of the RTDs on 25 July 1979 to discuss the requirements of the Trends Working Party [DHSC0002193_094]. Dr Lane is recorded as having:

…doubted whether in setting their targets for factor VIII and albumin procurement the Trends Working Party had anticipated the difficulty

Regions would meet in producing the necessary volumes of fresh plasma. He stressed that it was important to plan a valid production programme to include Regions.

891. Dr Lane said he anticipated that moving to the single donation pack would allow RTCs to step up plasma production, and a second prototype of that pack would be available shortly. The group then went on to discuss blood product distribution which it would appear, at that time, was distributed in terms of need or number of haemophiliacs irrespective of the amount of plasma provided to BPL. It was noted that the current policy was now a "*great disincentive to Regions to produce more plasma*". As a result, it was decided all of the Regional Groups of Directors would be told about the proposal to issue BPL products based on the amount of plasma a region sent to BPL. A plan of the next steps was produced including that "*BPL would gear up (so far as resources allowed) to process the extra plasma which it was anticipated pro-rata distribution of finished products would generate*", as soon as the arrangement was generally accepted by Directors.

892. I have been provided minutes of a further ad hoc meeting on 26 September 1979 [DHSC0002195_044]. Dr Lane had produced a paper "*Future preparations of plasma protein fraction by the NBTS – a reassessment of requirements*". I have also been provided with that paper [CBLA0000998]. The report focuses on provision of plasma and the recent and negative investigation into BPL by Medicines Division inspectors. In respect of the former, Dr Lane wrote that "*The deficiencies lie within the NBTS and its administration since it has been shown that, freed from constraints, the NBTS could make NHS self-sufficient in blood and blood products*". Dr Lane identified both funding and lack of central organisation as flaws. One aspect of his proposal was BPL providing products to regions based on pro-rata provision against the amount of plasma provided.

893. At the meeting there was a further discussion on pro-rata distribution of fractionated products. The minutes provide:

It was reported that there was not universal acceptance by Directors of the proposition that blood products should be distributed by BPL proportionally to plasma supplied, but with some safeguards for Regions with special problems, eg Regions which treated Haemophiliacs from other Regions, it was felt that a distribution scheme on this basis would prove generally acceptable.

Dr Lane pointed out that plasma input would have to be carefully matched to BPL's capacity to process it.

894. The meeting ended with a discussion about proposing a centralised blood transfusion service, and the proposal that NBTS might generate its own revenue.

895. I have been provided with a number of sets of minutes from the RTD meetings which appear to show the proposal of pro-rata distribution of blood products being progressed:

a. [CBLA0001041]: at a meeting of the JMC of the Central Blood Laboratories on 19 December 1979, Dr Lane notes that "*some Regions had made it very plain that they would not produce more plasma unless they could be assured of a proportional return of blood products*".
b. [SBTS0000290_004]: at the meeting on 25 June 1980 it would appear that the DHSS proposed to put the matter of pro-rata distribution to Regional Medical Officers.
c. [DHSC0002365_021]: at the meeting on 15 October 1980 it would appear that the proposal had been discussed with Regional Administrators and Regional Treasurers who were generally in favour. It was proposed that Regional Treasurers would discuss it with RTDs.

d. [CBLA0001207] at the first meeting of the Advisory Committee of the NBTS on 1 December 1980 Dr Lane raised this again, and proposed it begin from 1 April 1981. It was proposed that the DHSS produce a paper which considered the needs of special units and covered albumin as well as Factor VIII.

163. As was just noted, I have been provided the minutes of the first meeting of the Advisory Committee on the NBTS. At that meeting there was a discussion on expanding plasmapheresis, and it was noted that the DHSS would be preparing a paper on the matter. It was noted that the amount of plasma that the Factor VIII yield could be improved by quick freezing of the plasma. It was also noted that using CPD rather than ACD anticoagulant could further increase the yield although it was a matter for the clinical judgment of each RTD. Dr Jenkins also proposed internally charging for blood products to demonstrate how much more cost-effective BPL product was. It was agreed that the matter would need to be fully discussed.

896. The paper AC (80)3 produced by Dr Tovey was discussed at the meeting. Dr Tovey's paper suggested that the requirement of 30m i.u. by 1982 could be met in all but two regions by improving the quality of plasma and increasing the proportion of donations converted to plasma to 45%.

897. I have been shown a discussion paper produced by Dr Lane and Dr Gunson [CBLA0002451]. It is unclear, but it would appear to precede the meeting of the Working Party to Advise on Plasma Supply in June 1981. The paper concerns plasma supply self-sufficiency. A number of matters for discussion are noted:

a. It was noted that Factor VIII intermediate concentrate production had peaked in March 1977 at 15m iu per annum. It was said that "with no planning or finance forthcoming, the rate of production had not changed". It was also noted that over the period, use of Factor VIII had approached 60m iu, largely through the use of imported

product. The report explained that a new facility at Elstree was "urgently needed".

b. The paper went on to discuss the processing needs of a new factory to meet demand in 1980 and the full capacity required for 90m iu.
c. The paper also discusses the different ways that there could be an increase in the collection of plasma. The difficulties of plasma demand and how demand for products arose was discussed. This includes a discussion of the difficulties with funding the collection.
d. The paper discussed the meeting of an intermediate target of twice the present production of FFP and an ultimate target of a six-fold increase in supply of FFP.
e. Various routes to meeting these needs are considered including various forms of plasmapheresis and increasing and expanding blood donations.

898. I have also been provided the chairman's briefing note from the first meeting of the Advisory Committee on the NBTS [DHSC0002201_056]. That document notes the difficulty of whether clinicians using blood will accept the use of more red cell concentrates. It also notes that more production of FFP for fractionation will have an effect on cryoprecipitate production at RTCs. The notes also indicate that neither increasing the quality of plasma nor converting higher proportions of donations to FFP will be enough to meet the requirements for the mid-1980s. The note discusses the need to "*consider in depth the issue of a voluntary donor plasmapheresis programme*".

899. I have been provided the minutes of a further meeting of the Advisory Committee on the NBTS on 23 February 1981 [CBLA0001287]. At that meeting there was a further discussion about the introduction of pro-rata supply of products, and the specific needs of places such as Lord Mayor Treloar Hospital were discussed. There was also discussion on the provision of albumin at a straightforward percentage return ("*a*

Region supplying 10% of the input would normally receive 10% of the total production"). There was discussion some of the difficulties of this approach. At the meeting it was agreed stocks of freeze-dried plasma would be excluded from pro-rata distribution, and ad hoc supplies to the Army would continue. It was proposed the system would be reviewed in 1982.

900. At the meeting a paper, AC (81)3 for pro-rata distribution was discussed. I have been provided this paper [CBLA0001294], and it proposed the details of the pro-rata scheme. This included a calculation for each RTC region of the provision of Factor VIII concentrate. The initial pro rata allocation was proposed to be 80% of notional gross yield (such an approach taking account of material used for quality control, failed batches, and contaminated batches). I have been shown a letter from Mr Godfrey of the DHSS to Dr Lane at BPL dated April 1981 where the proposals of the Advisory Committee were accepted [CBLA0001328].

901. At the second meeting of the Advisory Committee on 23 February 1981 [CBLA0001287] there was also a discussion of plasmapheresis as a means of increasing plasma supply. Papers AC (81)4 and AC (81)8 were produced but these have not been available to me. There was a discussion of the role of plasmapheresis in meeting self-sufficiency. Dr Gunson set out his analysis of the need for plasmapheresis:

On the assumption that the target for Factor VIII would be 90/110 million international units, and assuming that this would require a total input of 490,000 litres of plasma, Dr Gunson calculated that 207,000 litres of fresh-frozen plasma could be collected by normal donation, and 283,000 litres by plasmapheresis. He envisaged that 55-60,000 active plasmapheresis donors would be required per annum. Equally, if the target requirement for Factor VIII was 135 million international units per annum, requiring a total plasma volume of 720,000 litres, on

the assumption that 207,000 litres would be obtained from whole blood collection, then 513,000 litres would need to be collected by plasmapheresis. This would require approximately 100,000 active plasmapheresis donors. Dr Gunson considered that the number of plasmapheresis facilities would need to be increased, and to collect 283,000 litres would probably require a total of 28 8-bedded centres in England, Wales and Northern Ireland, and to collect 513,000 litres would require a total of 50-52 centres.

902. It is recorded in the minutes that it was agreed a working party headed by Dr Gunson would be set up with the terms of reference being "*[t]o advise on supplies of plasma for self-sufficiency in blood products in England and Wales*". See further below.

903. I have been provided the minutes for an RTD meeting that took place on 17 March 1981 [NHBT0018341]. At that meeting Dr Lane announced that single packs would be available towards the end of the year. At this meeting Dr Darnborough agreed to chair a committee on the recruitment of donors. There was also a discussion of the implementation of pro-rata provision of products. The utility of CPD adenine as an additive was discussed and it was thought "*CPA A-1 formulation should be that of choice for routine use*".

904. I have been provided minutes of the RTD meeting which took place on 19 May 1981 [NHBT0018340]. At that meeting there was a discussion of progressing the use of CPD adenine to extend the shelf life of blood. This issue, and the broader issue of supply of blood in hostilities, was also discussed at the RTD meeting on 7 October 1981, for which I have also been provided minutes [NHBT0018339]. At the latter meeting Dr Lane also announced that the coagulation laboratory would be commissioned that week and allow the phasing in of single packs.

905. I have been provided the minutes of the third meeting of the Advisory Committee on the NBTS dated 22 June 1981 [CBLA0001388]. Plasma supply was discussed and a paper AC (81)11 was produced; I have not had access to this paper, but I assume it is linked to the proposals relating to Dr Gunson referred to above. Using the figure of 100 million i.u. Dr Gunson explained that 200,000kg from whole blood donation was possible to obtain. He thought the remaining 300,000kg could be obtained from whole blood donation, "*but this option had several disadvantages, not least the fact that there would be a considerable excess of red cells which would have to be discarded*". The alternative was to harvest by plasmapheresis. Dr Gunson preliminarily costed this at £50 per kg. He noted that "*[a]thought one kg, if fully utilised, produced more than £50 worth of products, harvesting 300,000kg would require a substantial investment from RHAs*". The committee then went on to discuss cost, and proposed that the costing in the report should be refined before consulting RHAs formally.

906. I have been provided the minutes of the fourth meeting of the Advisory Committee on the NBTS which took place on 28 September 1981 [CBLA0001457]. At that meeting Dr Gunson discussed the estimated need for FFP. A paper AC (81)18 was produced, which I have been provided with [DHSC0002211_030]. This updated AC (81)11. The paper discussed obtaining the needed plasma through whole blood donation or plasmapheresis. Dr Gunson provided figures for producing the total needed plasma (including the £7.5 million cost of obtaining the 200,000kg of plasma through whole blood donations): 235,000kg obtained through whole blood donation (discarding red cells): £28.1 million; 235,000kg through machine-pheresis: £19.1 million; 235,000kg through manual pheresis: £17.3 million. The paper also calculated the cost of producing 200,000kg, 325,000kg and 435,000kg of plasma. Dr Gunson provided an action point for the Advisory Committee:

The <u>ADVISORY COMMITTEE</u> is asked to approve the supplementary report to AC (81)11 and to seek Ministers' agreement with respect to

consultation with R.H.As with a view to determining the supply levels of plasma for the redeveloped BPL.

907. Looking at the minutes, it would appear the members approved the report and asked that Ministers' approval be sought for formal consultations with RHAs on blood supplies. There was discussion of using PFC and a redeveloped BPL for such production.

908. I understand that there was the fifth meeting of the Advisory Committee on the NBTS on 31 March 1982, for which I have been provided the minutes [CBLA0001572]. At that meeting Dr Gunson reported that a machine plasmapheresis centre had been established in Bradford, where it was hoped there would be 6 machines by June 1982. The North Western RHA proposed to set up a manual centre in Lancaster with the assistance of the DHSS. Dr Gunson commented the centres "*would provide other Regions with an opportunity to assess the relative merits of manual and machine plasmapheresis*". There was also a discussion asking for comment on inter-regional charging. The minutes report that "*[m]embers saw little advantage in a system of intra-regional charging*" but Mr Layzell offered to consult District Treasurers in Wessex and report back.

909. I have been provided the minutes of a meeting of the Joint Management Committee of the Central Blood Labs dated 27 April 1982 [DHSC0002217_011]. In those minutes, Dr Gunson commented on plasma supply and "*explained that the improvements in plasma supply had been stimulated by the introduction of the pro-rata distribution of products and the increasing co-operation between Regions and BPL*".

910. I have also been provided the minutes of the sixth meeting of the Advisory Committee on the NBTS on 15 September 1982 [CBLA0001621]. Mr Layzell reported back that intra-regional charging had received a mixed response in Wessex. After discussion it was

thought the time was not yet right for its introduction. He offered to carry out a pilot study in 2-3 years. The question of charging for BPL products was to be considered by the NHS Finance Technical Forum. There was also a discussion over the taking into account of specific plasmas not used for Factor VIII production (such as those collected instead for hyperimmune products) in the pro-rata production of products.

911. I have been provided the minutes of an RTD meeting on 20 September 1982 [CBLA0001623]. At that meeting Dr Lane confirmed that the single pack programme was progressing to its second phase to allow reception of more than the current annual plasma supply.

912. I have been provided the minutes of the seventh meeting of the Advisory Committee on the NBTS on 10 January 1983 [BPLL0007254_001]. At that meeting Mr Layzell reported that the question of charging districts for RTC services had received little support at the Regional Treasurers' meeting. He confirmed that the study in the Wessex Region which looked into the feasibility of charging Regions for BPL products would also cover intra-regional charging, albeit the Committee had presently concluded there was little scope for progress in that.

913. I have been provided the minutes of the RTD meeting on 14 January 1983 [CBLA0001663]. At that meeting the supply of blood in hostilities had been discussed. It was noted there that RTDs had previously agreed to supply between 30-50% of normal intake and increase blood intake for use by the MOD to accommodate civilian and military casualties. There was also a discussion of the introduction of SAGM (saline-adenine-glucose-mannitol):

Dr. Parry reported that from evaluation carried out so far on SAGM the Working Party recommended that SAGM could be introduced as soon as possible. Dr. Parry also reported that from figures available it

appeared that transition to SAGM from SAGS would yield a considerable increase in plasma. From evidence gained from the filtered blood trial which was nearing completion it seemed that there was no longer need for frozen blood for leucocyte depletion. The Working Party was concerned as to whether the much increased provision of source material from regions was being matched by returns of FVIII from BPL. In particular the use of SPP did not seem to be reflected in improved FVIII yields.

914. As part of reporting on behalf of the single packs committee Dr Lane also commented on the introduction of SAGM:

Dr. Lane replied to the points raised by the Blood Preservation Working Party and circulated figures to confirm that VPL had, in fact, managed to make a substantial increase in FVIII productivity. Dr. Lane also supported the development of the SAG-M program with regard to the plasma program. He confirmed that a major research commitment towards improved FVIII yields and hepatitis inactivation existed at BPL.

The Single Plasma Pack committee will investigate the need to increase the size of the SPP for plasma from optimal additive donations. Dr. Lane agreed that Dr. Ala join the SPP committee to assist in consideration of optimal additive introduction.

Mr. Pettet (BPL) addressed the meeting to report the BPL figures for plasma supply and FVIII production (papers tabled).

Dr. Lane reported that the Working Party could continue to meet to consider packs manufactured by companies other than Travenol that were suitable for automated opening.

915. I have been provided the minutes of the RTD meeting on 22 September 1983 [CBLA0001742]. In that meeting Dr Napier explained

that Cardiff RTC occasionally had an excess of red cells as a result of satisfying demand for components. A system of providing red cells to centres with a deficit was proposed for a six month trial. Cardiff was to act as a liaison point between those with excesses and deficits of red cells.

916. I have been provided the minutes for the eighth meeting of the Advisory Committee on the NBTS from 17 October 1983 [CBLA0001763]. At that meeting Mr Layzell reported that limited progress had been made in the study on inter and intra-regional charging in Wessex. There had been issues with the related exercise in NBTS costing. Dr Gunson and Mr Layzell were asked to examine a simplified format for cost forms.

917. I have been provided the minutes of the tenth meeting of the CBLA held on 25 January 1984 [CBLA0005002]. At that meeting Dr Gunson reported on plasma supply, and expressed concern about the provision of funding for plasma. Paper CBLA 84/1 was presented, but this paper has not been provided to me. It was recorded:

Dr Gunson expressed concern that during the latter part of 1983 the targets, which had been agreed earlier in the year as a planned programme of producing sufficient plasma to ensure optimum working of the new BPL and ensuring self-sufficiency in blood products, were now in jeopardy because of the difficulties in obtaining the necessary funds. He said that may RHA's were reluctant to commit themselves for more than 1 year at a time, and that he understood their views on fulfilling other priorities.

Dr Gunson outlined possible options for consideration as a result of the probable difficulties. Then most feasible option was for the production of plasma above the 1983/84 figure being financed through CBLA with RHA's acting as agents for this part of their activities. In the meantime, Dr Harris stressed the need for pressure to be put on

Regional Medical Officers and Regional Treasurers, emphasising the importance of making sufficient plasma available to BPL. He suggested 3 possible ways of dealing with the problems which were, respectively: - through meetings of the Regional Chairmen with the Secretary of State; through Annual Regional Reviews; and through NHS Supervisory Board as suggested in the Griffiths Report.

The Chairman thanked Dr Gunson for his report, the contents of which were viewed with the gravest apprehension and said that the situation should be kept under review both by the CBLA and DHSS.

918. I have also been provided the minutes of the ninth meeting of the Advisory Committee on the NBTS on 10 April 1984 [CBLA0001835]. At that meeting Mr Layzell reported that Price Waterhouse Associates had carried out a study on inter and intra-regional charging. Following discussions with Dr Gunson and the DHSS it was proposed a seminar be held and Ministers' approval for 3 regional trials be sought. There was also discussion concerning increasing supply of plasma to BPL, and it was proposed the matter be brought to the attention of the new NHS management board.

919. I have been provided the minutes of a CBLA meeting on 26 September 1984 [CBLA0001896]. At that meeting there is a discussion raising concern about plasma provision. It was proposed that Mr Williams would follow up on the issue of "*Regional Treasurers… not being made fully aware of all the facts in the argument for ensuring that sufficient plasma was made available to BPL*".

920. I have been provided the minutes of the tenth meeting of the Advisory Committee on the NBTS dated 8 November 1984 [PRSE0004783]. At that meeting there was a further discussion of inter and intra-regional charging:

3. A feasibility study had been further progressed by Mr Layzell prior to a decision on the principle of charging RHAs for BPL products. Two Regions would be chosen for trials, to be conducted in liaison with Dr Lane at BPL. Consultation would evaluate the trials and produce a micro system and documentation; a seminar to explain proposals could be arranged. The trials would start in January with an evaluation by June 1985.

4. The Committee saw the scheme as an extension of handling charges for blood and blood products. Blood should be included in the present considerations too, so that the NBTS moved towards clinical budgeting. Dr Lane welcomed the initiative and sought rapid implementation; it would minimise problems over funding and plasma supply to BPL.

921. I have been provided the minutes of a meeting of the CBLA on 28 November 1984 [DHSC0001101]. At that meeting Mr Williams noted all RHAs had responded to the DHSS letter about plasma supply, and "*three or four regions had been unable to give any commitment either in finance or time to plasma supply*". There was a discussion of charging for products, but it was noted neither the DHSS nor the RHAs had accepted that at that time. The section discussing plasma concluded:

Dr Gunson expressed the opinion that even the more committed Regions would only provide finance for plasma supply in respect of their own population and he felt that there should be some kind of national integration. Dr Lane felt that plasma procurement could be speeded up by promoting the growth of plasmapheresis, which Dr Gunson had highlighted in his report to the CBLA in January 1984. After discussion it was agreed that a paper should be prepared within the next two weeks…

Period 1985 to 1988

922. I have been provided the minutes of an RTD meeting on 23 January 1985. At that meeting the events at the most recent Advisory Committee meeting in respect of self-sufficiency was discussed [CBLA0001995]. Dr Gunson reported:

The major topic was on self-sufficiency in plasma supply. Only 6 RHAs agreed a plan with this timescale. 3 Regions agreed but no timescale was approved, 2 Regions opposed the estimate of plasma required and one Region had not replied.

This amount was too little for self-sufficiency and too little for optimum working of BPL. The Department were to consider the whole issue.

923. I have been provided the minutes of a meeting of the CBLA on 1 February 1985 [CBLA0002007]. At that meeting plasma supply was discussed, and paper CBLA 85/1 was raised. I was also provided with paper [DHSC0001472]. This paper is discussed in the minutes below.

924. I have been provided the minutes of the eleventh meeting of the Advisory Committee on the NBTS held on 6 November 1985 [CBLA0002277]. At that meeting the final report on inter/intra-regional charging was produced by Price Waterhouse and concluded to be technically feasible. The matter was sent to the Management Services Division. A paper AC(85)5 was referenced here but I have not had this document available to me. The paper described the current production position, and proposed various methods to remedy the issue: (1) purchasing the additional plasma; (2) further discussions with RHAs; (3) independent collection of plasma by CBLA; and (4) establishment of central coordination of plasma supply. The paper provides the preferred option of collection of plasma through whole blood collection by RTCs, plus centrally coordinated and funded plasmapheresis through the CBLA. The paper went on to estimate the price of such work.

925. This report was received at the meeting. The discussion is recorded as follows:

Dr Gunson introduced the subject against the background of the failure of some Regions to make provision for meeting their targets. Mr Williams outlined the Government's policy on funding. It was noted that 'Top Slicing' was not favoured since the cash had already been allocated, was known, and identified. The Chairman stated that the DHSS should be asked to ensure plasma deliveries against this cash allocation to avoid the factory having insufficient source material on commissioning. He pointed out that although less heat treated Factor 8 would be produced from a given pool, the BPL product value remained ahead of that from commercial sources. Mr Williams said that the matter of securing increased supplies following cash allocations was under consideration at the Department but the post-Griffiths reorganisation appeared to cloud methods of dealing with this type of situation. Mr Williams was asked to provide a progress report for the March meeting.

In the subsequent discussion Dr Gunson introduced his recommendation on collection by plasmapheresis referring to the availability of plasmapheresis machines and the advantages of central funding.

926. There was a further meeting of the CBLA on 22 May 1985, for which I have been provided the minutes [BPLL0011025]. It was noted that there had been a meeting the previous day concerning data provided by the DHSS from RTCs on projections of plasma volumes for the next four years. These minutes have not been available to me. The CBLA minutes record a shortfall from four regions. There was a discussion of mechanisms for attracting additional donors and the possibility of bringing in consultants to look at the issues in the regions. Dr Thomas

expressed concern about the underutilisation of plasmapheresis; Dr Gunson confirmed he was pursuing the issue.

927. The recommendations in the minutes of the previous day's meeting were accepted. It was agreed that Mr Williams would keep the CBLA informed about further pressure to be exerted by DHSS on those Regions giving an unsatisfactory reply. It was also agreed that Dr Lane as director of BPL would give six monthly reviews of RTCs' performance in achieving targets. Pro rata distribution of products was to continue.

928. There was a further meeting of the CBLA on 18 September 1985 for which I have been provided the minutes [CBLA0004979]. In that meeting Mr Williams noted that the DHSS were still pursuing RHAs on the subject of plasma supplies, and further correspondence had been sent to the Regions who had not agreed to meet target requirements. It was noted that "*if the Regions concerned had not produced satisfactory explanations for their position in the near future, the matter would be the subject for parliamentary debate in October*".

929. I have been provided the minutes of a meeting of the CBLA on 20 November 1985 [BPLL0011017]. At that meeting Dr Gunson noted that RHAs were looking at next year's plan and the matter of plasma supply was now at a critical stage. The Secretary of the CBLA expressed his concern at the problem and he expressed the thought that DHSS would have to continue to exert as much pressure as possible on RHAs. Dr Gunson noted that donations had initially decreased from the impact of AIDS but the situation had now reversed and the donations had actually increased.

930. I have been provided the minutes of the twelfth meeting of the Advisory Committee on the NBTS on 12 March 1986 [PRSE0000128]. At that meeting Dr Lane "*advised that SAG (M) processes had been effective in increasing plasma stocks*".

931. There was a meeting of the CBLA on 25 March 1986 for which I have been provided the minutes [BPLL0011012]. Dr Lane noted that the BPL was in a satisfactory position with regard to plasma supply, with "*the effectiveness of the SAG programme [being] particularly relevant*".

932. I have been provided the minutes of a meeting of the RTDs on 7 October 1987 [CBLA0002389]. At this meeting the issue of cross-charging was raised, and it was noted that "*about two thirds of the RTD's had replied indicating various degrees of lack of enthusiasm for cross-charging by their RHA's, particularly from Regional Treasurers*". Dr Ala noted that his RHA was proposing the BTS have no formal budget and would generate income from products and services made available to hospitals. He reported a parallel dry run was being undertaken, and expressed concern that "*areas of the service such as ante-natal screening would suffer as a result of clinicians reducing the number of samples in an ill-advised attempt to save money*".

933. I have also been provided the minutes of an RTD meeting on 20 January 1988 where the issue of cross-charging was considered further [PRSE0001355]. It was noted some RHAs were pushing ahead and representatives of the CBLA expressed enthusiasm for the principle.

934. I have been provided the minutes of an RTD meeting on 13 April 1988 [CBLA0002409]. At that meeting Dr Gunson reported that he was determining the costs for blood products for cross-charging.

935. Insofar as it assists, I note that I have been provided a table of annual plasma supply (including a percentage of plasmapheresis) for the period 1975-1989 [NHBT0017098]. The table is headed "*Supply of fresh frozen plasma from RTCs 1975-1985*" so it is unclear to me whether for 1985-1989 these are actual or predicted numbers. For

1985 plasma supply is 238,258 with 8.4% by plasmapheresis. By 1989 the figure is 433,000 with 16% by plasmapheresis.

Period 1988 onwards

936. I have been provided the minutes of a meeting of the RTDs on 20 January 1988 [PRSE0001355]. At that meeting there was a discussion of changing the gaps between donations. Following discussion there was "*support for changing to a minimum interval of 16 weeks between donations allowing three donations per annum for male donors*".

937. I have been provided the minutes of a meeting of the CBLA from 28 July 1988 [CBLA0004826]. At that meeting there was a discussion of increased targets, set out in my answer to Q18 above. It was noted that to meet the increased need for plasma it would be necessary to increase plasmapheresis; new centres would be needed and funds would need to be provided.

938. I have been provided the minutes of a meeting of the CBLA on 22 September 1988 [NHBT0015546]. At that meeting Dr Gunson noted that 550 tonnes of plasma was the maximum that the CBLA could expect from the RTCs, and that any increase above this would need to come from yield improvement.

939. I have also been provided the minutes of a meeting of the RTDs on 18 January 1989 [NHBT0018188]. At that meeting some of the particulars of the cross-charging scheme were provided, and it was noted that the scheme was proposed to be introduced on 1 April 1989. The minutes also have some significant discussion of how cross-charging will work for BPL.

940. I have been provided the minutes of a CBLA/NBTS Liaison Committee meeting on 8 March 1989 [NHBT0000077_037]. Those minutes set out the detail of the ordering process. It was noted that because of variable supply, RTCs would supply plasma to BPL which would weigh

it and reconcile with the RTC. The RTCs would then invoice for plasma on a monthly basis. It would appear that further detail on specific prices and procedures for cross-accounting is addressed in other CBLA/NBTS Liaison Committee minutes.

941. I have been provided the minutes of a meeting of the Management Committee of the National Directorate of the NBTS on 2 November 1989 [NHBT0046964_001]. At that meeting steps taken to attract and retain donors are discussed. It would appear from the other Management Committee of the National Directorate minutes that I have been shown that such discussion was a regular occurrence. There was also a lengthy discussion of the apheresis working group being coordinated by Dr Robinson.

942. I am also aware that there was a meeting of the Management Committee of the National Directorate of the NBTS on 5 July 1990 [NHBT0046958_002]. At that meeting there was a discussion of the Provision of Donors Committee's paper on communications strategies, for communication with donors. It was strongly recommended that RTCs adopt the proposals in the paper.

943. These matters are also identified in *Fifty Years of Blood Transfusion* [NHBT0000028] where the authors from p.80 onwards identify some of the changes made in the National Directorate period of the NBTS. Such work includes:

a. The inter-regional transfer of blood: from *Fifty Years of Blood Transfusion* it would appear that the RTCs would provide details of their blood stocks each day to the central office and the National Directorate would then arrange for supplies to be moved around. The authors describe this as successful, and they note only one case of adverse publicity due to a shortage of stock.

b. Blood-donor retention and recruitment: the authors describe Dr Moore chaired a working party which took such steps as securing

an 0800 telephone number. There is also a description of the steps taken in advertisements and a major study undertaken into those donating. More detail is provided in *Fifty Years of Blood Transfusion*.

c. Cross-charging: as was already described above this was introduced in April 1989 and contributed to increasing plasma supply with the 8.82 tonnes per million population figure in mind.

d. The Gulf War: *Fifty Years of Blood Transfusion* describes the uptick of donations as a result of the Gulf War (from 17 January 1991). The authors report that there were 19,000 donations on the first day of the appeal. It is also noted that the RTCs were overwhelmed with donations, with the blood stocks remaining at a higher than normal level to autumn 1991.

944. In *Fifty Years of Blood Transfusion* [NHBT0000028] at p.84 there is a discussion of some of the work done by the NBA. One such item is *"[i]ncreasing efficiency of blood collection to accommodate demand*". The authors wrote there:

Over the past 2 years the demand for blood has increased by 3-4% each year. To meet this increase in demand the NBS is reviewing its collection programme to achieve flexibility so that donors can more easily find a convenient blood-collection session. Collection venues are being assessed for accessibility, the provision of general facilities and for confidential donor interviews (see above). Working practices are being reviewed to improve session organization and reduce wait times.

It has been noted previously that blood-collection teams have not always been based in the most convenient venues; several hours each day have been spent in travelling when some of this time could be used for collecting donations. The process of siting collection teams

closer to the donors has begun, with one based on the Isle of Wight and one in Thetford, Norfolk. Apart from logistical advantages, such teams can engender close links with the local community, improve knowledge of blood-collection premises and provide opportunities for publicity and recruitment.

945. The position of the collection of plasma in the late 1990s onwards is discussed in my answer to Question 18. For the 1990s I have had more limited documents and am aware that various clinicians working at the NBA/NHSBT in that period are providing evidence personally and on behalf of the institution.

40. How effective are NHSBT's current functions, policies and practices in ensuring the sufficiency of the blood supply in England? Please compare the current approach with the historical approach, highlighting significant differences and developments.

946. As with the answer to Q39, this answer should also be read alongside the answer to Q18. The former addresses the steps taken to improve the supply of plasma from the blood service; the latter addresses the setting of plasma targets. In this answer I am considering whether in fact the blood service did meet those targets. In respect of the historical aspects of this question, for which I have no first-hand knowledge, I place particular reliance on the four documents that I have already identified.

947. I explain the position regarding the collection of plasma in the UK from 1998 to 2021 in my answer to Q18.

948. As with my answers to Q18 and 39, there are two aspects to my reply. Firstly, around meeting the requirements for blood components, although I recognise this is of lower importance for the Inquiry, but I include these today to demonstrate how NHSBT has learned lessons from the past. However, largely for my reply to this question and Q18

and 39 I have focused more on provision of plasma for fractionation and specifically for meeting the need for Factor VIII (rather than other plasma derivatives) as this appears to me to be most in issue for the Inquiry. Further information on these other products is available if the relevant minutes are reviewed.

949. In line with the Committee on Safety of Medicines decision in 1998, we have not collected plasma from implementation of that decision. As a result, it is hard to draw meaningful comparisons between this period and the position further back in history in respect of collection. Insofar as it assists, I have provided comment at the end of the answer to this question.

Current position

950. This part of my answer addresses NHSBT's ability to meet the requirements for blood components today.

951. Currently, NHSBT measures its ability to provide a sufficient supply to hospitals through an industry standard measure of "On Time, In Full" performance. Over 2020/21, NHSBT achieved OTIF performance of 98.6%. In February 2021, this number was 98.84%[57]. In April 2021 the figure was 98.8%[58] Where NHSBT was unable to fulfil demand "in full", a clinically suitable alternative product was provided. The last 5 year's OTIF performance is summarised below:

2016/17	2017/18	2018/19	2019/20	2020/21
97.0%	98.1%	98.4%	98.4%	98.6%

[57] NHSBT Board Performance Report February 2021 at pg. 3[WITN0672066]
[58] NHSBT Board Performance Report April 2021 [WITN0672067]

952. In 2019/20, the percentage of hospitals scoring NHSBT 9 or 10 out of 10 for Overall Hospital Satisfaction was 77%, while the percentage of donors giving NHSBT this score for Overall Donor Satisfaction **('ODS')** was also at the highest on record at 78.4%.[59] In February 2021, the ODS percentage was at 81.4% against a target of 75%[60].

953. The current structure of NHSBT and the relationships it maintains with other institutions is crucial to maintaining the blood supply currently. There is a coordinated approach with a single national management and leadership structure. The Blood Operations Leadership Team oversees this approach and includes membership from Donor Experience, Blood Supply, Clinical Services, Finance and many other departments. By having this oversight and unified approach, NHSBT can quickly assess the situation of the blood supply and take appropriate steps to remedy any deficiencies.

954. NHSBT also has a good relationship with the DHSC Sponsor team. We hold quarterly accountability review meetings with them and maintain communications with them regularly. In addition, the DHSC attend all our Board meetings to ensure they are fully informed of the work that NHSBT is doing, which includes in respect of sufficiency of the blood supply.

955. Through increased data provision and more coordination in the relationships with our customers, NHSBT is able to better arrange the supply of blood. This includes the coordination and relationships maintained through the National Blood Transfusion Committee. We also have a range of internal data collection systems which allow us to maintain a good understanding of supply and demand on the blood supply.

[59] NHSBT Annual Report 2019 – 2020, pg. 24 [WITN0672060]
[60] NHSBT Board Performance Report February 2021 at pg. 3[WITN0672066]

956. Aside from data collection, we have significant infrastructure and tools in place to understand demand and supply. These include computer models which predict demand; and processes to manage it. We are able to communicate internally and with donors by fast and efficient modern means of communication.

Historic summary

957. For the period 1976 to 1977, the documents I have seen indicate that, broadly, the provision of plasma was either increasing to meet the target amount or had satisfied the target amount. It would appear that by the end of 1977 there was more capacity, and it was later noted that plasma provision had been broadly static from April 1977.

958. For the period 1977 to 1984, the period appears to have been marked by significant increases in plasma targets. There appears to have been an initial tailing off of production which somewhat improved over time. However, significant improvement appears to have been limited in a major way by a lack of sufficient funding from RHAs. I have reviewed part of Dr Lane's statement from the HIV litigation, and he appears to indicate that the provision of plasma from 1982 was broadly in balance with the available capacity at BPL and PFL combined.

959. For the period 1985 to 1988, it would appear that there was an initial shortfall in production from the papers. However, this appears to have been mirrored by delay in the development of available capacity at BPL. It would also appear that the SAG (M) programme made a significant impact on the availability of plasma such that by 1986-1987 it was BPL pushing back targets for plasma. This would appear to be in accordance with the statement of Dr Lane for the HIV litigation that the situation between supply and fractionation capacity was in balance. I also note that there appears to have been stockpiling in effect at BPL. Because of the introduction of HIV testing it would

appear there was an issue that some of this stockpile had not been tested at the time of donation.

960. For the period from 1988 it would appear that BPL's capacity to fractionate came on-line and thus plasma production by the RTCs fell behind targets (although it was covered in part by the available stockpile). This would appear to have recovered in 1989. In 1990 it would appear there was a significant increase again in plasma targets as a result of demand, albeit the reports for 1991 were that plasma production was on or near target. Indeed, reminding myself of my answer to Q18, it would appear there was some concern BPL might not be able to purchase all of the plasma obtained by RTCs. This position of RTCs meeting targets appears to have broadly continued from then based on the documents I have been shown. Indeed, reminding myself of my Q18 answers, it would appear that demand was dropping off around 1993 (possibly because of recombinant introduction).

961. I have had limited access to information about plasma supply in the NBA era. As explained in the answer to Q18, plasma ceased to be collected in England and Wales due to vCJD following the 1998 Committee on Safety of Medicines recommendation.

962. I would note that, as is set out in Q18, the significant and constantly increasing plasma targets presented a moving target through the documents I have read (from 1975-1990 in particular). There are various occasions where the service met targets set, only for them to be revised significantly upwards.

963. From my reading of the documents, I think that the supply of blood components historically was largely not an issue, although I note four cases where shortages were noted in the document below between 1984 and 1989. I suspect that the reasons for this were that the driver for plasma targets in the 1970s-1990s meant that there were sufficient donations collected to meet the demand for red cells and platelets.

964. I have again adopted the division of the periods set out in Q18. This is for ease of reference rather than identifying specific events and time periods – the period is one continuous one.

Period to 1977

965. I have been provided the minutes of the RTD meeting held on 21 January 1976 [NHBT0016480]. At this time Dr Maycock reported that the total volume of plasma for albumin for the last quarter of 1975 had equalled that available in the second quarter of 1975. He also reported that the amount of fresh plasma from the AHG programme would improve the position further in 1976. Because of repairs due to begin at BPL, it was thought that amounts of normal immunoglobulin and albumin would diminish, but it was thought reserves were at that time sufficient to maintain supplies at a level present for that time. RTDs had also reported that consumption of red cell concentrates was growing.

966. I have also been provided the minutes of the RTD meeting on 17 March 1976 [NHBT0016478]. Dr Maycock reported that the volume of plasma received at BPL was increasing and the amount of FFP received in February was only 300 donations short of that for 31 March 1976. The increasing use of red cell concentrates was also noted.

967. I understand there was a meeting of the RTDs on 26 May 1976 for which I have been provided the minutes [NHBT0016477]. At that meeting Dr Maycock reported the volume of time-expired plasma sent to BPL was being maintained, and the RTDs were increasing the volume of FFP for AHG in accordance with the programme. At the meeting it would appear RTDs were asked whether they could hold back 5 litre bags of frozen time-expired plasma since BPL's cold storage capacity was rapidly filling while repairs were being done. Later into the meeting the FFP intake was reported as on target, but

that the needs of haemophilia would likely exceed the estimates on which the current programme was based.

968. I have been provided the minutes of a meeting of the RTDs on 21 July 1976 [NHBT0017095]. At the meeting the Chairman reported that supplies of plasma for the production of AHG concentrate were reaching the central laboratories in accordance with the Department's schedule.

969. I have also been provided with the minutes of a meeting of the RTDs on 6 October 1976 [NHBT0016475]. The Chairman reported:

…although three centres still had some way to go, 90 per cent of the current plasma production for Factor VIII Concentrate had already been achieved, although it was suggested that this might be at the expense of time-expired plasma.

970. I have also been provided the minutes of a meeting of the RTDs on 8 December 1976 [DHSC0105496_010]. In respect of the current plasma supply scheme the Chairman reported:

…that the plasma production target for December 1976 was likely to be achieved. Prospects for the coming year were clouded by the expenditure constraints on RHAs. Mr Dutton said that as a further allocation of central money was most unlikely, it was all the more important to make efforts to improve the yields of active factor from the available material.

971. I have been provided minutes from the Regional Transfusion Director Meetings for 1977 which appear to indicate that, until the end of the year, plasma provision was close to or on target:
    a. [NHBT0016473]: the minutes for 2 March 1977 record that the amount of plasma reaching fractionation centres was on target despite the fact 2 centres had not yet reached full production.

b. [DHSC0002367_012]: the minutes for 4 May 1977 report that the quantity of plasma received by fractionation centres continued to be on target.
c. [DHSC0200019_002]: the minutes for 6 July 1977 report that the quantity of plasma received continued to be on target, and Dr Maycock hoped that centres would be able to maintain the supply.

972. I have been provided the RTD minutes for 14 December 1977 [NHBT0016469_001]. At that meeting Dr Maycock reported that BPL could fractionate more FFP and asked that those RTCs that could provide more plasma send it for fractionation into Factor VIII.

973. In Dr Lane's statement [CBLA0000005_002] when commenting on 1977 at para 135 he comments that in his view "*I am bound to say that at the time, so far as England and Wales was concerned, there was not yet enough FFP being provided to keep BPL and Elstree working to capacity*". It is unclear when in 1977 he was speaking to, or if he was speaking to the entire year.

Period 1977 to 1984

974. I have been provided a paper produced by Dr Lane dated 19 September 1979 titled *Future preparation of plasma protein fractions by NBTS: a reassessment of requirements* [CBLA0000998]. The paper noted that there has been a growth in the requirement during the 1970s for plasma products, "*an exercise in production maintained without adequate planning, co-ordination or finance from the outset*". Dr Lane reported that, in respect of the production of Factor VIII, production has been "*essentially static since April 1977, is at present deficient by some 30 M iu per annum. The deficiency will increase in 1979 and beyond*". He does not indicate whether the static nature of the production is due to lack of plasma or lack of fractionating capacity. As has already been mentioned in answer to Q39, Dr Lane notes in the section of his report commenting on plasma supply that:

The deficiencies lie within the NBTS and its administration since it has been shown that, freed from constraints, the NBTS could make NHS self-sufficient in blood and blood products.

975. I have been provided with the minutes of an ad hoc meeting of the RTDs from 26 September 1979 [DHSC0002195_044]. The report identified in the preceding paragraph was discussed at this meeting. At the meeting Dr Lane:

…drew attention to the fact that supplies of fresh frozen plasma were beginning to tail off in many regions. It was agreed that this was not the result of any shortage of donors but was generally due to shortage of money needed to maintain the level of plasma supplies. Regional Health Authorities were not sympathetic to requests by Directors for money to finance plasma collection if they were not to receive a proportional part of the finished factor VIII or PPF in return.

976. I have also been provided the minutes of the first meeting of the Advisory Committee on the NBTS on 1 December 1980 [CBLA0001207]. At that meeting AC (80)3 was presented with the current plasma figures and upcoming targets proposed for 1982. I have also been provided with this paper [CBLA0001209]. All of the RTCs were between 0.2 and 2.4 million iu away from that target for 1982 (save for Oxford which was recorded as already above target). In addition, I have also been provided the chairman's notes from this meeting which includes a table of usage of BPL product, RTC product and imports for the years 1973 to 1979 [DHSC0002201_056].

977. I have also been provided the meeting minutes for an Advisory Committee on the NBTS meeting on 31 March 1982 [DHSC0001136]. At that meeting a paper AC(82)2 was discussed. That paper has not been available to me. The meeting notes explain that there was a growth in plasma provision to BPL between 1979 and 1981. Dr Lane

reported that the upgraded BPL now had the capacity to process all the available FFP.

978. I understand there was also a meeting of the Joint Management committee of the Central Blood Laboratories on 27 April 1982. I have been provided the minutes for this meeting [DHSC0002217_011]. There was a discussion that Regions accepted the principle of self-sufficiency but were "*unable to commit resources immediately to increase plasma collection to the required level. It would be necessary to build up supplies in stages...*". Dr Lane also commented on plasma and explained that there had been an increase in volume and improvement in quality. He said that, as a result, the laboratory had achieved record production levels.

979. I have been provided the minutes of another Advisory Committee on the NBTS meeting from 17 October 1983 [CBLA0001763]. At that meeting paper AC(83)10 was presented, which I have also been provided at [CBLA0001762] and provides FFP figures for 1982 and early 1983. In respect of plasma supply Mr Winstanley reported that FFP provision was increasing but a dramatic rise would be needed to achieve self-sufficiency. Dr Lane reported that adequate supplies would be available until 1986.

980. I have been provided the minutes of a meeting of the RTDs on 18 May 1983 [CBLA0001707]. At that meeting it was noted that in respect of FFP "*[c]urrently 125 tonnes pa are received at BPL. Regions will be notified individually of targets required to reach the BPL capacity figure of 150 tonnes pa (RSL)*".

981. I am aware that there was a meeting of the Advisory Committee on the NBTS on 10 April 1984 [CBLA0001835]. At that meeting Dr Gunson commented on achieving targets:

…in mid-1983 RTDs were confident of increasing the supply of plasma to BPL to a self-sufficiency level. However, it was evident from a recent survey of RTCs (summarised in AC(84)4) that, because of resource constraints within Regions, Directors were now less optimistic of attaining their targets. Indeed, through the pro-rata method of product distribution, some Regions whose demands for albumin were being met in full, may now find it more economical to purchase commercially produced Factor VIII than to invest heavily in plasma procurement. The position was of considerable concern to both the CBLA and DHSS and the Committee's views were invited on the best means of tackling the problem.

982. A paper AC(84)5 was also produced. I have been provided that document [DHSC0002239_030]. It provides the FFP (and specific plasma) provision from 1981 to 1983.

983. I have been provided the minutes of a meeting of the CBLA from 26 September 1984 [CBLA0001896]. At that meeting plasma supply was discussed:

The Director BPL expressed concern that the plasma curve did not indicate sufficient momentum in the growth of fresh frozen plasma stock. He said that discussions had commenced with a contractor for the storage of plasma, although in the current financial year the FFP stock had only increased by 1,500kg against a targeted 10,400kg. Dr Gunson said that some regions had started to respond but only the Trent and NE Thames regions were progressing satisfactorily.

[…]

The Director BPL referred to the recent meeting he and the Secretary had held with officers of the West Midlands RHA. Dr Lane reported on the last meeting of the National Advisory Committee on Blood Transfusion when it had been evident that Regional Treasurers were

not being made fully aware of all the facts in the argument for ensuring that sufficient plasma was made available to BPL. It was agreed that Mr Williams would follow up this point.

Dr Thomas suggested that some form of contingency planning might be necessary if the required plasma supply looked in jeopardy. The chairman expected the DHSS to explain to the Regions the consequences they would face in this event, which might mean their being charged for products.

984. I have been shown the minutes of a meeting of the Advisory Committee on 8 November 1984 [PRSE0004783]. In respect of plasma supply to BPL the minutes record:

The Department had sought comments on progress from all Regions. The Committee noted that many had given only qualified or limited assurances, and considered it essential that BPL had the raw material to process; the Department should vigorously pursue procurement targets.

985. I have also been directed to Dr Lane's statement for the HIV proceedings [CBLA0000005_002] at para 64. In that paragraph he discusses BPL from the period that it was managed by the CBLA and works were undertaken to upgrade the facility. In this statement he noted:

Arrangements were also well in hand to ensure an adequate supply of FFP from Transfusion Centres to match the manufacturing capacity. From 1982 until the commissioning of the new manufacturing facility by 1988 the supply of FFP from Blood Transfusion Centres to BPL/PFL and the capacity to fractionate, were broadly in balance.

986. Aside from supply of plasma to BPL, there was also a paper AC(84)12 tabled on blood shortages. I have been provided access to this paper

[CBLA0001914_005]. On two occasions in London public appeals by radio, newspaper and television had been made for donors. One London hospital cancelled elective surgery as a result of one of the shortages, and on two separate occasions the Group O supply reached critical levels. Various factors were identified including bad publicity due to the introduction of blood handling charges, a reduction of industrial sessions due to the economic recession and publicity due to "*recent Old Bailey convictions*" [RLIT0001555] and [RLIT0001556][61]. The meeting minutes also note an uptick in cardiac surgery provoking a 20% increase in demand. It was noted that national media publicity to restore the London supply had caused problems in the provinces. It was noted that closer liaison between RTCs and management was required.

Period 1985 to 1988

987. For this period I begin by noting again the passage extracted from Dr Lane's statement in the HIV proceedings set out above.

988. I have been provided the minutes of a meeting of the CBLA on 22 May 1985 [BPLL0011025]. At that meeting there was a discussion of anticipated supply against targets for the next 4 years. It was noted there was a principal shortfall in 4 regions and there was a discussion of remedying this. It was noted in the minutes that "*DHSS was currently looking at mobility of plasma supply and additional finance*".

989. I have been provided the minutes of an RTD meeting on 30 September 1985 [CBLA0002212]. At that meeting there was a discussion of the provision of Factor VIII. As part of that discussion it was noted "*[n]ot all Regions have committed resources to plasma collection. Stockpiles are adequate to start production but a 10% deficiency is apparent by 1987*".

[61] I understand this relates to the trial of six individuals, including two senior staff from the Army Blood Supply Depot. I have been shown: [RLIT0001555] and [RLIT0001556]

990. I have also been provided the minutes of a meeting of the CBLA on 20 November 1985 [BPLL0011017]. At that meeting plasma supply was discussed:

Mr Williams reported an unchanged situation in regard to the expected plasma returns from Regions. He said that DHSS would have to closely monitor the figures already promised from RTC's.

Dr Gunson said that RHA's were currently looking at next year's plans and the matter of plasma supply was now at a critical stage. The Secretary expressed his concern that the problem Regions, in terms of supply, remained a concern and he thought that DHSS would have to continue to exert as much pressure as possible on them.

991. I have also been provided the minutes of a meeting of the Advisory Committee on the NBTS for 6 November 1985 [CBLA0002277]. Paper AC (85)5 was provided on plasma returns. This document has not been available to me. In respect of plasma supply the following provision was noted:

Dr Lane reported progress on the BPL project and said that commissioning would be gradual; he was concerned to maintain a quarantine supply of plasma. Mr Williams advised that the plasma supply situation seemed to be improving, with the forecast being a supply of 400 tonnes against 435 tonnes demand. It was agreed that the DHSS would continue to monitor the conversion of Regions' firm promises into action plans for plasma production.

992. It was also noted under blood shortages at that meeting that Edgware were "*importing*" blood due to exceptional demand and a fall in supply locally. It would appear this means obtaining blood from other RTCs. There were also difficulties elsewhere.

993. I have also been provided the minutes of a meeting of the Advisory Committee on the NBTS on 12 March 1986 [PRSE0000128]. At that meeting provision of plasma to BPL was discussed:

Dr Moore reported that the rate of plasma supply was at present generally satisfactory; BPL could advise how the supply curve related to the construction and commissioning curves when available. Dr Lane advised that SAG (M) processed had been effective in increasing plasma stocks. He now anticipated completion of the building by September; the date of completion of commissioning had been put back but some mechanical commissioning had begun.

994. I have also been provided the minutes of a meeting of the CBLA on 25 March 1986 [BPLL0011012]. Of note is the discussion of plasma supply in those minutes:

The Director BPL commented on BPL's satisfactory position at the current time in regard to its supply of plasma. The effectiveness of the SAG programme was particularly relevant. He said that this position had created some difficulties in regard to storage but these difficulties would be alleviated when additional cold storage facilities were available in May.

[…]

The Director BPL did highlight the main area of concern which was the four Regions which were not meeting their targets with a real solution likely to emerge within these Regions in the 4/5 year period.

995. In my answer to Question 18 I have provided the detail of the pushing back of plasma targets in 1986 as a result of the lack of storage, and will not repeat the full detail of these here. I have been provided the following:

a. [CBLA0002307]: a meeting of the RTDs on 24 and 25 April 1986. Dr Moore advised the Directors that because of uncertainty as to when BPL would be ready for full production, plasma targets have been modified so that, while eventual targets remained unchanged, the achievement of them could be delayed.
b. [CBLA0002312]: a meeting of the RTDs on 9 July 1986. There was a further discussion of the delay of increasing of the plasma targets due to delay in the commissioning of BPL.
c. [DHSC0002363_020]: a meeting of the CBLA on 22 July 1986. Dr Moore noted that plasma targets needed to be maintained with stocks being stored as necessary at BPL. It is noted that "*[h]e had been concerned to note in a recent BPL commissioning report that a slower rate of plasma supply was needed to alleviate storage problem*".
d. [CBLA0004966]: a meeting of the CBLA on 23 September 1986. Dr Moore confirmed that most Regions were up to target. The memo goes on to say "*[h]e referred to the target levels of plasma supply up to 1990 and the problems of maintaining the flow together with the storage at BPL*". There was also a discussion about an amount of stored untested plasma available at BPL.
e. [CBLA0004964]: a meeting of the CBLA on 25 November 1986. It was recorded that there was nothing to report on plasma supply. There was a further discussion on the stored untested plasma available at BPL.
f. [NHBT0087416]: a meeting of the CBLA on 29 January 1987. It was recorded that there was nothing to report in respect of plasma supply, although donations had dipped due to media interest in AIDS. There was further discussion on the stored untested plasma at BPL.
g. [CBLA0004844]: a meeting of the CBLA on 26 March 1987. There was nothing to report in respect of plasma. There was a further discussion on the stored untested plasma at BPL.

996. I have been provided the minutes of a meeting of the RTDs on 15 April 1987 [CBLA0002372]. There was a discussion about insufficiency of screened FFP or time-expired plasma being provided to BPL for albumin production. There was a discussion about dipping into the screened FFP stockpile for five to ten tons per month.

997. I am aware that there was a meeting of the CBLA on 24 September 1987 [CBLA0002385]. At that meeting Dr Lane reported that the plasma supply situation had not changed since the last meeting, and that they were receiving adequate supplies at that time. It was noted that when full production began in the new factory that would come under review. There was a discussion about the stock of untested plasma, and Dr Lane said he was still awaiting a directive on that issue.

998. I have also been provided the minutes of a meeting of the Advisory Committee on the NBTS dated 17 June 1987 [BPLL0007202]. At the meeting there was a discussion of the commissioning of BPL and use of plasma:

13. Dr Moore spoke to his Paper. Commissioning of the new Blood Products Laboratory (BPL) was going well, and the potential product output figures could be given with some degree of confidence. There had been a great clawback on delay which was cause for congratulation.

14. Dr Lane agreed that the plant was commissioning very well. He expected to put the first batch of Factor VIII through the building in July, and hoped the grievance over fees would not delay the process.

15. Dr Fraser said that RTDs had lost credibility because of the delays which had occurred at BPL; he thought there would now be more

difficulty in obtaining funds from Regions and the future plasma supply would suffer.

16. Dr Tovey asked to be assured clinicians would use the BPL product and asked whether a charging system would be introduced. Dr Moore advised this was being considered in the NHS Management Services Report; no decision had yet been made.

17. The Chairman advised that the Management Board would be informed of progress; meanwhile continuing regional support for plasma collection was imperative.

999. There was also a discussion concerning the stockpile of unscreened plasma at BPL. It was decided the 50 tonnes of FFP could be confirmed by validating the donations. This could be done by RTCs checking that all donors in the stockpile had subsequently tested negative. The time expired plasma was still under consideration, and there was significant discussion.

Period from 1988

1000. I have been provided the minutes of an RTD meeting on 20 January 1988 [PRSE0001355]. At that meeting it was noted that Greater London had a shortfall of approximately 50,000 donations (red cells) per annum. Dr Harrison proposed to write to other directors to establish if there were any surpluses. It was thought this could lead to contracts with London to supply the blood. There was a discussion concerning whether this was a nationwide phenomenon.

1001. I have been provided the minutes of an RTD meeting on 13 April 1988 [CBLA0002409]. At that meeting Dr Lane reported that fractionation was now exceeding supply by 180 tonnes per annum. He said once full production was achieved it would be necessary to readdress supply and distribution. Dr Gunson reported the Advisory Committee

of the NBTS wished to reconstitute the plasma supply group to deal with the projected shortfall by 1990 unless input increases.

1002. I have been provided the minutes of a meeting of the CBLA on 22 September 1988 [NHBT0015546]. At that meeting Dr Gunson noted that 550 tonnes of plasma was the maximum that the CBLA could expect from the RTCs, and that any increase above this would need to come from yield improvement. It was also noted that the plasma stockpile had been calculated in gross weight, which resulted in packaging being included. That would make a difference of 20%. It was also noted yields had been overestimated. (This has already been referred to in the answer to Q18). The Chairman said the Chief Executive would investigate internally and apologised to Dr Gunson.

1003. I have been provided the minutes of the CBLA meeting on 24 November 1988 [CBLA0002428]. At that meeting it was noted that the stockpile of untested plasma would be used to create a strategic reserve of fraction 5 at the cost of the Ministry of Defence.

1004. I have been provided the minutes of a meeting of the Management Committee of the National Directorate of the NBTS on 29 August 1989 [NHBT0000188_033]. At that meeting there was a reference to a shortfall of the blood supply in June 1989. The minutes note that the steps taken in response were discussed and a Mr. Stewart was making enquiries. It was noted that Bank Holiday periods "*will always be a problem*" due to the days off.

1005. I have also been provided the minutes of a meeting of the Management Committee of the National Directorate of the NBTS for 2 November 1989 [NHBT0046964_001]. At that meeting Dr Gunson reported that nationally the supply of plasma was on target during the first six months of the year.

1006. I am aware that there was a meeting of the National Blood Transfusion Service / Central Blood Laboratory Authority **('NBTS/CBLA')** Liaison Committee on 16 November 1989 [NHBT0017187]. At that meeting there was a discussion of plasma returns and it was noted that the quantity of plasma provided was in line with the target of 420 tonnes FFP for 1989/90. Dr Lane stated that "*unless there was an increase to the 480/490 tonne rate in the early part of 1990/91, the stock of plasma available at BPL would be insufficient to maintain an adequate amount in quarantine*". Dr Gunson considered that the plasma supplied should begin to increase in the early 1990s.

1007. I have been provided a table of overall plasma supply, including portion of plasmapheresis, for 1975-1989 [NHBT0017098]. The table is headed "*Supply of fresh frozen plasma from RTCs 1975-1985*" so it is unclear to me whether 1985-1989 are actual or predicted numbers. For 1985 plasma supply is 238,258 with 8.4% by plasmapheresis. By 1989 the figure is 433,000 with 16% by plasmapheresis.

1008. I have been provided the minutes of an NBTS/CBLA Liaison committee meeting on 1 February 1990 [NHBT0000063_047]. At that meeting it was noted that supply of plasma was up to the target 420 tonnes for April 1989 to March 1990.

1009. I am aware that there was a meeting of the NBTS/CBLA Liaison Committee on 18 June 1990. I have been provided the minutes [NHBT0000066_056]. At that meeting it was noted that the 1989/90 plasma supply exceeded target. The April/May 1990 figure was below the monthly target for 1990/91, but this was thought atypical. An appendix is provided to this document with plasma returns. For 1989/90 it records 370275.8kg recovered plasma; 62759.0kg apheresed plasma; and, 12091.4kg special plasma. The total was 445126.3kg.

1010. I have been provided the minutes of a NBTS/CBLA Liaison meeting on 26 September 1990 [NHBT0017193]. At that meeting it was noted that the returns for the 4 month period indicated a shortfall which would amount to 40 tonnes by April 1991 if plasma was obtained at the same rate.

1011. I have been provided the minutes of a meeting of the Management Committee of the National Directorate of the NBTS for 25 October 1990 [NHBT0071860_002]. At that meeting it was noted that the demand for Factor 8Y was already above target and expected to increase further. It was noted that the NBTS would need to collect 500 tonnes of plasma or 9.7 tonnes per million population. It was noted that the half year figures for 1990/91 showed that plasma collection was below target and those RTCs below target had been urged to catch-up.

1012. I have been provided the minutes of a meeting of the NBTS/CBLA Liaison Committee for 16 January 1991 [NHBT0000065_019]. At that meeting it was noted plasma collections to end of November were very close to target and the outlook for achieving the annual target looked promising.

1013. I have been provided a graph of plasma supply to BPL for the period October 1989 to February 1991 [NHBT0017203].

1014. I have been provided the minutes of an NBTS/CBLA Liaison meeting for 10 April 1991 [NHBT0000077_056]. The minutes record that the data for April 1990 to February 1991 indicate that the 1990/91 target would be met. Dr Lane commented that the quantity of recovered plasma in the last year "*was most encouraging compared with some years ago and considered that RTCs should be congratulated on this achievement*".

1015. I have been provided the minutes of a Management Committee of the National Directorate of the NBTS meeting for 7 September 1992 [NHBT0071601_001]. At that meeting there was a discussion of plasma targets and stockpiles:

At present the BPL stockpile consists of 207 tonnes of recovered plasma and 25.6 tonnes of apheresed plasma totalling 232.6 tonnes.

The usage during 92/93 is expected to be 573 tonnes with an additional 12 tonnes of specific plasma. The target collection for 92/93 is 531 tonnes with an additional 8.6 tonnes specific plasma. The forecast usage by BPL during 93/94 is 560 tonnes.

All remaining non-HCV tested plasma at BPL, with the exception of some specific plasma will have been used and issued before 31 December 1992. DH have made representations to Brussels on behalf of BPL to allow the specific plasma to be used after 1st January 1993 but this is unlikely to be granted.

1016. I see from documents I have been provided that there was an NBTS/CBLA Liaison committee meeting on 9 September 1991 [NHBT0097471_015]. At that meeting plasma supply for April-July 1991 was discussed, and it was noted that this was slightly below target for the period. It was explained this was the normal pattern when the bank holidays in the period were taken into account. It was agreed no action needed to be taken to modify the regional targets at that time.

1017. I have been provided the minutes of an NBTS/CBLA Liaison committee meeting on 12 December 1991 [NHBT0017208]. At that meeting it was noted total plasma supplied to the end of November was 4% below target. A hope was expressed this would be made-up by March 1992.

1018. I have been provided the minutes of an NBTS/CBLA Liaison committee meeting on 15 June 1992 [NHBT0017221]. At that meeting the "*excellent achievement of RTCs in meeting targets for 1991/92 was noted*".

1019. I understand from documents I have been provided that there was a meeting of the NBTS/CBLA Liaison committee on 16 September 1992 [NHBT0017224]. At that meeting it was noted that Dr Williamson of Cambridge RTC had said she could supply an extra 2 tonnes of plasma. Dr Moore recommended this offer should be accepted as there was "*inevitably a shortfall at one or more RTC by the end of the year*".

1020. I have been provided a meeting of the RTC/BPL Liaison committee meeting on 27 October 1993 [NHBT0015802]. I understand the NBA was formed on 1 April 1993 which would appear to explain the change of name. At that meeting a paper for plasma supply in September 1993 was provided, which I have not had access to. It was reported that regional plasma performance for the month were 17.8% ahead of target with only South Western in shortfall. 53 tonnes of FFP were sent to BPL. There was also a survey of the last six months of plasma supply and it was noted that 278 of 273 requested tonnes of FFP had been provided, and it was thought this would level out by March. The minutes go on to note:

Centres have been asked to cut down on their plasma pheresis programmes as BPL required less plasma next year. The smaller centres have made a reduction of 18 tonnes and Mr Savery was meeting the four main centres next week to discuss their proposals and look at the cost implications.

1021. On 20 May 1994 there was a meeting of the RTC/BPL Liaison committee [NHBT0000542]. Data was supplied for October and November 1993 for which I have not had access. The minutes note

that "*[i]t was considered that the excess over target in this period would even out before the end of the financial year*".

Comment

1022. I have been asked to compare the historic and current position as part of this question. Unfortunately, because of the significant differences between NHSBT today and the blood service pre-1994 it is hard to undertake such comparison. Prior to 1994 it was not a central service, and from 1998 plasma supply ceased to be a notable part of what the NBA, now NHSBT, does. Such distinctions make the situation very hard to find any point of great comparison. However, I would make the following observations

1023. The comparison between supply of blood components today and blood components historically is difficult as they have very different drivers. What I would say is that largely the papers that I have seen do not reflect a lot of difficulty providing blood components for transfusion other than in a few cases. This is similar today.

1024. I have not seen many documents from the 1990s and 2000s where I understand blood component shortages were much more frequent (albeit largely managed within the blood services as I understand it). I have already noted above that I believe previous colleagues were more involved in these issues and, having not seen documents on the point, others are better placed to comment on this if required.

1025. I don't know, but I suspect, the reasons for this were that the driver for plasma targets in the 1970s-1990s meant that there were largely enough red cells and platelets. This was because the driver for plasma meant so many whole blood donations were collected that there were more than sufficient red cells and platelets available and although there may have been some occasional regional or short terms shortages this was not a common occurrence

1026. Furthermore, once plasma was no longer collected for fractionation the driver for blood component collection was driven by hospital usage which for a period of time increased year on year, resulting in some shortages which at times I understand from colleagues were not uncommon, and required some management.

1027. Comparison on the production of plasma for fractionation historically and today is difficult as collection for plasma for fractionation today is new and not yet well established. However, today's model is different with a substantial component of plasma collected by plasmapheresis today. Recovered plasma would only meet around 15% demand for immunoglobulin self-sufficiency, which is the major driver today. This is different to the historical model where plasma from plasmapheresis was only a small proportion of the plasma collected.

1028. Finally, perhaps the most significant difference between the historical position and today is the organisational structures and subsequent funding streams. The level of control that regions had over the funding for each individual RTC appears to have been a distinct issue in the late 1970s and 1980s, when RTCs and even the DHSS seem to have tried with only limited success in some regions to encourage the RHA to invest significantly in plasma production. While funding is still a significant matter for NHSBT, that historic funding was not centralised and required each RHA to be convinced to invest in plasma production appears to have been a significant difficulty. More generally, it is striking that plasma was the most significant driver for the blood service up until 1998. This is in common with many international blood services today who are striving to reach self-sufficiency for immunoglobulins. Having ceased collection following the 1998 decision, this has been in stark distinction to the modern blood service in England more recently. However, as we now start to collect plasma for fractionation and aim towards self-sufficiency for immunoglobulins it is important for all parties involved to learn lessons from the past.

Section 9: Safety of modern blood supply

One of NHSBT's responsibilities is "to optimise the safety… of blood, organs, stem cells and tissues and match them to patients". Another is to "help to raise the quality, effectiveness and clinical outcomes of blood and transplant services", as is to "commission and conduct research and development to improve outcomes for patients".

41. How does NHSBT understand its responsibility to ensure the safety of the blood supply in England? Has this responsibility changed over time in nature and / or extent? If so, please provide details.

1029. NHSBT is a national organisation operating across England. One of its responsibilities is to provide a safe and consistent supply of blood and components. In undertaking that responsibility, NHSBT takes a "*safety first*" approach where "*[t]he safety of our donors, colleagues and the patients we serve continues to be at the forefront of everything we do*" (Annual Report 2019-2020 p.13 [WITN0672068]). In that role it is our responsibility to optimise the safety of blood.

1030. Whilst this is undoubtedly our intent it should be stressed that the transfusion of blood components is not, and is unlikely ever to be, risk free. Transfusion services work within the confines of the NHS structure and budget and decisions should be made in this context eg on the basis of cost effectiveness within the greater system. With this in mind, as it is true internationally too, the Alliance of Blood Operators developed a Risk Based Decision Making Framework[62] which has been adopted by ABO Blood Services and within the UK JPAC and SaBTO. This contains the concept of risk tolerability which SaBTO are currently reviewing from a UK perspective. If it is accepted that transfusion is inherently not risk free, then the two concepts of education of professionals and informed consent of recipients become paramount.

[62] https://www.allianceofbloodoperators.org/abo-resources/risk-based-decision-making.aspx

1031. Blood safety policy today is broadly approached in the same manner across all of the UK Blood Services and this is described further in my answers to question 42.

1032. I have read the answers provided by previous senior blood service clinicians to Question 1 of the request under Rule 9 of the Inquiry Rules 2006 dated 14 August 2020. It is the corollary of the duty of care that we owe to patients and donors that we optimise the safety of blood, help to raise the quality effectiveness and clinical outcomes of blood services, and commission and conduct research and development to both improve the safety and experience of blood donation and improve outcomes for patients.

1033. As has been discussed elsewhere, the blood service was not a centralised service until 1993/94. As such, it is difficult to provide evidence of what the individual RTCs were doing prior to that point in history. As I joined NHSBT in 2010, it is also difficult for me to provide evidence of what the blood service was doing prior to that date. Insofar as I do make comment, I base this on the documents and information that I have been provided with by those advising me.

1034. The answers to Question 1 of the rule 9 request to NHSBT on 14 August 2020 provides much of the answer to this question. In addition, I refer to the answers to the remainder of sections 9 and 10 in explaining how we have understood our duty, how it has changed over time, and how we have discharged that duty.

1035. Whilst NHSBT has a duty to provide safe and effective components to hospitals and will provide education and guidance on the best and optimal use of these, their use in hospitals is the responsibility of those bodies providing care to the patient.

Collection and use of blood outside the blood service

1036. I am aware that in the past within hospitals blood was collected from members of staff or the public in some situations. This was not part of our service and was largely beyond our knowledge and control. As I understand it, this was for various reasons, including the support of pioneering surgery, in which fresh blood was regarded by some as having the best effect, or to treat babies who only needed a small amount of blood. The blood was tested for blood group before use but not for the routine microbiology tests which would have been standard in the blood service at the time. I understand that this was largely done without the knowledge or control of blood services. However, I have also heard from colleagues that where blood services were aware of this, they attempted to educate individuals to stop this practice over which they had no direct control. I have no personal knowledge or experience of this occurring, but it appears from conversations that I have had, that this was a practice that happened in the past.

1037. As a short summary, NHSBT will work with other stakeholders who also have a responsibility in ensuring blood safety as described in my answer to Q42. We also ensure that we comply with regulatory standards which have patient safety as a driving principle or tenet, we follow relevant guidance and we comply with instructions from Ministers, or the DHSC more generally, in all aspects of blood safety. However, it should also be recognised that as a DHSC Special Health Authority, NHSBT has a Board, and operational decisions regarding how we effect these instructions, guidance and standards may be a decision for the Executive team or the Board, this includes decisions made in procuring testing solutions (including the pooling of samples), of introducing initiatives that may be more cautious than guidance allows for and (after discussion with DHSC) for the timescale of implementing changes.

42: Does NHSBT share its responsibility to ensure the safety of the blood supply in England with other stakeholders (for example, government

departments or other medical / public health organisations)? If so, please provide details.

Current position

1038. Responsibility for ensuring the safety of the blood supply in England is shared between a number of organisations, including NHSBT, the Department of Health and Social Care ('DHSC'), Public Health England ('PHE'), the Medicine and Healthcare Products Regulatory Agency ('MHRA'), and the various committees and bodies referred to below combining the expertise of various health organisations.

1039. As blood safety policy recommendations and guidance is formulated across the UK, rather than for each nation separately, we share the responsibilities of the output of JPAC, as described below, with the other UK Blood Services. Each nation and service will decide how this is implemented within their blood service.

1040. Generally speaking, measures to maintain the safety of the blood supply in England fall into one of two broad categories: first, having appropriate policies in place around donor selection and, subsequently, donation testing and; second, having sufficient surveillance systems to ensure that such policies are working effectively. We also focus on education so that recipients are only transfused when this is in their best interest, and after being appropriately consented, and also to minimise errors performed by people working across the system. By doing so we reduce the risk of an adverse event in the recipient.

1041. The Secretary of State for Health and Social Care shares responsibility for the safety of the blood supply in England via DHSC. This is provided for in the BSQR 2005. In actuality, that role is fulfilled by the MHRA (see below). SaBTO is DHSC's expert advisory committee which includes within its remit advising 'on the most appropriate way to ensure the safety of blood, cells, tissues and

organs for transfusion / transplantation'. SaBTO provides independent advice on risk management for Ministers, UK Health Departments, NHSBT and the wider NHS. In formulating its advice, SaBTO will, among other things, interpret and where appropriate, commission risk assessments from a wide range of sources including DHSC and Public Health England, UK Blood Services, other advisory committees such as the Advisory Committee on Dangerous Pathogens, and independent researchers.

1042. SaBTO moreover takes full account of scientific uncertainty and assumptions used in researching conclusions, and clearly conveys the nature and extent of such uncertainties with its advice [WITN0672069]. Independent experts are appointed to SaBTO on the basis of their relevant expertise; current membership includes three senior staff from NHSBT with expertise in tissues, blood service operations and epidemiology and public health. There are also two lay members who provide important contributions to the work of SaBTO, one of whom currently also works for NHSBT. In addition, the Chair of JPAC, the Medical Director of Serious Hazards of Transfusion, SHOT (both of whom are currently NHSBT Consultants) and the other UK Blood Service Medical Directors have observer status at these meetings. I am a member of SaBTO representing the medical directors of the UK blood services. Minutes for around the last 10 years are available through the Government website and the National Archives.

1043. SaBTO members mainly perform this work in addition to their normal roles and, in common with many advisory and similar committees, this work is not recompensed other than through a substantive employer who will have its own requirements of the individual. There is often substantial amounts of work to be done by working groups outside the committee meetings themselves. Some may negotiate time within their normal employment to do this work but for others this is done in time outside normal employment.

1044. The responsible regulator in respect of the safety of the blood supply in England is the MHRA, which is an executive agency of DHSC. One sub-committee of the MHRA is the Commission for Human Medicines **('CHM')**. The CHM is discussed further in my answer to Question 18 in respect of the recent recommendations to approve plasma for fractionation. The MHRA regulates blood components for transfusion in the UK as well as medicines, and other medical devices. Specifically, the MHRA's responsibilities include '*ensuring that medicines, medical devices and blood components for transfusion meet applicable standards of safety, quality and efficacy*', '*ensuring that the supply chain for medicines, medical devices and blood components is safe and secure'*, and '*helping to educate the public and healthcare professionals about the risks and benefits of medicines, medical devices and blood components, leading to safer and more effective use*'.[63]

1045. The MHRA has moreover created a number of independent advisory committees to provide impartial advice to ministers about the regulation of medicines and medical devices. These committees may also establish working groups to address specific problems. One such committee is the Blood Consultative Committee, of which NHSBT is a member, as is DHSC, the other UK blood services, and the Haemophilia Society. The primary objects of the Blood Consultative Committee include to '*advise and provide information to stakeholders concerning the collection, testing, processing, storage, distribution and use of blood and blood components for transfusion*'. Minutes dating back to October 2014, and the presentations and papers produced by the Blood Consultative Committee, are available on the Government website.[64]

1046. I have set out some of the detail of JPAC in my answers to section 3. It has an important role in preparing service guidelines for, and being

[63] https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency/about
[64] https://www.gov.uk/government/groups/blood-consultative-committee

advisor to, the UK blood services. The details of the Red Book and the Transfusion Handbook are also discussed in my answers to section 3. I sit on JPAC as the Chief Medical Officer of NHSBT. The Medical Director – Organ and Tissue Donation & Transplantation in NHSBT has observer status and other members of NHSBT medical, scientific and other teams will be members of JPAC if they hold the Chair of one of the subcommittees described below.

1047. Within JPAC there are a further seven standing committees who have within their remit particular aspects of JPAC's work: the Standing Advisory Committee on Blood Components ('SACBC'), the Standing Advisory Committee on Care and Selection of Donors ('SACCSD'), the Standing Advisory Committee on Clinical Transfusions Medicine ('SACCTM'), the Standing Advisory Committee on Immunohaematology ('SACIH'), the Standing Advisory Committee on Information Technology ('SACIT'), the Standing Advisory Committee on Tissues and Cellular Therapy Products ('SACTCTP'), and the Standing Advisory Committee on Transfusion Transmitted Infections ('SACTTI').

1048. Each of these standing committees has its own remit but the following summary principles are of general application to each and every one of them: to prepare detailed service guidelines for the UK Blood Transfusion Services, taking account of the Blood Safety and Quality Regulations (2005) ('BSQR'); to provide professional and technical advice (where appropriate) to the four UK Blood Services; to provide documented summaries of the evidence and arguments on which these service guidelines are based; to keep guidelines up to date in the light of developments in scientific and medical knowledge and changes in the regulatory environment, consistent with good practice and the 'state of the art' provisions of the EU Directives and UK Regulations; to provide scientific, medical, technical (where appropriate) information for staff training; and, to ensure JPAC is kept

informed of any significant developments both nationally and within the remit of the standing committee.[65]

1049. When formulating its advice and guidelines JPAC will take into consideration guidelines from international sources and groups, including but not limited to the Council of Europe CD-P-TS[66], the Emerging Infections Group, and ECDC European Centre for Disease Control SOHO groups. This is particularly important for horizon scanning for emerging infections; some more detail is given in the next paragraphs.

1050. Since 2007, the NHSBT / PHE Epidemiology Unit has as part of its surveillance function undertaken horizon scanning for infections which may affect the safety or sufficiency of the blood supply. The Unit regularly scans publications for news of emerging infections relevant to blood, tissue and organ donation safety in the UK.

1051. The horizon scanning process performed in UK blood services is managed by the SACTTI and involves the robust analysis of a monthly Emerging Infections Report **('EIR')** compiled by the NHSBT/PHE Epidemiology Unit.[WITN0672141]

1052. The EIR includes information provided by a range of national and international evidence sources such as the European Centre for Disease Control, the European Infectious Diseases Monitor group of the European Blood Alliance, EpiIntel, the EU Rapid Alert System, the World Health Organisation and other literature.

1053. The EIR is then reported to the Chair of SACTTI for risk assessment and action by SACTTI and JPAC according to the Horizon Scanning – Management Process Description: Preparedness for emerging infectious agents (2021). [WITN0672070]

[65] https://www.transfusionguidelines.org/about/remits-of-the-jpac-standing-advisory-committees
[66] https://www.edqm.eu/en/blood-transfusion-work-programme.html

1054. NHSBT has recently asked our Internal Audit Team (Government Internal Audit Agency), in the light of EU Exit and the COVID-19 pandemic, to review the adequacy and effectiveness of the current NHSBT and JPAC processes for horizon scanning for emerging infections. They have given a 'Substantial' level of assurance.[WITN0672071]

1055. As noted above, measures to maintain the safety of the blood supply in England consist of a) policies, and b) surveillance. I have given more detail on surveillance in my answer to question 45. This surveillance function is covered by two bodies. Donor surveillance is carried out by the joint NHSBT/PHE Epidemiology unit on behalf of the UK and haemovigilance carried out by the Serious Hazards of Transfusion ('SHOT') haemovigilance scheme.

1056. International blood services work closely together and, whilst this is not a shared responsibility, work with bodies such as the Alliance of Blood Operators, the European Blood Alliance and the International Society of Blood Transfusion allows us to share knowledge and information to ensure that we learn from each other quickly and effectively.

1057. There are two other measures, more related to public health, that are carried out with other stakeholders and these are mentioned here for completeness.
    a. Since 1998, the HCV National Register has been based at PHE. The HCV National Register helps inform the natural history of HCV infection in the UK with patient data. The register contains data for one of the largest cohorts of patients in Europe who have acquired their HCV infections on a known date. Most cases are transfusion recipients who were traced during the national HCV lookback programme. Systematic collection of clinical data using standardised report forms allows PHE to gather data consistently

about every 3-5 years. NHSBT has a representative on the steering group for this register but it is managed by PHE and has a dedicated website within the PHE site. These data, along with linked mortality and cancer data for cases and controls, allow PHE and NHSBT to establish the clinical course of HCV infection, and investigate risk factors for progressive disease. The work of the HCV National Register is undertaken by a multidisciplinary team, under the guidance of an expert steering group.[67]

b. Similarly, since 2003, the HTLV National Register has been based at PHE. All UK blood services test blood donations for HTLV – the HTLV National Register describes the epidemiology of HTLV among blood donors as well as asymptomatic patients and their contacts in the UK. The HTLV national register collects information on a group of HTLV-1 infected individuals, their contacts, and follow-ups to investigate the signs and symptoms of disease or if they develop. HTLV diagnoses data from the NHSBT, which monitors HTLV infection in blood donors, are also incorporated into the surveillance dataset. The HTLV National Register is conducted by PHE in collaboration with NHSBT, Imperial College and colleagues at HTLV specialist referral centres.[68]

43: To what extent does NHSBT ensure the safety of the blood supply through its management and oversight of transfusion centres?

1058. As has been set out elsewhere in my answer to this Rule 9 request, NHSBT does not have transfusion centres. It is one centralised service that provides its services from various locations.

1059. From a management and oversight perspective, we have in place a number of management and assurance steps. These include the following; a system of clinical governance, a Quality Management System **('QMS')**, an audit programme (which includes clinical,

[67] https://www.gov.uk/government/publications/hepatitis-c-national-register
[68] https://www.gov.uk/guidance/human-t-cell-lymphotropic-virus-htlv-national-register

regulatory and internal audits), a risk management system and a haemovigilance programme (SHOT, which is described elsewhere). These assurance mechanisms are overseen by the Executive and Board members and committees including the Board subcommittee, the Audit, Risk and Governance Committee. These are described below.

1060. NHSBT has an Executive Director of Quality who holds the responsibility for regulatory compliance and a Chief Medical Officer who holds the responsibility for clinical governance in the organisation.

1061. NHSBT runs a 24-hour Consultant on call system across the country which can be accessed by any individuals in hospitals needing urgent (or other) clinical and/or laboratory advice relating to transfusion.

1062. Our Hospital Services departments are available to provide advice to hospital laboratories around the clock and will refer individuals or problems to the Consultants on call too, where appropriate.

Clinical Governance

1063. An international framework for clinical governance in blood services is described in the paper written by the ABO Medical Directors Group published in 2015. [WITN0672072] This details the components of good clinical governance in blood services, which should encompass:

- Corporate arrangements for clinical governance, including regular reports to Board/Executive team, who must show commitment and ultimate responsibility for clinical outcomes
- Monitoring measures of patient and donor safety, including surveillance for emerging infections, new trends and technical developments
- Assessment of potential risks to donors and patients, at a local, regional and national level
- Clinical effectiveness and appropriate use of donated material, including research uses

- The patient and donor experience, through satisfaction surveys, focus groups and review of complaints/legal claims
- Incident reporting, particularly where a donor or patient is involved
- Quality assurance/Quality improvement
- An effective clinical workforce, including personal development, appraisal and handling of poor performance
- Clinical audit of practice against external clinical guidance.

1064. NHSBT has a clinical audit department which performs clinical audits with a rolling three-year audit plan, recommendations from these audits are logged on the QMS to ensure that information sharing on lessons learned and actions are completed. Our approach to clinical audit is documented in POL132. [WITN0672073]

1065. We have a process for managing failures in patient safety which is formalised through our management of serious incidents which is defined in our controlled document MPD772 but also occurs through our routine operational management team and directorate clinical governance (CARE) meetings [WITN0672074]

1066. The levels of infections detected in donors is assessed each year by the joint NHSBT/PHE epidemiology team who publishes this annually and publicly through PHE as 'Safe Supplies' with a number of infographics to aid understanding. https://www.gov.uk/government/publications/safe-supplies-annual-review/safe-supplies-2018-monitor-inform-progress This report is considered by our clinical governance meeting (CARE) annually.

1067. Clinical risk is managed through our risk management processes more widely. This has a formal process described in our Risk Management Manual MPD 1336 and our Quality Risk Management document MPD 1094 [WITN0672075, WITN0672076]. These include the documentation, mitigation and management of strategic risks, clinical risks and organisational risks. Clinical risks include the risk of

transmission of an infection. For all risks there is a score using a conventional risk scoring matrix, a list of mitigations, a mitigated score and a target score. These are managed on an IT system called Pentana.

1068. Haemovigilance (SHOT in the UK) is described more in my answer to question 45 but is a key aspect of assuring blood services on the effectiveness of the processes described above and the outputs of the annual SHOT report are considered by the clinical governance meeting (CARE) in NHSBT to assess for future actions we need to take.

1069. The processes taken to ensure an effective clinical workforce are described in my answer to Question 46 on education and staff keeping up to date.

1070. Clinical audits on guidance which have direct effects on patient outcomes are led in hospitals by our National Comparative Audit team. Previous audits are available at https://hospital.blood.co.uk/audits/national-comparative-audit/

1071. Donor satisfaction surveys are taken on a monthly basis and a net promoter score derived and reported to the Board, which is currently 83% (eg 83% respondents scored 9 or 10/10 on a satisfaction score). Complaints from donors are captured by a Customer Services department and learning is derived from these. These are also shared with the Board on the NHSBT Performance Report, which also includes Quality and Clinical measures [WITN0672077].

Quality Management System

1072. The QMS is designed to provide the systems (and assurances) needed to meet regulatory and accreditation requirements. These systems and oversight are based on Good Manufacturing Practice principles which are part of the BSQR requirements. A crucial aspect

of this system is that management and oversight does not encourage the covering up of errors and does not produce a 'blame culture' which makes it less likely that people will come forward to raise concerns. This ensures that consequences for donors, patients, and the reputation of NHSBT are engaged with and understood. There are frameworks in place at the site and national level to ensure that issues can be escalated appropriately. There is also an emergency 24-hour Quality Assurance team number which is provided for internal advice.

1073. The Good Manufacturing Practice principles arise out of BSQR and are applied in the work that NHSBT does. This is to assure the quality of medicinal products, assure the safety, well-being and protection of the patient, and ensure consistent production and control of products.

1074. NHSBT identifies a number of elements that are particularly important to its quality assurance system. These include:

a. Audit: we undertake local and national self-inspections. These include process audits, for cause audits, and external inspection management.
b. Document control: as has been set out in section 2, we have various document management controls in place. This extends to control over the creation, identification, validation, approval, distribution and recall of documents.
c. Change control: we have in place various risk/impact assessments, approval procedures for plans to include stakeholders, extensive validation of decisions, and staged sign-off of decisions.
d. Adverse event management: we have frameworks in place for the investigation of such events and for corrective and preventative action within agreed timeframes.
e. Recall of products: we recall items which are found to later not meet specification.
f. Archiving of documents: I have addressed this issue in my answer to section 2.

1075. In respect particularly of quality assurance, we have various systems and tools in place to protect against failings. An important technique we use is root cause analysis to ensure the proper identification and categorisation of QA issues. We also have Q-Pulse which has event logging to ensure that there is an audit trail for events that need to be investigated. There is monitoring of trends within NHSBT through the QA team, and appropriate escalation where required. There is also management quality review which is linked to both the senior management team, BDCARE, and operational governance through BCS.

Assurance meeting papers and structure

1076. The assurance on clinical governance is discharged through our CARE (clinical audit risk and effectiveness) committees which are held bi-monthly. This is an executive subcommittee. A CARE report is seen at directorate senior management team meetings and by the Executive and Board.

1077. A Quality Management Quarterly and Annual Review is reviewed by both the Executive and Board. Regular Quality Directorate senior management team meetings are held (at least monthly).

1078. The NHSBT Board has a standing agenda item at every meeting on Clinical Governance which includes a section on serious clinical incidents, on other adverse events, and blood safety changes. These are also discussed in more detail (together with the clinical audit plan) at each meeting of the Board subcommittee: the Audit, Governance and Risk Committee.

1079. We have an executive subcommittee, the Risk Committee which ensures that risk is appropriately recorded and managed within the organisation and that this is done on an appropriate system for recording and managing risk.

1080. Items on risk are reviewed at the Risk Committee, the CARE committee and the ARGC.

1081. With respect to the historic position, I have commented on the level of control that the predecessors to NHSBT had over the RTCs in my answer to Q18. Insofar as is relevant to my other answers in sections 9-11, I address the control that the blood service had over the RTCs in the context of specific issues.

44: Please explain how NHSBT's functions and practices contribute to maintaining the safety of the blood supply in England. For example, you may wish to comment on the NHSBT's policies, guidance or practices that relate to:

a. identifying risks of infection associated with the use of blood and / or blood products;

b. risk reduction measures, including but not limited to donor selection policies, the screening of blood donations for infections, the tracing of blood donations and other policy measures;

c. sharing information with relevant stakeholders about infected donations;

d. sharing information to the public about infections that may affect the safety of the blood supply; and

e. achieving and maintaining self-sufficiency of the blood supply.

1082. As I have repeated in this statement, I have no first-hand knowledge of the historic position in respect of the safety of the blood supply, having only commenced working for NHSBT in 2010. As such, I have first set out the current and recent position at NHSBT, made up of my own knowledge and information that has been passed to me by other staff at the organisation. I will then turn to the historic position, relying on documents which have been shown to me by my advisors.

Recent position

Recent – summary

1083. NHSBT takes various steps to ensure the safety of the blood supply in England. At a high level, in addition to measures described in my answer to Q43 above, we do the following:

a. Educate donors on who is eligible to donate blood. Select donors according to guidelines set by JPAC as described elsewhere.

b. Clean the donor's arm as required by JPAC guidance using a strict, standardised and validated procedure for the preparation of the venepuncture site which is captured in our QMS documentation, failures of this are captured as quality incidents.

c. Divert the skin plug formed through the insertion of the needle into a sample pouch taking the first blood to be drawn to avoid skin bacteria which may remain after cleaning being drawn into the donation itself.

d. Screen blood and blood components for various infections. Some screening procedures are applied to all donations, some only to new donors and some are 'discretionary' and used only when indicated by risk factors identified when health screening the donor (for example lifestyle, country of birth or travel risks). If a donor is found to be positive for a screened infection, we notify the donor and investigate that person as appropriate. There will also be communication with the donor's GP if this is consented to. We will also defer the donor and mark their record on Pulse so that they cannot donate (either permanently or within a set period of time, depending on the infection or other issue).

e. We undertake other risk reducing measures. If a donor has been identified as having the markers of a positive test to a screening procedure, we will undertake appropriate tracing. We also refer

matters and take advice from the relevant JPAC standing committees.

f. We share information where appropriate with stakeholders. NHSBT has obligations to make notifications of infectious diseases to PHE. We will also receive information from bodies such as PHE which will allow us to investigate the possible onwards transmission of infection. We also have procedures for sharing information, where indicated, with other healthcare professionals such as GPs.

g. We take various steps to keep the public informed about donation. For example, we recently issued a new donor campaign to inform the public of the changes to our selection policy, which moves to a more individualised approach. NHSBT also makes a lot of its information easily accessible through publication online and the use of extensive infographics. In this example of moving to an individualised risk approach we formed this policy through the FAIR steering group, which involved various stakeholders from public life and patient groups (e.g. Stonewall, National Aids Trust, Freedom to Donate, Sickle Cell Society, UK Thalassaemia Society). This allows us to take in public concern, in this case about donation criteria.

Recent - Donor Education and Selection

1084. Education of the general public on the importance of who can donate blood and blood safety is one of the roles of our Donor Experience team. They provide information for the general public in our awareness and recruitment campaigns, on our website for blood donors www.blood.co.uk and in the leaflets given to donors prior to donating blood.

1085. Prior to giving blood, donors are required to complete a health check. This health check consists of a comprehensive questionnaire about medical history and lifestyle and enables NHSBT to assess whether it

is safe to give blood – the health check is additional to the screening described above. Donors are asked to read NHSBT's 'Donor Consent for Blood Donation' booklet, so they understand the importance of accurately answering the health check questionnaire (internal name INF1571 [WITN0672081]). A similar document exists for platelets and plasma donation (internal name INF1572 [WITN0672082]). These consent booklets make it extremely clear when a donor must not or never give blood or platelets. For example, it makes clear that individuals must never give blood or platelets if they are HIV positive, have HBV, HCV, HTLV or syphilis (or ever been treated for syphilis), or where a donor has ever injected, or been injected with, drugs. I also provide INF234 which is the more general welcome booklet which repeats some of this detail [WITN0672083].

Recent – Cleaning the donor's arm

1086. Clean the donor's arm as required by JPAC guidance using a strict, standardised and validated procedure for the preparation of the venepuncture site which is also captured in our QMS documentation, failures of this are captured as quality incidents. This, together with the requirement to divert the first part of the donation, is documented on their website [RLIT0001562]

Recent – Screening

1087. I start with a note on terminology; testing and screening are often used synonymously, however the term testing can, more correctly, be divided into 'diagnostic' tests (after which a patient can be given a diagnosis) and 'screening' tests (which whilst still valid and reliable, give indicative or early information but which require a confirmatory diagnostic test thereafter if applied to patients). Screening tests may have a higher false positive rate as not missing true positives is important in screening. The routine tests blood services apply to all donations are more correctly termed screening tests and confirmatory tests.

1088. NHSBT screens all donations of blood components for several bloodborne infections, including the following: HBV; HCV; HEV; HIV; and Treponemal (Syphilis) antibodies. Moreover, donations from first time donors are also screened for HTLV 1 and 2. Platelet donations are tested for the presence of bacteria using an automated bacterial screening system. Platelets are issued as 'negative to date' a minimum of 42 hours post-donation. Further detail of testing and how it is managed is in my answer to section 6.

1089. NHSBT also screens donors for 'discretionary' tests where a donor's risk profile puts their donation at a particular risk of specific infections, for example risks relating to travel, country of birth, and lifestyle. These discretionary tests include serology tests for antibodies to Malaria and *Trypanosoma cruzi* and Nucleic Acid Testing for West Nile Virus for travel risks. An additional test for HBV core antibodies may be requested where a donor declares past hepatitis of unknown origin or history of jaundice. More recently additional tests were introduced for antibodies to SARS-CoV2 as part of a convalescent plasma collection programme.

1090. Furthermore, certain specific recipients (for example babies or those immunocompromised) may require components that are negative for certain infectious markers, primarily CMV, and hence a subset of specialist components will have additional screening tests done on them.

1091. All routine screening is undertaken by NHSBT laboratories based in Manchester and Filton. Any positive or 'reactive' test is confirmed by another screening test. For those tests by serology (antibodies) two further screening tests are done and if one or both of these second tests are positive then these donations are termed 'repeat reactive'. For NAT (nucleic acid testing) these are done in pools and a positive pool requires each of the donations within it to be tested individually and the positive donations are then 'repeat reactive'.

1092. Repeat reactive donations then require confirmation by a different (confirmatory) test, these are done in other NHSBT laboratories. For more unusual or low volume tests we sometimes use external laboratories, and these are described in section 6, however these external tests are usually used for reasons other than for donor screening.

1093. Any donations that test positive or reactive in the initial test and that are confirmed positive on the second screening test and are thus 'repeat reactive' donations are automatically discarded irrespective of the results of the confirmatory test. The only exception to this is in the case of a donor testing positive for the discretionary test anti-hepatitis B core antibody (which we qualify with anti-HbS level) any are removed from the blood supply.

1094. Samples are normally tested on automated systems to minimise any risk of error – donation samples are labelled using the same barcodes used to label the donation and the screening results generated are then automatically downloaded directly onto the NHSBT core IT system. In the case of virology that will be PULSE. Product release is only enabled where the results are present and indicate that the products are safe for clinical use.

1095. All donors with markers of infection (except hepatitis E) and any possible transfusion-transmitted infections are discussed within NHSBT at a weekly multi-disciplinary team **('MDT')** meeting of clinicians, scientists and epidemiology experts to ensure and confirm that all risks to donor and any patients have been explored. For each donor the microbiology reference results are reviewed together with the information recorded during the post donation discussion when the donor was informed of their results and asked a series of standard questions related to possible risks. The post donation discussion also allows: the donor to ask any questions they may have; consideration of whether permission will be given for their GP to be informed if

indicated; and consideration of whether direct referral to specialist care will be made. If additional public health measures are required these can be discussed with the donor, for example, advising for other household members to be immunised against hepatitis B.

1096. NHSBT receives reports of possible transfusion-transmitted infection on a regular basis; a reporting form is available on the Hospital and Science website https://hospital.blood.co.uk/diagnostic-services/reporting-adverse-events/investigation-of-possible-transmission-of-non-bacterial-transfusion-transmitted-infection/ . These reports are reviewed and next steps discussed, for example requesting more information from the hospital or requesting stored archives for further testing. Discussions and action for individual donors are recorded in their clinical file. These regular MDT meetings have been minuted since January 2014. MDT did have meetings before this date, but they were not minuted; at that time the team was much smaller.

Hepatitis E is an exception, in part, from this process just described where there is routine discussion at the MDT. This is because, while if there was a possible TTI it would be discussed in this manner, routine positives are dealt with by a predefined process. Donors whose donations test positive for hepatitis E RNA are informed and given advice about their infection and that they will be deferred for 6 months before returning to donate.

1097. As is noted in my answer to Question 18, since 2020 NHSBT has been collecting plasma from donors. Currently, plasma donors are treated exactly the same as blood donors in this respect. The eligibility testing and release criteria are the same. As part of the NHSE process to award the fractionation contract to a manufacturer, NHSBT will be discussing additional tests required for fractionation. We have frozen additional sample tubes to allow this to be done at the appropriate time to allow fractionators to meet their regulatory responsibilities. It may be

that once a fractionator is assigned that further tests (e.g. for hepatitis A virus or Parvovirus B19) are undertaken.

1098. I have been provided with two blood safety timelines from the Safe Supplies 2018 report. Among a range of other things, those timelines show the various points at which different kinds of screening for blood and blood components were introduced. The timelines relate to viral and bacterial infections [WITN0672078, WITN0672079]. This document also includes the surveillance events for relevant infections. These documents were put together by the NHSBT/PHE Epidemiology Unit and the infographic was made by PHE.

Recent – Risk reduction measures

1099. In that event that a donor provides a relevant new or unusual history, this may be a previously undisclosed behaviour e.g. previous drug use; or finding out that partner is hepatitis B positive, that history will be discussed at the clinical multidisciplinary team meeting or MDT which is detailed in the section below entitled *Recent - Screening*. The MDT will decide whether a lookback exercise needs to be carried out. If there is no guidance on a particular risk this will be referred to JPAC SACCSD for consideration of an additional entry in the JPAC whole blood guidelines on who can donate blood. Or alternatively to SACTTI if there is a previously unknown risk for consideration of a risk assessment.

1100. The SACCSD has the following remit: to set, and update as required, guidelines for i) care, pre and post donation, of people who offer to donate blood and components; ii) donor selection to identify and exclude those for whom the act of donation could be unsafe; and, iii) donor selection to identify and exclude those whose donation could be unsafe, of inadequate quality, or contrary to relevant legislation. The SACCSD moreover, also advises on the staffing, environment, equipment and procedure for a blood donation session, in addition to

coordinating with the SACTTI to ensure integrated advice on all aspects of microbiological safety of donors and donations.[69]

1101. The SACTTI has the following remit: to maintain awareness of new or previously unrecognised microbiological threats to safety of blood and tissues; to advise on the epidemiological basis for targeting or avoiding particular groups as potential donors – in respect of both recognised and emerging transfusion transmissible agents; to recommend laboratory and related procedures for detection and exclusion of donations that may pose a microbiological risk; to co-ordinate with the SACCSD and where appropriate prepare joint recommendations to JPAC that take account of all relevant aspects of microbiological safety of donors and donations; and, to coordinate with the SACBC and SACTCTP on guidance to improve microbiological safety of donations. SACTTI moreover conducts regular risk assessments on any infection related transfusion risks, using a standardised form. I provide this form as [WITN0672084] to this statement. This information is used to evaluate the required further action and will contribute towards the position statements produced by SACTTI and published by JPAC. These position statements are all publicly available[70].

Recent – sharing information with stakeholders

1102. NHSBT has a statutory duty to inform PHE of notifiable infections – 'Notification of infectious diseases' **('NOIDS')** is the term used to refer to NHSBT's statutory duties for reporting notifiable diseases in the Public Health (Control of Disease) Act 1984 and the Health Protection (Notification) Regulations 2010. For completeness, these duties also apply to Registered Medical Practitioners and all laboratories in England performing a primary diagnostic role. PHE collects these notifications and publishes analyses of local and national trends every

[69] https://www.transfusionguidelines.org/about/remits-of-the-jpac-standing-advisory-committees
[70] https://www.transfusionguidelines.org/latest-updates

week, available online.[71] The principal relevant notifiable diseases for NHSBT's purposes are HBV, HCV, and HEV. NHSBT carried out notification by reporting to the relevant local health protection team.

1103. In some cases, usually infectious hepatitis, PHE will share information with NHSBT if a member of the public is known to be a blood donor and is found to have an infection which is bloodborne – PHE have moreover included history of blood donation in some of their routine case information. Reference to blood donation has been included in the enhanced surveillance forms for hepatitis A, these are used when someone tests positive for hepatitis A as part of collecting possible risk information. These changes were made following the hepatitis A outbreak of 2016/17.

1104. Additionally, information may be shared with a donor's GP – NHSBT asks all donors for written consent to share their infectious disease results (internal name FRM1516) [WITN0672085]. Where a donor cannot be contacted but NHSBT has details of that donor's GP we will ask the GP if they can make contact with the donor. To undertake that process we will write to the donor and say if we do not hear from them within 7 days that we will contact their GP. We will also contact them by text and/or email. We would be very reluctant to adopt this approach for HIV and would usually ask the genitourinary medicine team to assist. Rarely, NHSBT will make contact with other UK blood services regarding previous donations that the donor may have made to their service. NHSBT's privacy policy is compliant with the GDPR and is available online.[72]

Recent – sharing information with the public

1105. NHSBT carries out a number of campaigns every year to encourage new donors and inform current donors about other types of donation e.g. platelets. In addition, NHSBT may have specific campaigns for

[71] https://www.gov.uk/government/collections/notifications-of-infectious-diseases-noids
[72] https://www.nhsbt.nhs.uk/privacy/

certain donor types or communities. The recent change to donor selection criteria in June 2021 moving to a more individualised approach to donor selection policy required a major campaign to inform donors of the changes, create new content for the blood.co.uk website and encourage donors to use a new tool to check that they were eligible to donate. As part of this campaign a new cartoon was developed, as was content for sharing on social media channels.

1106. I have already described above the nature of the information given to donors prior to donation, which contains information not only as to factors which might exclude a donor from donating blood products, but also information about infections that may affect the safety of the blood supply. Additionally, the annual reviews for 2019 and 2018 of the NHSBT and PHE's Epidemiology Unit's data and research activity are freely available online.[73] These are produced as infographics and aimed at a non-specialist audience.

1107. NHSBT established the *For the Assessment of Individualised Risk* steering group **('FAIR')**. This is a good example of how donors and patients are involved in the process of assessing risk. FAIR membership includes NHSBT, the Scottish National Blood Transfusion Service, the Welsh Blood Service, the Northern Ireland Blood Transfusion Service, Public Health England, the University of Nottingham, the National Aids Trust, Stonewall, Freedom to Donate, Terrence Higgins Trust, patient and donor representatives, and experts in epidemiology, virology and psychology.

1108. The FAIR steering group was established at the beginning of 2019 following a request by DHSC to explore an individualised approach to donor selection criteria. It was set up to explore whether there was sufficient evidence to change the then current blood donor selection policy from a time-based deferral policy based on population-based risk to a more individualised risk-based approach. This included the

[73] https://hospital.blood.co.uk/epidemiology-reports/

criteria related to men who have sex with men which meant that a man who has had sex with a man was deferred from donating blood for the three months.[74] FAIR has since reported its recommendations, which have been implemented.[75] Insofar as it assists the Inquiry I provide the SaBTO report and appendixes for the FAIR conclusions [WITN0672086, WITN0672087].

Variant Creutzfeldt-Jakob Disease (vCJD)

1109. An example of how blood safety worked in practice is demonstrated by the actions taken with the emergence of vCJD and this is described in this section. These steps occurred prior to my working for NHSBT and I have sourced this information from colleagues and documents, together with an understanding gained since joining NHSBT. There will be others who had a personal knowledge of these events at the time presenting to the Inquiry.

vCJD - summary

1110. An important aspect of maintaining the safety of the blood supply were the steps taken by the blood service and others to respond to the threat of vCJD. This is a more recent example demonstrating the steps taken in response to a newly identified risk to blood safety, by the blood services together with other bodies involved in blood safety, who acted in a proportionate and responsible way to protect recipients.

1111. I explain these events here although the majority of the below is outside of my knowledge. In summary:

a. Various steps were taken to identify the risk of vCJD. This includes national surveillance programmes that the blood service assisted with and relied upon: NCJDRSU and the TMER scheme. The DHSC also took various relevant steps including the undertaking of risk assessments to assess the risk posed.

[74] https://www.nhsbt.nhs.uk/news/collaborative-report-into-evidence-on-gay-and-bisexual-men-and-blood-donation-still-due-in-2020/
[75] https://www.blood.co.uk/news-and-campaigns/news-and-statements/fair-steering-group/

b. Minimising the risk to the blood supply was crucial, and included action to exclude various donors, the decision to stop using UK-collected plasma for fractionation in 1998, and the costly steps taken in the leucodepletion of blood. Also, the steps generally taken to educate clinicians so as to minimise the number of transfusions, and the amount of transfused volume.
c. The sharing of information was an important aspect of the response. This was particularly relevant to the surveillance undertaken with NCHDRSU and through TMER. In addition, transparency and the publication of information relevant to stakeholders (e.g. through JPAC) was an important step.
d. Steps were also taken to be open and communicate with the public at large. Important monitoring steps were taken by the PHE, and (particularly due to the increased use of the internet in the 21st Century) far more information was published in a way that was obtainable by the public.

vCJD – identifying risks of infection associated with the use of blood and / or blood products

1112. In addressing this issue I have relied significantly on the position statement on vCJD produced by the Joint UKBTS Professional Advisory Committee. The paper is approved by the SACTTI [WITN0672088].

1113. Creutzfeldt-Jakob disease (CJD) is one of a group of diseases called Transmissible Spongiform Encephalopathies (TSE) or prion diseases. These diseases, in general, have long incubation periods and are characterised by severe and irreversible damage to the central nervous system resulting in death. Sporadic or classical CJD was first described in the early 1920s and occurs worldwide. A series of epidemiological case control, look back and surveillance studies over the last 35 years have not revealed any confirmed cases of transmission of sporadic CJD by blood components, plasma products or peripheral tissues. The UK Blood Services nevertheless apply UK

and European exclusion criteria (in line with WHO recommendations) to exclude anyone who could have an increased risk of iatrogenic or familial CJD from donating blood, tissues or haematopoietic stem cells.

1114. Variant CJD (vCJD) was first reported in 1995. vCJD is the human form of bovine spongiform encephalopathy (BSE, sometimes referred to as 'mad cow disease') – the clinical, epidemiological, neuropathological and experimental data all point to vCJD being caused by the same strain of prion as BSE. This is a different strain of prion from those seen in sporadic CJD.

1115. Regarding identification of the risk of vCJD infection from the use of blood and / or blood products, it is critical to note that there is not at present a blood test available for vCJD. The existing types of tests that are used to screen blood and tissue donations for viruses cannot be applied to vCJD because of the different type of infectious agent (abnormal prion protein rather than bacteria or virus).

1116. Researchers from the MRC Prion Unit, based at University College London, have developed a blood test which has been demonstrated to be sensitive enough to detect abnormal prion in the blood of some patients with clinical vCJD. Similarly, two international groups have developed assays which can detect prions in the blood of experimentally infected animals. Having the ability to detect infection in that asymptomatic incubation period would significantly bolster NHSBT's ability to identify the risks of vCJD infection associated with the use of blood and/or blood products. However, none of these tests have moved beyond the research laboratory to the clinic and there remains uncertainty as to whether these tests will prove accurate enough to reliably detect infection in the asymptomatic incubation period of infection.

1117. Consequently, the response of the UK Government, in consultation with the UK Blood Services, to vCJD in relation to the safety of the blood supply, has been on a far more precautionary basis – an approach which has moreover been informed by the experiences earlier in the 20th Century with HIV and HCV. I discuss this precautionary basis in the question below in relation to risk reduction measures.

1118. Regarding the identification of risk, and on a macro level, the national surveillance programme for CJD in the UK was initiated in May 1990. The programme, known as the National CJD Research and Surveillance Unit **('NCJDRSU')**, is based at Edinburgh University and monitors all forms of CJD, including vCJD. The NCJDRSU is funded by the Department of Health and Social Care, UK and by the Scottish Government Health Department. The NCJDRSU releases monthly information on the number of suspected CJD cases referred for diagnosis and follow-up, and the number of deaths of definite and probable cases. It further produces an annual report, most recently covering the period 1990-2019 [WITN0672089]. I should note that the NCJDRSU's work is not limited to monitoring the risk of vCJD infection through the use of contaminated blood and/or blood products, but its reports are important components in identifying the risk vCJD poses to the blood supply by monitoring the prevalence of the disease in the community. Fundamentally, the NCJDRSU aims to monitor characteristics of CJD to identify trends in incidence rates and to study risk factors for the development of the disease.

1119. Estimates of the number of people likely to develop vCJD (and therefore currently incubating the disease) continue to vary. It is also possible that some people could be 'infected' with this agent but never progress to clinical disease. Data collected by the NCJDRSU show that vCJD mortality in the UK peaked in 2000 and has since fallen with the last patient (who was infected not as a result of a transfusion) described in 2016. There is currently, however, a discrepancy between

the likely number of cases projected from the current clinical evidence of vCJD and the number of infected people projected from retrospective studies of appendix samples which suggests that around 1/2,000 (range 1/1,250 to 1/3,500) healthy people in the general population could be sub-clinically infected: see http://www.cjd.ed.ac.uk/projects/transfusion-medicine-epidemiology-review-tmer.

1120. The Transfusion Medicine Epidemiology Review is a collaborative project between the NCJDRSU and the UK Blood Services, which commenced in 1997. The main purpose is to investigate whether there is any evidence that CJD or vCJD may have been transmitted via the blood supply. I understand that the Inquiry is concerned with vCJD and therefore I will limit my answer accordingly. The principal investigators in relation to the TMER are Professor RSG Knight (NCJDRSU) and Dr H Harvala-Simmonds (NHSBT). Previously, the principal investigators were Professor Robert Will (NCJDRSU) and Dr Patricia Hewitt (NBA, then NHSBT). Dr Hewitt explains her involvement in the TMER in some detail in her evidence.

1121. In terms of TMER's methods, vCJD cases (definite and probables) are notified to the UK Blood Services by the NCJDRSU. Donation records are checked and all components traced through hospital records. Details of all identified recipients are forwarded to the NCJDRSU for subsequent checking. In the reverse procedure, patients with CJD/vCJD reported to have received blood transfusions are traced through hospital records and relevant blood donors identified. The identity of donors is notified to the NCJDRSU for subsequent checking.

1122. The data to 29 November 2019 show that thirty-one vCJD cases were reported to have been blood donors. Four additional cases who were not reported to have been blood donors were found to be registered with UKBTS. One of these cases was found to have been a blood

donor while the other three cases were registered as donors but never made any donations. Twenty-four of the cases have been traced at blood centres including the four additional cases mentioned above. Components from 18 of these individuals were actually issued to hospitals. It has been established that 67 components were transfused to named recipients (53 dead, 14 alive). The doctors of those recipients have been informed of their exposure to these products.

1123. Eleven blood donors who later developed variant CJD contributed to 25 plasma pools from which 191 plasma product batches were manufactured. The CJD Incidents Panel (since disbanded) requested a model to help assess the level of risk of exposure to variant CJD for recipients of plasma products. This model was developed by the Health Protection Agency and is now maintained by its successor body, PHE. The model allows one to calculate a dose of each product (in implicated or non-implicated batches) beyond which it is likely that an infection-control threshold will be surpassed. It has been kept under regular review and has informed patient notification (and de-notification) exercises. Patients recognised to be at increased risk of exposure have, where possible, been informed of their exposure to these products and precautionary steps taken to minimize the risk of any further transmission through blood, tissue or organ donation, or by medical or surgical instrumentation. Further information can be obtained from the PHE website: https://www.gov.uk/government/collections/creutzfeldt-jakob-disease-cjd-guidance-data-and-analysis.

1124. Regarding the identification of instances of presumed transfusion transmitted infections, the following three have been identified:
    a. In December 2003, the first presumed transmission of vCJD by blood transfusion was described, being the date of diagnosis of vCJD. The transfusion itself occurred in 1996; the blood donor was well at the time but went on to develop symptoms of vCJD in 1999.

Dr Angela Robinson was the Medical Director of NBA at the time of this first confirmed transmission and she was responsible for NBA's response to vCJD.

b. In February 2006, the second presumed blood-associated transmission leading to clinical disease was reported. The patient developed symptoms about 8 years after receiving a blood transfusion from a donor who developed symptoms of vCJD about 20 months after donating blood.
c. In January 2007, the third presumed blood-associated transmission leading to clinical disease was reported in a patient who developed symptoms just over 8 years after receiving a blood transfusion from a donor whose symptoms of vCJD appeared about 17 months after donating this blood. This donor was also associated with one of the earlier transmissions.

1125. For completeness, a probable transmission of vCJD prions, not leading to clinical disease, was also reported in July 2004. The patient received blood in 1999 from a donor who went on to develop symptoms of vCJD 18 months later. The recipient died of unrelated causes 5 years after the transfusion with no evidence of neurological disease but at post-mortem was found to have evidence of abnormal prion accumulation in the spleen and a lymph node. Moreover, a further presumed transmission of prions was described in February 2009. The patient suffered from haemophilia and had received batches of Factor VIII to which a donor who subsequently developed vCJD had contributed plasma. The patient died of other causes but was found at post-mortem to have evidence of prion accumulation in his spleen (see Peden *et al.* Haemophilia 2010; 16: 296-304, https://pubmed.ncbi.nlm.nih.gov/20070383/).

1126. These findings strongly suggest that vCJD may be transmitted via blood transfusion.

1127. In the reverse study, 15 vCJD cases were reported to have received blood transfusions in the past. A further case received a blood transfusion after onset of illness. This case is excluded from the figures quoted. Checks revealed that of these 15 cases, one was not transfused, 4 had transfusions which predated available records (pre 1980), and 10 had records of transfusion which could be traced (see vCJD cases who received blood transfusion(s) in the past below). These 10 had received 209 donor exposures (with one patient given 103 components), which have been traced to 192 named donors (two of whom had vCJD as described above). It is not possible to give an accurate figure for the total number of people who have been transfused in the UK since the appearance of vCJD (1996) but the total will be many millions of people. Ten of these many millions have developed clinical vCJD, including the three (referred to above) who have been linked to a donor who also later developed vCJD. In one case the transfusion was given close to disease onset, and in two cases the donations could not be linked to identified blood donors. In the remaining four cases all, or most of, the blood donors could be identified, and none of the donors has developed vCJD.

1128. In addition to the NCJDRSU, the DHSC continues to carry out risk assessments of the transmission of vCJD by blood components – the most recent risk assessment was published in October 2019 and is available [WITN0672090]. The previous DHSC risk assessment was carried out in 2013. The purpose of the risk assessments is to present a mathematical model designed to examine how many future clinical cases and infections of vCJD might be caused through receipt of donated blood components. The model and its outputs are reviewed by independent experts on the Advisory Committee on Dangerous Pathogens – Transmissible Spongiform Encephalopathies (ACDP TSE) Sub Group who support it as providing 'both a highly precautionary estimate of the number of future cases and infections and also the only practicable way of assessing the benefit of further interventions until more empirical evidence becomes available.' The

risk assessment acknowledges that while the number of clinical cases due to future transfusions is low the number of asymptomatic vCJD infections could be much higher. It is further acknowledged that the uncertainties in the scientific community's basic understanding of vCJD present a fundamental difficulty in assessing the risk posed by blood-borne transfusions, which makes follow-up of 'at risk' individuals (which I discuss below) and continued surveillance essential if evidence on vCJD risks is to accumulate.

vCJD – risk reduction measures, including but not limited to donor selection policies

1129. Partly as a result of the difficulty in testing blood for vCJD, and partly as a result of the experience of HIV and HCV in the preceding decades, the UK Government, in consultation with the UK blood services, took a precautionary approach on the emergence of vCJD in the mid-1990s. Accordingly, the UK Blood Services have taken a number of measures to try to reduce the risk of transmission of vCJD by blood, plasma and tissue products, including the following:

a. In 1997, the Department of Health commissioned Det Norske Veritas (DNV) to undertake a '*Risk Assessment to vCJD infectivity in blood and blood products*'.
b. Withdrawal and recall of any blood components, plasma derivatives, cells or tissues obtained from any individual who later develops vCJD (announced December 1997);
c. Cessation of the use of UK plasma for fractionation. Instead, plasma from countries other than the UK is imported for fractionation to manufacture plasma derivatives (announced May 1998, fully implemented in 1999). This is discussed more fully in my answer to Q18, as is the recent reintroduction of donation and use of such plasma;
d. Adoption of leucodepletion of all blood components as a precautionary policy which sought to minimise any potential risk – a costly measure at £20 per unit of blood. At the time of its full

implementation in Autumn 1999 (the decision having been announced in July 1998) leucodepletion was believed to be a prion reduction measure though there is no conclusive evidence that leucodepletion in fact mitigates risk;

e. Importation of clinical fresh frozen plasma (FFP) for patients born on or after 1 January 1996, announced on 16 August 2003 and implemented by the end of June 2004 following the report of the first presumed case of transfusion-transmitted vCJD. This was extended to all patients under the age of 16 by July 2005. As those born on or after 1 January 1996 began to turn 16 from 1 January 2012, this rule reverted to its original wording to ensure that these individuals continued to receive imported plasma past their 16th birthday. This measure was withdrawn in September 2019;
f. Exclusion of whole blood donors who state that they have received a blood component transfusion in the UK since 1 January 1980 – decided in April 2004. Extended to whole blood and apheresis donors who may have received a blood component transfusion in the UK since 1 January 1980 – decided in August 2004 following the report of the first presumed case of transfusion-transmitted vCJD – and to any donors who have been treated with UK plasma derived intravenous immunoglobulin or have undergone plasma exchange. This was further extended in November 2005 to transfusions anywhere in the world;
g. Exclusion of live bone donors who have been transfused since 1 January 1980 – decided in July 2005 following the report of the first presumed case of transfusion-transmitted vCJD;
h. Exclusion of blood donors whose blood has been transfused to recipients who later developed vCJD, where blood transfusion cannot be excluded as a source of the vCJD infection and where no infected donor has been identified - decided in July 2005 following the report of the first presumed case of transfusion-transmitted vCJD;

i. Importation of solvent detergent plasma for adult patients undergoing plasma exchange for thrombotic thrombocytopenic purpura – decided in 2006; and
j. Promotion of appropriate use of blood and tissue products and alternatives throughout the NHS.

1130. Regarding the last of these measures, best practice dictates that blood, plasma, cell and tissue products should only be given when they are essential to the quality of life, health or survival of the patient, and where there is patient consent. In these circumstances the benefits are carefully weighed against other transmission risks including vCJD. In some circumstances alternatives are available which could reduce the exposure to blood or tissue products. UK Blood Services' clinicians continue to work with colleagues throughout the National Health Service in establishing and implementing guidelines for the appropriate use of blood and tissues. It is a priority for the UK Chief Medical Officers and the medical community in the UK to ensure that patients are treated with blood or tissue products only when there is real clinical need. SaBTO recommends that patients be offered the opportunity to give informed consent to blood transfusion whenever practicable and a series of information leaflets are available explaining the potential benefits and risks including those relating to vCJD.

1131. To this end, on the advice of the UK Chief Medical Officers, national programmes for good transfusion practice have been established, supporting the work of local Hospital Transfusion Committees. Transfusion practitioners in hospitals carry out a role. which includes training staff in safe blood administration (including detailed documentation), assisting with clinical audit, the development and implementation of evidence based clinical guidelines for the use of blood, and assisting with the investigation and reporting of adverse events to the SHOT. There is increasing use in the NHS of techniques that can, for some patients, reduce the need for transfusion of donor

blood or avoid it all together. Among these are: the use of regional and hypotensive anaesthetic techniques, good temperature control in the perioperative period, salvage and reinfusion of red blood cells lost during surgery and the use of antifibrinolytic agents. However, transfusion may be unavoidable and life saving for patients who suffer massive blood loss and, for those undergoing chemotherapy for leukaemia or being treated for cancer, there may be no alternative to the use of donor blood components during periods when the bone marrow is not functioning normally.

1132. As I have noted above, Dr Robinson was the Medical Director of NBA at the time of the first confirmed transfusion transmitted infection of vCJD in 2003.

1133. I have already described above the work of the NCJDRSU, whose annual reports amount to a risk reduction measure in addition to a risk identification measure, by ensuring that the relevant decision-makers are properly informed as to the risk posed by vCJD when deciding on what risk reduction measures to implement in respect of vCJD. In the transfusion specific context, so too does the TMER amount to a risk reduction measure. NHSBT's initial principal investigator on the TMER was Dr Hewitt until her retirement. Currently, NHSBT's principal investigator is Dr Harvala-Simmonds.

1134. The precautionary approach to vCJD and the various risk reduction measures are monitored through the risk assessments performed by DHSC to model the number of future infections and clinical cases of blood-borne vCJD in the UK. I have referred to the most recent risk assessment, dated October 2019, in my answer to the question above.

vCJD – Sharing information with relevant stakeholders about infected donations

1135. I have already described above how relevant stakeholders, including NHSBT, seek to identify the risks of vCJD infection associated with the

use of blood and/or blood products, which has been broadly in collaboration with one another. The identification of risk necessarily entails the sharing of information between stakeholders about infected donations.

1136. The rate of vCJD infection generally is monitored principally by the NCJDRSU, as I have described above. This is relevant to information about infected donations as it will be the NCJDRSU who notify the UK Blood Services, including NHSBT, about cases (definite and probable), from which NHSBT can undertake searches to establish whether any have acted as donors or received blood transfusions.

1137. The mechanism through which this information is shared is the TMER, which I have described above. The TMER is a collaborative project between the UK NCJDRSU and UK Blood Services. The main purpose is to investigate whether there is any evidence that CJD or vCJD may have been transmitted via the blood supply. As I have already stated, cases (definite and probable) are notified to the UKBS by NCJDRSU; a search establishes whether any have acted as donors or received blood transfusions. Donation/transfusion records are checked and all components traced through hospital records. Details of all identified recipients/donors are forwarded to NCJDRSU for subsequent checking to ensure none appear on the NCJDRSU database as a case of CJD.

1138. Moreover, JPAC produces a position statement in respect of vCJD which outlines the latest developments in respect of vCJD, including any infected donations. The latest JPAC position statement, which is publicly available, is dated November 2020 and is provided as an [WITN0672088].

1139. Further, the potential for secondary transmission of CJD has led to collaborative studies undertaken between the UK Haemophilia Centre Doctors Organisation, Institute of Child Health (London), NHSBT,

National Prion Clinic, Public Health England and Health Protection Scotland aimed at identifying whether there is evidence of clinical or sub-clinical infection in those judged to be at increased risk of CJD, such evidence is investigated through review of clinical records and medical histories, and through post-mortem investigations.

vCJD –sharing information to the public about infections that may affect the safety of the blood supply

1140. The methods of information sharing with relevant stakeholders about vCJD infected donations I have identified above is of equal application to this answer – the documents produced are publicly available.

1141. On CJD generally, the NCJDRSU states that providing information to the public is an important aspect of its activities. It liaises closely with CJD Support Network, providing articles for their newsletter, updating their information booklets and giving presentations to their Annual Family Day meetings.

1142. In addition to the JPAC position statement, which is publicly available, Public Health England produces biannual CJD updates on the enhanced surveillance of potential iatrogenic (healthcare-associated) exposure to CJD. The data used in these updates is from the NCJDRSU. The latest biannual update (April 2021) is provided as an exhibit [WITN0672091].

1143. The PHE updates moreover identify those patients who are considered to be 'at increased risk' of CJD and the measures taken to monitor those patients. The PHE CJD Section coordinates the collation of data on individuals identified as 'at increased risk' of CJD, and who have been informed of this. These individuals are followed up through public health monitoring and research activities by different organisations. The PHE CJD Section currently holds data on the following groups of patients who have been identified as 'at increased risk' of CJD, namely:

a. Recipient of blood components from donors who subsequently developed vCJD;
b. Blood donors to individuals who later developed vCJD;
c. Other recipients of blood components from these blood donors;
d. Recipients of certain plasma products between 1990 and 2001 (non-bleeding disorder patients);
e. Certain surgical contacts of patients diagnosed with CJD; and
f. Highly transfused recipients.

1144. Further at risk groups include:
a. Bleeding disorder patients who received plasma products between 1990 and 2001 – revised in 2012 from 1980 to 2001. Individuals who were treated with UK source plasma products during the 1980s, but not between 1990 and 2001, have been informed of this change, where possible (data held by the UK Haemophilia Centre Doctors' Organisation);
b. Recipients of human derived growth hormone before 1985 (data held by UCL Institute of Child Health/Great Ormond Street Hospital);
c. Patients who could have received a dura mater graft before August 1992 (data not currently collected);
d. Individuals treated with gonadotrophin sourced from humans before 1973 (data not currently collected); and
e. Family risk of genetic prion disease (data held by the National Prion Clinic).

1145. As will be seen from the above, these data are not held by NHSBT. NHSBT is, however, involved in the public health follow up activities in relation to those at-risk individuals, who are followed up to help determine the risks of CJD transmission to patients through different routes and to ascertain whether any people who have been exposed to increased CJD risks go on to develop CJD. These activities include clinical monitoring, general practitioner updates, and post-mortem

investigations to determine whether asymptomatic individuals in these groups have been infected with the CJD agent. A number of different organisations are involved in these activities: PHE, Health Protection Scotland, UCL Institute of Child Health/Great Ormond Street Hospital, NHSBT, NCJDRSU, National Prion Clinic NPC, and the UK Haemophilia Centre Doctors' Organisation.

1146. PHE, in collaboration with Health Protection Scotland, moreover, provides information for those who have an increased risk of CJD. See [WITN0672092]

vCJD – Achieving and maintaining self-sufficiency of the blood supply

1147. As I have already noted and is set out in more detail in my answer to Q18, following a decision of the Committee on the Safety of Medicines on 30 April 1998 UK plasma was not used for fractionation. This fundamentally changed how plasma and plasma-derived products were sourced in the UK. As I also note in my answer to Q18, the position has now changed and NHSBT has begun collecting plasma for fractionation once again. This decision was made by Ministers following a recommendation from the Commission on Human Medicines on 8 and 9 October 2020.

Historic position on blood safety generally

Historic – introduction and summary

1148. As I noted at the start of my answer, I have no first-hand knowledge of the periods that I discuss below. I have been reliant on large swathes of documents that I have been provided with by those who are advising me. This significantly limits my ability to provide any useful comment; a fact which is exacerbated by the knowledge that not all the relevant documents are available to me (or the Inquiry).

1149. Three previous senior NHSBT clinicians provided answers to the amended rule 9 request of 14 August 2020. They are Dr Patricia

Hewitt; Dr Lorna Williamson; and Dr Angela Robinson. The questions in that rule 9 request had significant overlap with this section. Those senior clinicians also have considerable first-hand knowledge of the events which they discussed. This places them in a far better position than me to provide evidence in respect of those events. With this in mind, I will not seek to add to what they have said on the following topics:

a. The history of surrogate testing for HCV.
b. The introduction of HCV screening in 1991.
c. The undertaking of the HCV lookback from 1995.
d. Counselling for HCV.
e. The introduction of HBV testing.
f. The introduction of HTLV-I screening.
g. The undertaking of the HIV lookback from 1985.

1150. While I cross-refer to the evidence provided by these now retired members of staff, I do not adopt their comment on the events that occurred which is their own comment. As I do not have the first-hand knowledge of those witnesses, I do not have the information required to make a judgment on their comments. I do, however, provide my own comment when appropriate.

1151. I have also addressed self-sufficiency in my answer to section 8 and do not propose to go over those matters again here.

1152. As part of my evidence in this section I propose to discuss the following events and matters. The reason I have included these particular events is because I think they are the events most relevant to the Inquiry's Terms of Reference which have not already been addressed by other evidence given on behalf of NHSBT. To try to cover everything would make this response impractically long:

a. The publication of the AIDS donor leaflet.

b. The introduction of HTLV-III testing.
c. Provision of factor concentrates rather than cryoprecipitate.
d. Blood donation by prisoners.

1153. There are other matters in which the blood service had more limited involvement, but were primarily issues for the BPL. For example, I have been shown some CBLA minutes which show Dr Gunson had significant involvement in discussions and development of heat-treated products from BPL. In my answer here I have focused on those issues primarily addressed by the blood service.

The introduction of the AIDS leaflet

Summary

1154. I have been shown a number of documents detailing the introduction and development of the AIDS leaflet. In summary it would appear:

a. The initial AIDS leaflet was introduced on 1 September 1983 after being proposed at a meeting of the RTDs on 18 May 1983. It would appear to have gone through various iterations before reaching its final form. The last document I have been shown before publication appears to be from July 1983, so it is unclear to me why the document was not published until September 1983. I note that I have not been shown any documents which deal with the logistical issues of printing and distributing the document.
b. Following evidence from DHSC/Lord Glenarthur, I understand that the leaflet was used for a 'six-month trial' period and was subsequently withdrawn pending an updated version.
c. It would appear from the correspondence I have been shown that the second version of the AIDS leaflet was broadly prepared and agreed with RTDs by April 1984. Based on the documents I have seen, it is unclear why the leaflet in fact was only released in January 1985, particularly when an SNBTS equivalent was published in mid-1984. Based on a DHSS memo I have seen it would appear that the leaflet took significant time to be reviewed

internally at the DHSS after it had been approved in April 1984, although the reasons why are not clear to me.

d. I have briefly also noted that in 1984 the North London RTC began using active questioning of donors through the use of an AIDS questionnaire and commenting on the efficacy of the leaflet "*some reasons why you should not give blood*".

e. I have been provided with an outline of events following the publication of the revised leaflet in January 1985. It would appear that there were several revisions which took in the changing landscape, including the emergence of HIV-2 and its link to Africa. It would also appear based on the documents that a significant part of the steering of the leaflet was directed by the DHSS EAGA working party.

1155. Viewed from a contemporary perspective, these timescales appear to be much longer than I would expect or consider desirable or reasonable. To the extent that the reason for that lies with the blood service and any harm was caused by it, I offer my sincere apology on behalf of our service.

Detailed history

Initial introduction

1156. I have been provided with the minutes of a meeting of the RTDs on 18 May 1983 [NHBT0015768]. Dr Walford for the DHSS was present. On AIDS, Dr Walford reported the DHSS's position on the matter. A letter of Dr Gunson setting out four options that Regional Transfusion Directors could accept was considered: "*1. Questioning of donors at sessions \ 2. Sessions to be discontinued in areas of high risk donors. \ 3. Pamphlets explaining AIDS to donors. \ 4. Publications in newspapers*". The meeting rejected 1 and 2. It was proposed that a leaflet would be drawn up (it was hoped within six weeks), taking in the example provided by Dr McClelland from Edinburgh, and that there would be a conversation with the Gay Society suggesting that practising homosexuals be asked not to donate blood until more is

known about the disease. It was decided that, if printing of an AIDS leaflet could not be done quickly through the DHSS, then funding would be sought for printing outside the department.

1157. I have been provided with the minutes of a meeting of the SNBTS directors on 14 June 1983 [MACK0001960_001]. Dr Gunson and Dr Wagstaff attended the meeting. Dr McClelland tabled a revised version of the SNBTS's draft donor leaflet, which had been amended following discussions with representatives of the Scottish Homosexual Rights Group and was ready for issue. Dr R Mitchell circulated a revised blood donor questionnaire into which he had inserted an invitation to donors who were worried about AIDS to discuss it with the doctor at the blood donor session.

1158. Dr Gunson reported on developments in England and Wales. A draft donor leaflet had been circulated and revised following comments from the NBTS and DHSS and arrangements for distribution were under consideration. He reported that there was pressure for the leaflet to be sent or given to every donor rather than simply being made available at sessions. It was acknowledged that if the purpose of a leaflet was to deter donors, it would need to be issued before they attended a session and Dr Gunson explained that it might be circulated with donor call-up letters in England and Wales. There was discussion on how best to deter certain donors without causing offence to others. It was also noted that the DHSS were closely involved in discussions about the approach to take to high-risk donors in England and Wales.

1159. I have been shown an internal SHHD memo from Dr Bell to Dr McIntyre reporting on the discussions of the SNBTS meeting dated 15 June 1983 [PRSE0002473]. Dr Bell advised that: *"All the Directors present are now more aware of the complexity of the issues involved particularly in relation to the views of the homosexual community, the scope for misrepresentation by the press and the public, and the diplomacy required in presenting the AIDS issue in donor centres".* It

was also noted that the matter of leaflet distribution (namely "pick up" or "hand out") and whether there was a need for two leaflets, one for donor centres and a modified version for distribution through the homosexual community, was yet to be resolved. However, Dr Bell became aware later the same day that the revised SNBTS leaflet had now commenced circulation through the SHRG network [PRSE0004927 para 28.33 - 34] .

1160. I have also been provided with a note of a meeting including Mr Kenneth Clarke, Minister of State for Health, and Lord Glenarthur, Undersecretary of State for Health, which took place on 6 July 1983 [DHSC0001511]. The meeting note records that the Minister of State thought the draft leaflet read well, however he wanted it to emphasise more strongly how few cases of AIDS there had been in the UK and also state unequivocally that donors would not be questioned about sexual matters. It was said to be inevitable that the leaflet would attract wide publicity and a carefully drafted press notice and briefing session would be needed.

1161. I have been shown a memo prepared by Dr Bell of the SHHD dated 6 July 1983 which discusses the revised version of the draft donor leaflet, which appears to have been received from the DHSS that day [PRSE0000049]. He noted that the most significant alteration from the draft version prepared by Dr Gunson was the amendment from "*...a person who is in any of the high risk groups of developing AIDS described in this leaflet should not give blood even though they are in normal health at the present time"* to *"... donors are requested not to give blood if they think they may either have the disease or be at risk from it".* However, he understood that the initial reaction of Mr Norman Fowler, Secretary of State for Health and Social Services, had been that the terms of the leaflet were too strong and the DHSS may therefore be making further amendments.

1162. I have been shown a letter from Dr Wagstaff dated 6 July 1983 addressed to "*Dear Colleague*" enclosing a copy of what he described to be the final form of the donor leaflet, which would be going to print [PRSE0000161]. He advised that the majority of RTDs still felt strongly that the approach to donors should be as low key as possible, however one or two regions considered there might be some benefit in a slightly more aggressive approach. These RTDs might be asked to run a trial of either posting or handing out the leaflets. There was a consensus against causing undue stress or alarm at donor sessions in respect of the vague symptoms associated with AIDS and it was considered that the 'illness notice' should be minimally altered to include "*unexpected loss of weight*" (if this wasn't already part of the local list) and emphasis on some form of words to the effect of "*are you in good health or have you needed to see your doctor recently*".

1163. I have been shown an undated DHSS submission which states that officials revised the text of the AIDS leaflet following the meeting on 6 July 1983 to incorporate the points made by Ministers and sought the Minister of State for Health's approval for printing the leaflet and the proposed distribution arrangements [PRSE0004171]. The submission details that a survey of the RTDs had been undertaken to determine their views on the best means of distributing the leaflet. Opinion had been divided as no one method seemed to fulfil all the necessary criteria, namely:

- All existing and potential donors should receive a leaflet.
- Donors should not be caused embarrassment by picking up or reading the leaflet at sessions.
- The distribution method should be the most effective in reducing the number of high risk donations.
- There should be minimal administrative and resource implications.

1164. I have also been shown an extract from Hansard from 14 July 1983 which has a response from Lord Glenarthur to Baroness Dudley on questions concerning AIDS [PRSE0001886]. At that time Lord

Glenarthur noted that the DHSS was considering the introduction of a leaflet concerning when a person should avoid a blood donation due to the risk of AIDS.

1165. I have been shown a press release dated 1 September 1983 which says that the leaflet *"A.I.D.S. And how it concerns blood donors"* was published by the DHSS [DHSC0006401_006]. The leaflet, which I have also been shown [NHBT0001068], included the following information (emphasis in original):

What is AIDS? AIDS is short for Acquired Immune Deficiency Syndrome…. AIDS destroys the body's immune system which normally protects against infections and other illnesses. A person with the disease is therefore at risk of developing serious infections such as pneumonia, or even cancer. AIDS is probably caused by a virus, but this is not known for certain.

Who is at risk from AIDS? Most of the information about AIDS has come from the USA where approximately 1,500 patients have been found to be suffering from the disease, up to the middle of 1983. Certain groups of people appear to be particularly susceptible; these are: 1. Homosexual men who have many different partners. 2. Drug addicts, male and female, using injections. 3. Sexual contacts of people suffering from AIDS. It has also been found in a number of immigrants to the USA from the island of Haiti. Patients with AIDS also seem more likely to have suffered, at some time, from various other diseases such as hepatitis B, syphilis or other sexually transmitted diseases.

Has AIDS occurred in the United Kingdom? Yes, about a dozen cases have been reported, by the middle of 1983. No-one knows whether more people in the United Kingdom will develop AIDS and a careful watch is being kept for possible cases.

Can AIDS be transmitted by transfusion of blood and blood products? Almost certainly yes, but there is only the most remote chance of this happening with ordinary blood transfusions given in hospital. However, in the USA a very small number of patients suffering from haemophilia, an illness in which the blood will not clot, have developed AIDS. Haemophiliacs are more susceptible to AIDS because they need regular injections of a product called Factor VIII. This is made from plasma obtained from many donors. Should just one of the donors be suffering from AIDS, then the Factor VIII could transmit the disease.

How can the risks be reduced? At present, there is no screening test the Transfusion Service can use to detect people with AIDS. So, until there is and until more is known about this disease, donors are asked not to give blood if they think they may either have the disease or be at risk from it.

Will donors be questioned on sexual matters when they attend to give blood? Definitely not. The National Blood Transfusion Service has a very high regard for donors as extremely responsible people who give blood for the benefit of others and is confident that they would not knowingly put patients at risk from such a serious disease.
Where can donors obtain further information on AIDS? Donors can discuss in confidence whether to give blood, with the doctor on the blood collection session, their own doctor or the Director of their local Blood Transfusion Centre.

Please remember, AIDS is a rare disease but a serious one.

First redraft

1166. I have been shown the minutes of a meeting of the UK Working Party on Transfusion-Associated Hepatitis dated 27 September 1983 [PRSE0001299]. The meeting was chaired by Dr Barbara in Dr Gunson's absence. The current position on AIDS was summarised by Dr Craske. As part of the discussion, it was noted that different RTCs

were trying different ways of distributing the AIDS leaflets, ranging from inclusion with call-up cards, free availability on donor sessions and restricted availability on donor sessions. The effects of these different strategies would be compared and reviewed by the RTDs. Dr Lane, BPL, presented the fractionator's view that a variable approach did not provide material of uniform specification, however Dr Mitchell, SNBTS, pointed out the problems associated with any infringements of the integrity of the donor. It was agreed that Dr Gunson would be asked to communicate the Working Party's preference to the RTDs for a uniform approach as soon as possible. In the meantime, it might be helpful if the RTD's provided details of how they get AIDS information to the attention of high-risk donors.

1167. I have also been shown the minutes of the first Working Group on AIDS in relation to Blood Transfusion dated 14 October 1983 and chaired by Dr Gunson [CBLA0001755]. The AIDS leaflet was discussed, with a focus on its method of distribution. In general, the Group considered that a uniform system of distribution would be advantageous, and it was noted that RTCs had been asked to feed back to the DHSS in respect of leaflet distribution by the end of November 1983. It was agreed that special (STD/GUM) clinics should be included in the distribution, health education councils and gay societies should be approached and possibly comments invited on the leaflets from blood donors. In respect of the leaflet's content itself, it was felt that the important message not to give blood if you were in a high-risk group should be highlighted. The Group agreed that these matters would be raised at the DHSS on 17 October 1983 at the meeting of the Advisory Committee on the NBTS.

1168. I understand from a draft report I have been shown that in November 1983 there was a meeting of the WHO on AIDS held in Geneva. Dr McClelland, SNBTS, attended. A report titled "*AIDS, An Assessment of the Present Situation in the World",* dated 12 December 1983 has been provided [CBLA0001775].

1169. Approaches to reducing the possibility of spreading AIDS by blood and blood products included: 1) educating the general public and donor groups, 2) excluding donors who belonged to established risk groups, 3) avoiding non-essential use of blood and blood products and 4) preparing and using blood and blood products in such a way as to reduce the risk of transmitting AIDS. The report advised that sufficient information was now available to permit health authorities to make recommendations that may decrease the incidence of AIDS among groups at the highest risk of acquiring the syndrome. Measures which could be instituted now relating to public and donor education included:

- Persuading individuals with AIDS and persons in groups with an increased incidence of AIDS to voluntarily refrain from donating blood. Blood and plasma organisations should provide relevant information about AIDS to promote and encourage this voluntary self-exclusion policy.
- Providing information to homosexual men to prevent the sexual transmission of AIDS in this group. For example, by public health authorities working together with representatives of homosexual groups to formulate and distribute recommendations to lower their risk of contracting AIDS.
- Informing haemophiliacs and their physicians about the potential risk of AIDS associated with Factor VIII or IX products.

1170. I have been shown a letter from Dr Wagstaff to the DHSS dated 3 January 1984 enclosing a summary of the feedback received from RTCs following the first three months of distribution of the AIDS leaflet [PRSE0000387]. He highlighted that handing a leaflet to each donor at the session was the only method that caused offence. One or two people (presumably RTDs) had also expressed that the leaflet should be revised before reprinting. Dr McClelland, SNBTS, was re-drafting the leaflet taking into account up to date views and Dr Wagstaff hoped

to have a draft copy for consideration at the next RTD meeting on 25 January 1984 and would inform the DHSS of their proposals.

1171. I have been provided with a copy of the feedback attached to a letter from Dr Wagstaff to Dr McClelland requesting a revised draft version of the AIDS leaflet [PRSE0000249]. The feedback demonstrated the different distribution methods adopted by 14 RTCs (12 in England, one in Cardiff, one in Glasgow). Nine had the leaflet available solely at donor sessions (via various means) and five sent the leaflet with call up cards (two of which also had the leaflet available at sessions and one handed them to donors at industrial sessions). The RTCs who had leaflets available at sessions mostly reported a low uptake of the leaflet. Two RTCs reported that some offence had been caused when leaflets were handed out to donors at sessions. The majority reported no adverse comments from donors and there appeared to be a small number of self-exclusions.

1172. I have been shown a letter from Dr McClelland to Dr Wagstaff dated 10 January 1984 [PRSE0000351]. The version of the letter I have been shown does not appear to include the revised leaflet. Dr McClelland advised that his proposed changes, based on discussions with his colleagues in Edinburgh, US contacts and in particular on ideas from the leaflet used in the New York Blood Centre, had not yet been discussed with the SNBTS or any other committee or group involved with this issue. He would be discussing his proposals with the SNBTS on 17 January and also sending them to Dr Gunson in the near future with a view to his CBLA Working Party on AIDS discussing them at the end of January.

1173. I have been shown the minutes of an RTD meeting held on 25 January 1984 [NHBT0018332]. Dr Wagstaff reported that feedback from RTDs had revealed no offence had been caused to donors regarding the introduction of the AIDS leaflet at sessions (although it is to be noted from the feedback sent to the DHSS on 3 January 1984 that two RTCs

reported some offence when it was handed out at sessions). There is also no reference to a revised draft leaflet.

1174. I have also been shown a redacted DHSS memo dated 14 February 1984 [DHSC0002239_015]. In that memo it is observed that in view of the published evidence of transmissibility of AIDS by blood transfusion, the current advice to donors could seem too lax. It may also be necessary to raise the need for more positive distribution of the leaflet with the RTDs. The author asked how soon a re print of the leaflet was required and planned to discuss the re-draft with a (redacted) colleague and the RTDs if this was fairly soon. However, if a large amount were still available, consideration would need to be given to whether these should be substituted with the re-drafted version.

1175. I have been shown the minutes of a meeting of the SNBTS directors dated 13 March 1984 [PRSE0003405]. Dr Gunson and Dr Wagstaff attended this meeting as representatives of the NBTS. The minutes note it had been previously agreed that the AIDS leaflet should be sent out once to each blood donor with the call-up letter to a session and that Dr McClelland would revise the existing leaflet for this purpose. The revised draft leaflet had been circulated with the agenda. It was reported that Dr Smithies, DHSS, would undertake revision of the leaflet for England and Wales. Whilst the (existing) leaflet had been mailed to all blood donors by some RTCs in England, it had been made available at donor sessions and some STD clinics in Scotland and the Scottish Directors felt their position would be strengthened by mailing it to all blood donors. The Directors undertook to send Dr McClelland comments on the draft leaflet within two weeks, following which he would submit a further draft for consideration.

1176. I have been shown the minutes of a meeting of the Advisory Committee of the NBTS dated 10 April 1984 [CBLA0001835]. I have also been provided with a summary of a survey of details provided by

RTDs [CBLA0001820]. The six month trial period of the leaflet, *"AIDS and how it concerns blood donors",* was now complete and the survey of RTDs showed little adverse comment. The survey also indicated that there was considerable variation in the numbers of the leaflets used between regions, and method of distribution. This ranged from 1,000 used in Oxford to 139,000 used in Manchester (including Lancaster). The summary reported limited donor response or effect on attendance, with 3 regions reporting donors withdrawing. The DHSS now proposed to prepare, in consultation with RTDs, a revised version of the leaflet for submission to Ministers.

1177. Dr K Rogers, Director from the South London RTC, suggested that RTDs should adopt a more aggressive approach to discourage donors from high-risk groups from giving blood. The Committee recommended that, although the method of distribution during the trial period had been left to the discretion of RTDs, Ministers should now consider the issue of the revised leaflet with donor call up cards in all regions.

1178. I have been shown a timeline produced by an M Thornton dated 30 November 1984 [PRSE0004615]. In that timeline it is indicated that the SNBTS had published a donor leaflet on 14 August 1984 entitled an *"Important Message to Blood Donors",* sent out with call-up letters in September 1984. I have also been provided with the leaflet [PRSE0000286].

1179. In the report of Dr Gunson for the HIV litigation [DHSC0000142] it is explained that in July 1984 the North London RTC introduced a questionnaire for donors attending their permanent blood collection centre. He said that this questionnaire was used because it was suspected that North London RTC was liable to have more donors at risk than RTCs in other regions. The results of the trial use of the questionnaire and tests carried out on donors who declared themselves at risk or not at risk were published in the BMJ on 9 March

1985. After a successful trial at this centre, the questionnaire was used in a second permanent centre in April 1985 and on the mobile blood collection teams from June/July 1985.

1180. I have seen a submission by DHSS officials dated 10 August 1984 [DHSC0002309_044] which sought Ministers' approval to issue a revised leaflet, agreed within the department and by the RTDs, and for a more uniform method of distribution to be adopted by RTCs in England and Wales [PRSE0004685]. It is unclear whether the covering letter is referring to this specific submission, although the referred paragraph numbers do agree.

1181. The submission advised that the re-drafted leaflet updated factual matters and strengthened its warning to high-risk groups not to donate blood. Ministers were reminded that RTCs had been asked to distribute the original leaflet in the way most suitable to their individual service and officials had monitored the distribution, its reception by the blood donor population and any effect on the numbers volunteering to give blood. The monitoring exercise indicated that distribution of the leaflet had not caused any fall in the number of blood donors and that there had been little if any adverse comment. There had been a wide variation in distribution methods by RTCs, including the leaflet being sent individually to all donors with their recall notifications, others offering donors the leaflets to read when they attended a donor session whilst a few had them available for donors to pick up as they wished.

1182. The submission recommended that all RTCs who did not send out the leaflet individually to their registered donors should now be asked to do so at the next recall of those donors. This would have relatively minor cost implications for some RTCs. Donor teams should also make certain that new or unregistered donors had an opportunity to read the leaflet before they were committed to donation.

1183. I have been shown the minutes of an Advisory Group on Hepatitis meeting held on 9 October 1984 [CBLA0001904]. Dr Contreras was a member. Dr Contreras pointed out that 1.6% of her male donors were homosexual and the risk of AIDS was reduced by discouraging donation by homosexuals. Dr Smithies said that a new AIDS leaflet would be published shortly which would advise practising homosexuals not to donate.

1184. I have been shown the minutes of a meeting of the Advisory Committee on the NBTS dated 8 November 1984 [PRSE0004783]. Dr Smithies reported that by the end of October 1984, 88 cases of AIDS had been reported to the CDSC, of which 75% were homosexuals and three were haemophiliacs. None had been associated with blood transfusion.

1185. It is noted that at the previous meeting, the Committee had recommended the adoption of a uniform system of distribution for the revised NBTS leaflet. Ministers had accepted this recommendation and the leaflets would shortly be distributed to RTCs for issue to every donor. The Committee advised on the particular problems of getting the leaflet to new donors and its use at industrial sessions. There would also be some cost implications for RTCs using a card call-up system. It is further noted that the Health Education Council's leaflet, an independent health education body, had been approved by Ministers for issue early in the New Year. Both leaflets would be cross-referenced and supplied to STD clinics.

1186. I have been shown a paper which appears to have been circulated to the members of the Advisory Committee on the NBTS's Working group on AIDS in advance of its first meeting on 27 November 1984 [CBLA0001934_003]. The paper set out various issues on which the group's views were sought in order to protect the blood supply from the increasing prevalence of AIDS.

1187. The paper summarised current practice in respect of donor selection and advised that blood donors had been made aware of the risk of AIDS through leaflets issued by the NBTS, which warned those in high-risk groups not to give blood. When the leaflets were first introduced, there were concerns about the possible reaction of donors, so different ways of making the leaflets available were used. RTDs were contacted by people who felt themselves to be at risk and there was no evidence that the leaflets deterred any volunteer who believed themselves not to be at risk. The revised leaflet which would be available shortly, extended the high-risk group to include all practising homosexuals and was intended to be distributed to all donors to ensure that every donor was aware of the situation. More intensive interviewing of donors, as done in some RTCs, was noted as a possible further measure to discourage high risk donors from giving blood, particularly in areas known to have an increased population of homosexuals and drug abusers.

1188. I have then been shown the minutes of the first meeting of the Advisory Committee on the NBTS's Working Group on AIDS, which was held on 27 November 1984 [CBLA0001934_002]. Dr Abrams subsequently prepared a memo summarising the main points that were discussed [DHSC0002251_011]:

- The Group was not in favour of closer questioning of donors to see if they were homosexual etc, which might be counter-productive. They favoured the use of a local session leaflet (such as was used currently) which asked people to answer a list of questions, amongst which were the AIDS questions.
- There was general endorsement of the draft revised donor leaflet on AIDS. A few small but important changes were suggested. The leaflet in Scotland mentioned the countries where AIDS was prevalent, which was not agreed and should be covered either by the session doctor or the local session leaflet. It was considered that any such list was likely to be out of date very quickly, could

potentially be politically offensive and donors had to be questioned about whether they'd been abroad anyway.

1189. I have been shown a DHSS memo dated 3 December 1984 [PRSE0000898]. That memo confirmed that the revised blood donor leaflet had been discussed at the Working Group on AIDS meeting and members only had minor comments which were appended to the memo for approval. The Group considered that the information in the leaflet was sufficient to give adequate warning to high-risk donors and would not deter other volunteers. It was not thought necessary to adopt a stronger line, as had been suggested by the Information Division. The memo advised that if the Minister of State for Health agreed, arrangements could now be made for printing and distributing the leaflet to RTCs, who would be asked to ensure that all donors received a copy.

1190. I understand that the new NBTS AIDS leaflet was due to be released in January 1985. However, I have been provided with the minutes of the RTD meeting on 23 January 1985 [CBLA0001995]. At that meeting:

Dr Gunson was required to update the meeting on the DHSS situation. The new leaflet will be available on 1st February and instructions will be issued to Regional Administrators with a copy to RTDs. This was expected to insist on a positive approach to its distribution. Dr Gunson stressed the efforts made by Dr Smithies and Mr Williams and the regrettable delays are in no way attributable to them.

1191. I understand that in January 1985 the revised NBTS leaflet entitled *"A.I.D.S. Important New Advice for Blood Donors"* was issued. I have been shown a DHSS memo which explained the position regarding the timing of the implementation of this replacement leaflet [DHSC0002273_002]. The details of the author of the memo are unclear:

Just to put the record straight about the last leaflet. It was revised within the Department by MED SEB and was agreed with HS1 and the RTDs in April 1984. Because of delay within the Department for one reason an another it was not issued until January 1985. The information finally issued was virtually the same to that agreed in April 1984 although ID Division suggested alternative methods of presentation.

The delay between drafting and issue caused considerable concern amongst RTDs. In view of the need to issue a further redraft I suggest that before it goes to RTDs we should ensure that there will be a smooth uninterrupted path to its issue.

However, the redrafted leaflet must also be considered in the context of advice to blood donors about the test for HTLV III antibody. It is possible that some sort of combined leaflet might be appropriate which includes the draft by MED SEB and agreed with the Working Party of the Regional Transfusion Directors about testing donors. The advice of Information Division on the advisability of combining the two should be sought.

1192. The revised leaflet updated the known facts about AIDS, amended the layout and most significantly, extended the high-risk groups who should not donate blood. I have been provided with the leaflet [NHBT0096480_022]. The following risk groups were now listed:

1. Practising homosexual and bisexual men (revised from homosexual men with many different partners).
2. Drug abusers, both men and women, who inject drugs.
3. Sexual contacts of people in these groups (revised from sexual contacts of people suffering from AIDS).

1193. The leaflet states that AIDS had occurred in a small number of haemophilia patients who were treated with blood products. Further, there was evidence that some people who had lived in Haiti or Central Africa, particularly Zaire and Chad, may have been at risk from AIDS (revised from immigrants to the US from Haiti). The leaflet confirmed that donors in the risk groups must not give blood, strengthened from the original leaflet which stated that donors were asked not to give blood if they think they may be at risk from the disease.

1194. I have been shown a DHSS Health Circular which was issued alongside the leaflet [DHSC0002159]. The circular asked Regional Health Authorities to ensure that RTCs distributed the revised leaflet individually to every blood donor. This would normally be achieved by sending each donor a copy of the leaflet with their next call-up notification, however it was recognised that this might not be practicable for industrial sessions or new donors presenting at sessions. In these cases, alternative arrangements should be made to ensure that each donor was individually given the leaflet before any blood was taken. Displays of leaflets, whilst useful, would not meet these new distribution requirements. RHAs should also identify establishments outside the NBTS where similar action should be taken.

1195. The Circular advised that supplies of leaflets would be sent directly to RTCs and STD clinics. Any retained copies of the 1983 edition should be destroyed and as the advice had changed significantly, the revised leaflet should still be sent to those who received the 1983 version. The DHSS was funding the printing, however the RTC costs associated with distribution would have to be found within existing RHA funds.

North London RTC

1196. I have also been shown a letter from Dr Hewitt to Dr McClelland concerning the AIDS questionnaire that was used at the North London RTC dated 16 January 1985 [PRSE0003435]. As this directly relates

to another witness who will be giving evidence, I only comment on this in summary.

1197. The AIDS questionnaires had been in use for almost six months and were examined to see if there were any "double ticks" (i.e. confirming the donor had read the AIDS leaflet and thought they were in a high risk group). These donations were removed without being processed. The RTC's main problem had been the lack of a questionnaire from every donor. A member of staff put the returned questionnaires in numerical order and any missing donation numbers were traced. In addition, a small proportion of donors failed to tick the first box (asking if they had read the AIDS leaflet). When those donors were contacted, it was almost invariable to find they had misread or misinterpreted the questions. Although this was not a large problem at the time (as their West End Donor Centre collected only 15% of the total donations) it could be a significant amount if extended to all their sessions, which was being seriously considered. It could also not be extended until they had additional staff due to the significant amount of extra work involved. The RTC had only received one refusal to fill in the questionnaire from a donor in a high-risk group.

1198. Dr Hewitt also enclosed a leaflet entitled *"Some Reasons Why You Should Not Give Blood",* which they had devised to overcome the reluctance of donors to pick up and read the leaflet on AIDS. Although all donors at their West End Donor Clinic must read the AIDS leaflet, there was a room in which the donor could have privacy. Men were noted to be very reluctant to pick up the AIDS leaflet, but this new one had proven very popular and they were printing hundreds each week as they were taken away by the donors. Their other recent change had been to overprint their call-up cards with *"We are asking homosexuals not to donate*". They had received one or two protests, but generally a favourable response.

1199. The enclosed explanatory note read: *"Dear Donor, Because of the current concern about the disease AIDS, which can be transmitted by blood products, we are asking all our donors, at each attendance, to complete the enclosed questionnaire in order to try and reduce this risk to a minimum. After booking in, would you please… 1. READ THE A.I.D.S. LEAFLET, 2. ENTER THE SIDE-ROOM ON THE LEFT AS YOU APPROACH THE MAIN CLINIC. (One donor at a time.) 3. COMPLETE YOUR QUESTIONNAIRE IN CONFIDENCE. 4. POST IT IN THE SPECIAL BOX PROVIDED. 5. TAKE A SEAT OUTSIDE, READY TO ENTER THE MAIN CLINIC AND DONATE".*

1200. The enclosed questionnaire read: *"Please write your donation number in the space below… Have you read the AIDS leaflet? If so please tick the box* [first box]. *If you think that you may be in a HIGH RISK GROUP as defined in the leaflet and you would still like to donate please tick the box* [second box]. *In this case, we shall use your blood for research purposes only. ONLY TICK THIS SECOND BOX IF YOU ARE IN A HIGH RISK GROUP. All information provided by you on this sheet will be kept strictly confidential".*

1201. The enclosed leaflet *"Some Reasons Why You Should Not Give Blood"* asked donors to read the leaflet, before seeing the receptionist, on the front page. It set out a varied range of conditions in which blood donations may not be accepted to protect either the donor or recipient from ill effects. The list included, for example, women who were pregnant or had a baby within the last year, those who had received acupuncture, ear piercing, electrolysis or tattoos in the last six months, anyone who'd ever had cancer or were *"not feeling 100% fit today"* (amongst others). The list also notably included people belonging to any of the risk groups listed in the AIDS leaflet. Donors were advised not to give blood if any of the reasons listed applied and to ask to see the Medical Officer in strict confidence if they had any doubts or questions.

Selected other events

1202. I have been provided with some documents which map out a skeleton of the progress of the AIDS leaflet after this point. These are set out below.

1203. I have been shown the minutes of the first meeting of the Expert Advisory Group on AIDS on 29 January 1985 [PRSE0002734]. The issue of health education was considered and the Chairman sought the Group's views on AIDS leaflets issued by the HEC, the Terrence Higgins Trust and the leaflet produced by the DHSS for the NBTS. The blood donor leaflet was not considered to be sufficiently forceful and needed some redrafting, particularly with regard to its objective of persuading homosexuals not to donate blood. It was recommended that consideration be given to the introduction of some means by which a "closeted homosexual" could confidentially withdraw from the system at a visit to an RTC. Another proposal was to include information about AIDS in the literature that was being prepared as part of the current drug abuse campaign after a recent 15% reported increase in IV drug abusers, 2-3% of whom were HTLV III positive, together with examining the possibility of providing free needles and syringes. It was also suggested that greater use might be made of the national press and possibly the involvement of publicity agencies. It was agreed that a member of the Department's Information Division should be invited to the next meeting.

1204. I understand there was an RTD meeting on 8 October 1986 [CBLA0002345]. Dr Fraser reported that the new AIDS donor leaflet had been printed and distributed to RTCs. Some concern was expressed about the African risk group, but Dr Moore, DHSS, emphasised the importance of the heterosexual context in Africa. He agreed to provide a list of countries to which visits did not constitute a risk and suggested that this could be incorporated in an update of the appropriate section of Care and Selection of Donors. Dr Moore indicated that the new leaflet should be distributed with donor call-ups.

Dr Cash, SNBTS, expressed concern that the leaflet dated the risk factors from 1978 and not 1977 in line with WHO and North America.

1205. He was also concerned that the leaflet was not being taken seriously and supported this with evidence of his own experience as a donor recently. He said that Directors in Scotland were considering sending a health check letter with every call-up which would incorporate the details in the AIDS leaflet. Dr Cash appealed for cross border co-operation in the preparation of future literature and asked Dr Fraser to approach the DHSS regarding his proposals for a study into the effectiveness of the literature in self-excluding donors in high-risk groups.

1206. I have been provided with a memo that Dr Martlew sent to all medical officers (copied to Dr Gunson) on 28 November 1986 [NHBT0004481]. The memo referred to a second virus associated with AIDS (LAV2) that the current antibody test for HIV (LAV1) lacked the sensitivity to detect. She stated it was therefore imperative to ensure no donations were collected from individuals who had visited Sub-Saharan Africa since 1978 and had sexual relations with natives of either gender. She enclosed a copy of the latest AIDS leaflet which stated this information and advised that clerical staff had been instructed to ask every donor whether they had visited Africa since 1978 and refer any such people to the medical officers for further advice before being bled. No blood was to be collected from anyone who could not confirm that they had had no sexual relations with men or women living in Sub-Saharan Africa during that period. In the event of any doubt, she suggested that the donation be politely declined and that person withdrawn from the donor panel.

1207. I have been provided with a letter that Dr Gunson sent to all members of the National Management Committee of the NBTS on 7 November 1989 [NHBT0009868_007].He stated that following the meeting of the Management Committee on 2 November 1989 he had given

considerable thought to the proposal that sexual contacts of haemophiliacs should be given a separate heading and placed above the section on sexual contacts. He was loathe to do this because he had consulted the RTC Divisions on this matter and understood the majority were happy with the current wording. He had also presented to the EAGA that the consensus view of the NBTS was that the only change to the exclusion categories should be to make prostitutes the penultimate self-exclusion clause. He did not think this change could be made without reference to, at least, the Chairman of the EAGA who may in turn refer it back to the EAGA, which would open up discussions again on high-risk countries. Furthermore, the change could not be made logically without changing the last paragraph, as by placing the sexual contacts of haemophiliacs above people who had had sexual contact with anyone in the listed risk groups introduced the concept of a sexual contact of a sexual contact, which would not be practical. He was sure that sexual partners of haemophiliacs had been carefully counselled and to make a specific issue of them in the leaflet could be counter-productive. Dr Gunson therefore asked for agreement to leave the wording of this section as it was originally proposed.

1208. I have been provided with a letter that Dr Contreras wrote to Dr Gunson on 28 December 1989 [NHBT0009866]. The letter concerned Form NBTS 110. Dr Contreras informed Dr Gunson that NLBTC held a considerable proportion of donor sessions in industry, and that the centre did not send correspondence to such donors. Dr Contreras also noted that 10-20% of donors are first-time donors, and a significant number of known donors change donation venue without giving notice. She identified that these are the three main reasons why donors arrive for sessions without having had the opportunity of reading the AIDS leaflet. She noted that it would require a member of staff acting as a receptionist for all donor sessions to ensure that the leaflet was read before donors are asked to sign Form 110. Her letter identified a number of her concerns she had raised previously but were not

included in the minutes. Dr Contreras also indicated that the consultants at the centre would oppose point 5 in the revised form, which would require confirmation from the person signing the form that "*they are not at risk*". She went on to note that "*[w]e do not think that the Department of Health solicitors would be very happy if they knew that we were asking donors to sign such a form. Anyway, would this signature have any legal standing?*".

1209. I have been provided with the minutes of an EAGA subgroup on 23 April 1991 [NHBT0007522]. The meeting was held to consider the changes to the AIDS leaflet proposed by the UKBTS/NIBSC Standing Advisory Committee ("SAC") on the Medical Selection of Donors. Dr Gunson was in attendance as the NBTS representative. It was noted that problems with the leaflet had only arisen since the last revision was issued in June 1990 although a very similar leaflet had been in circulation since 1987. Criticism centred around the reference to African countries, the use of "AIDS virus" instead of HIV, the use of a prescriptive date (1977) and failure to recognise monogamous homosexual relationships and use of safe sex practices. The group worked through the SAC recommendations alongside consideration of the FDA's revised recommendations issued in December 1990.

1210. I have also been provided with the minutes of an EAGA meeting held on 2 July 1991 [NHBT0008407_003]. Dr Gunson was in attendance. The NBTS blood donor leaflet was discussed. Dr Gunson advised that following the revision of the leaflet in July 1989 a number of complaints had been received suggesting that the reference to Africa was discriminatory. It was noted that the Commission for Racial Equality considered the reference to Africa led to racial stereotyping and they would prefer to see no reference to geographic areas or failing that, all countries with high prevalence listed. Dr Gunson pointed out that one half of the donors found to be HIV antibody positive had links with Africa, however acknowledged that the present wording would be difficult to maintain in the circumstances and agreed to seek the help

of the CDSC to draw up a list of high prevalence countries for inclusion in a draft amended leaflet for further consideration.

1211. I have been provided with a letter that Dr Gunson wrote to Dr Wagstaff dated 17 September 1991 [NHBT0007517]. He noted discussion at the 2 September 1991 Management Committee meeting, and the fact that only two points of contention with regard to the leaflet remained. These were that the cut-off date of 1977 was "*becoming less realistic as time goes on*" and that there is "*good scientific evidence that the main source of heterosexual spread comes from Africa and that country should still be named, but perhaps in a way which will be acceptable to the Commission for Racial Equality*".

1212. He went on to ask Dr Wagstaff to reconsider these issues in the Special Advisory Committee for the Selection of Donors. He noted that Dr Wagstaff was not in favour of a specified time period in place of 1977 when they last met but indicated the WHO advocated period of two years which might make 5 years a sufficiently wide safety margin. As to citing the geographical areas of high risk, the lack of scientific evidence for heterosexual spread of HIV in the general population was causing major problems. He also noted that he had discussed with Dr DBL McClelland who was broadly in favour of the above, although he was to have discussions with his colleagues in Scotland and would like to put forward further proposals for longer term appraisal of this matter as any leaflet produced at that point "will have to be regarded as a holding operation". Dr Gunson said he would copy this letter to Dr McClelland.

1213. I have been provided with the minutes of an EAGA meeting on 8 October 1991 [NHBT0008406_002]. Dr Gunson was absent. The NBTS blood donor leaflet was discussed. It was reported on Dr Gunson's behalf that following consultation with Dr Noone at the CDSC, it had been impossible to draw up a list of countries with high HIV prevalence for inclusion in the leaflet. As an interim measure, the

NBTS considered the reference to African countries should be retained but the words *"had sex with people of any race"* be included. In the longer term, the NBTS was proposing to drop this and adopt the US approach of more face-to-face interviewing. It also proposed that *"since 1977"* should be removed and replaced by *"the previous 5 years".*

1214. I have been provided with a letter that Dr Gunson wrote to Dr Wagstaff on 6 February 1992 [NHBT0007485_001]. He advised that as Dr Wagstaff knew, there were good reasons for following the WHO's recommendations on donor selection. The WHO had reduced the exclusion period for persons who had received blood or blood products from donating from two years to one year and also had no time span in their recommended exclusions for IV drug users, homosexuals or prostitutes or the sexual partners of these persons. In addition, they had an exclusion clause which stated: *"Those with haemophilia and other clotting factor defects who have received clotting factor preparations".* He suspected that this was to exclude their sexual partners since persons in this category were unlikely to present as donors and were counselled not to do so. Dr Gunson suggested that thought be given to suitable wording to achieve exclusion of sexual partners of haemophiliacs and other patients who receive clotting factor preparations.

1215. I have been provided with the minutes of a meeting of EAGA held on 10 March 1992 [NHBT0007300_001] Dr Gunson was in attendance. The AIDS blood donor leaflet was discussed. Dr Noone from the CDSC presented an assessment of global HIV prevalence to explore the continuing validity of the sole inclusion of Africa as a self-deferral criterion. She stressed that the data on AIDS prevalence was of variable quality and could not necessarily be extended to the population in general, however accepting these defects might be interpreted to justify a broadening of the geographical exclusion area to include the Caribbean, Thailand and New York City. Members

recognised the questionable validity of the data and that it did not necessarily reflect the blood donor populations of these countries. It was agreed that the current geographic exclusion criteria should not be broadened on the basis of the available data and should read: *"Men and women of any race who have had sex at any time in the past two years with men or women living in, or who have lived in, African countries except those on the Mediterranean".* The position would be reviewed again in 12 months.

1216. The group also discussed whether generic STDs should be included as self-deferral criteria in the leaflet and agreed that donors should not give blood within two years of having an STD but that this exclusion would appear on the general list of exclusions rather than the AIDS leaflet. In addition, Dr Gunson reported that WHO had reduced the exclusion time for donors who had received blood from within two years to one year and asked the group to endorse this as the UK position, which was agreed.

Introduction of HTLV-III Testing

Summary

1217. I understand that Dr Hewitt has, in her response to the Amended Rule 9 Request of 14 August 2020, addressed the developing knowledge of HIV. I do not propose to repeat her evidence here, however it is relevant background to the introduction of HTLV-III testing by the blood transfusion service.

1218. From the documents I have been shown, it would appear that there were three stages in the introduction of HTLV-III testing.

a. Prior to the identification of the causative agent of AIDS, there were proposals and advancement of the introduction of surrogate testing. These appear to have been advanced in mid to late-1983 and primarily focused on anti-hepatitis B core (anti-HBc) antibody

screening of donors. It would appear from the documents that the causative agent of AIDS was identified in mid-1984 and therefore surrogate testing was overtaken by the development of tests for that agent.

b. There was then a period prior to the FDA approval of HTLV-III tests in America. From the documents I have seen, it would appear the blood service was concerned to get in place appropriate testing mechanisms so that review of screening tests could be undertaken once they became available. It was apparent at that time that there were concerns about difficulty in obtaining sufficient numbers of tests to do proper testing within the blood service, and also concerns about encouraging higher risk donors to donate as a result of the introduction of testing.

c. Following FDA approval of HTLV-III testing, the documents show that there was a two-stage testing procedure adopted for deciding whether the tests were sufficient for use in the UK. I note that a number failed at the first stage of that test, before two of the tests (Organon and Wellcome) were introduced in the UK in October 1985. It would appear that a great concern in the blood service, which it appears was criticised, was that donors should not suffer the threat of insufficiently specific and sensitive tests.

1219. Having seen these papers, I would make the following observations

a. At the time, this was an unprecedented situation for blood services and the world alike.
b. The importance and size of the undertaking required decision making at the highest levels with input from experts, thus this was, rightly, not a decision for blood services alone.
c. The considerations of the impact of these decisions on both recipients of blood and blood products and of donors, whilst not fully knowing or understanding them at the time, were both valid and competing and required balancing by those involved.

d. The principle that a test should not be introduced for screening without robust evaluation stands today.
e. The distinction between a screening and diagnostic test is important and both were being considered at the same time. Not having alternative testing places to avoid test seeking behaviour by potential blood donors was also a valid consideration.
f. Blood services have always had a duty of care to donors, unlike other parts of the 'system' and it was appropriate, and indeed vital, for the implications of a test evaluation or introduction to be considered by them. Introducing (or performing an evaluation of) a test with a high false positive rate, using blood donors, is difficult. Both then, and today, it would require the following considerations – how best to inform and consent donors, what to do with the positive donations, how to manage the donor testing positive and the previous donations given by such a donor.
g. The delay in the introduction of HTLV III screening between its introduction in the US in February 1985 and England in October 1985 appears to be due to the selection and availability of a test in the UK.
h. As mentioned above screening (testing) is not the only thing to ensure safety, as other measures such as donor education and selection are also important. It appears to me that in the context of no test being implemented, the AIDs leaflet was crucial and, of the two options, the leaflet was by far the simpler to implement.
i. A non-specific surrogate test is problematic for all the reasons above and pursuit of a specific screening test to implement would appear to be significantly preferable.
j. Finally, the framework for the implementation of screening, the management of donors including a lookback, in October 1985 as described in the document [PRSE0000636] *Screening of Blood Donations for anti-HTLV III in Regional Blood Transfusion Centres* laid the foundations for what we still do today.

1220. I would also note that, for a voluntary blood service, the relationship with the donor is key. Without the donor there would be no service, the reputation of the blood service and public opinion are thus important to maintain the sufficiency of supply for patients. We know this and nowadays have many more resources to ensure that we are able to maintain the confidence of the public. Both communications and recruitment of new donors today (with awareness, education and recruitment campaigns) rely on broad advertising and multichannel communications that require computers, mobile phones, email and social media, which were not available historically, together with the more traditional post. Hence at the time, the worry about losing donors should have been proportionally far greater than it might be today, as recruiting new donors was considerably harder. Today we remain significantly concerned about our reputation and losing donors, we always consider the impact on donors and sufficiency of any changes we plan to introduce. Thus, the fact that tests with a high false positive rate may have been introduced and could severely impact on sufficiency, as well as having a personal impact on donors, seems to have been a huge and both appropriate and important consideration at the time. Balancing this and the risks to patients must have been really difficult.

1221. None of the points made above are intended to detract in any way from the tragedy that subsequently enfolded.

1222. I have also provided a shorter review of the documents in respect of the introduction of HIV-2 testing. From the documents I have read, it would appear that there was a broad agreement nationally and internationally that targeted testing for HIV-2 was sufficient in the 1980s.

Detailed Response

Surrogate AIDS Testing

1223. I have been provided with the minutes of the first meeting of the CBLA Working Group on AIDS dated 14 October 1983 [CBLA0001755]. The group considered an investigation into surrogate tests for AIDS. It was generally agreed that if such an investigation was to be carried out, it would be preferable to investigate the use of anti-HBc screening rather than TPHA. A discussion took place on the possibilities of a pilot study. The follow up of donors and ethical considerations involved was identified as one area of concern. It was agreed that Dr McClelland would collate the information that had already been obtained on anti-HBc screening and submit outline proposals for a prospective study in time for the next meeting in early 1984. Dr Gunson stressed that economic considerations could not be ignored if it was concluded that an additional test for screening blood donors was proposed and it was noted that a reagent was available that may help to reduce the cost of testing. It was agreed that other surrogate tests were not yet suitable for large scale screening.

1224. I have also been shown the minutes of a meeting of the Advisory Committee on the NBTS dated 17 October 1983 [CBLA0001763]. At that meeting Dr Gunson relayed the discussions that took place at the recent meeting of the Working Group on AIDS. He explained that although there was no direct diagnostic test for AIDS, certain surrogate tests had been shown to give positive results with greater frequency in AIDS patients. Limited studies had already been undertaken and a survey of two studies at Bristol and North London RTC was to be carried out.

1225. I understand that in November 1983 the WHO held a meeting on AIDS in Geneva. It would appear that Dr McClelland of SNBTS attended. I have been shown a draft report entitled *AIDS, An Assessment of the Present Situation in the World,* dated 12 December 1983 [CBLA0001775]. Among a wide range of other things, the report refers to donor screening using non-specific tests to recognise high risk groups, which might theoretically help to identify individuals at risk of

AIDS who should not be accepted as donors. However, since such tests are not direct measures of AIDS, a certain number of individuals not belonging to a risk group would be excluded from donating blood, which may vary considerably in different parts of the world depending upon the characteristics of the risk groups. The specificity and sensitivity of any such test(s) would therefore be evaluated in the environment in which it is to be applied, taking into consideration the potential effectiveness of the test, the impact of the blood supply and potential alienation of donors.

1226. I have been provided with the minutes of a meeting of the CBLA Working Group on AIDS in relation to Blood Transfusion held on 27 January 1984 [CBLA0001799]. The group discussed proposals for the evaluation of surrogate screening tests on the donor population for anti-HBc and other non-specific markers possibly related to AIDS in order to identify donors in at risk groups. It was agreed that a protocol for the prospective study, co-ordinated by Dr Tim Wallington, consultant immunologist at the South Western RTC, would be drawn up prior to the next meeting of the Central Committee for Research and Development in Blood Transfusion. It was noted that a recommendation would then be put forward to the CBLA at its meeting in March.

1227. I have also been shown a letter dated 17 April 1984 from Dr Wallington to Mr Smart, Chairman of the CBLA, enclosing an application to the MRC for a research project grant to carry out an evaluation of screening tests for antibody to Hepatitis B Core antigen ("anti-HBc") in the detection and exclusion of blood donors at risk of transmitting AIDS [CBLA0001837].The application explains that whilst the causative agent of AIDS was unknown with no measurable specific pathological features, a number of non-specific abnormalities were found in AIDS cases and healthy members of groups at high risk of contracting AIDS.

1228. Anti-HBc was the commonest abnormality, which was also detectable in a small proportion (0.5-2%) of blood donors in the UK. The purpose of the project was to evaluate screening for anti-HBc in identifying blood donors belonging to groups at high risk of developing and transmitting AIDS. Samples were routinely taken as part of blood donations for blood grouping and other serological testing. Using these samples, 50,000 donations from two RTCs would be screened for anti-HBc, which would yield around 500 anti-HBc positive donors. Anti-HBc positive donors and matched controls would then be interviewed to establish whether or not they belonged to a high-risk group. Further tests on the samples would also be performed for certain other abnormalities associated with AIDS to establish their relationship to the risk status of the donor and their value, if any, when combined with a positive anti-HBc test as an extra discriminant of donors at risk of transmitting AIDS.

1229. I understand that on 23 May 1984 there was a meeting of the CBLA, the minutes of which I have been provided with [CBLA0004998]. Dr Gunson confirmed that the Working Group on AIDS had submitted a grant application to the MRC to carry out a study involving blood donors investigating the usefulness of performing non-specific tests and a decision was awaited. However, this had now been somewhat overtaken by events as it seemed most likely that a HTLV virus was the causative agent of AIDS. As a result of the latest developments, a paper modifying the proposals in regard to the grant application was being prepared. Dr Gunson also referred to a letter dated 21 May 1984 which he had received from Dr D A J Tyrell, Chairman of the MRC Working Party on AIDS, outlining its willingness to assist the CBLA in looking for antibodies against the AIDS agent. It was agreed that such collaboration would be advantageous and a positive reply should be sent.

The development of the first licensed HTLV-III tests

1230. It would appear that, following the letter written to Dr Tyrell, there was a meeting between him and Drs Gunson, Tedder, Wallington and Contreras on 28 June 1984. This is noted in a letter I have been shown from Dr Gunson to Dr Smithies dated 3 July 1984 [PRSE0003901]. Dr Gunson had received a letter response from Dr Tyrell at the end of May suggesting that the MRC could be helpful in setting up a study on blood donors using the detection of anti-HTLV III as a possible marker for donors who may be at high risk of transmitting AIDS.

1231. Dr Gunson explained that the work of Montagnier of France and Gallo of the US had suggested that the HTLV III virus was the causative agent of AIDS, although further work needed to be carried out before this was firmly established. However, Dr Tyrrell had pointed out that it could be the causative agent and it may be particularly useful for the detection of the pre-AIDS condition. A study on blood donors at the present time could therefore be a useful practical step.

1232. Dr Gunson advised that considerable pressure would be placed on the transfusion service if this test was introduced in the US. However, it was agreed that at the present time, the test should be regarded as a research project and should not be introduced into routine screening of blood donations without proper appraisal. It was important however, that a study should be started as soon as possible. The most important development in the study would be the availability of a viable test for anti-HTLV III. The work of Dr Tedder and Dr Weiss was very promising and although it was early days, there was reason to believe that a radio-immune assay may be available within the foreseeable future.

1233. Studies would be performed on patients in high-risk groups of contracting AIDS. With respect to studies on blood donations, the following general protocol was agreed:

a. **Stage 1:** Following successful development of the test, donor serum samples would be sent from the North West Thames RTC to Middlesex Hospital, where performance of the test would be evaluated.
b. **Stage 2**: The performance of the test would be transferred to the North West Thames RTC and experience gained on its use. At this stage, the tests would be retrospective and donations found to be positive may well have been used prior to the knowledge of the test result. The letter said that this approach could be defended ethically without problem and was entirely justifiable at that stage.
c. **Stage 3:** Donations would be tested at the Manchester RTC and Bristol RTC whilst tests would continue at the North West Thames RTC, which should give a broad view of the country as a whole. At this stage, donations would be tested prior to issue, plasma would be saved from the donation and donors would be followed up. In Manchester, if donors found to be positive had given blood within the last 8-9 months, a previous sample of stored serum would be available for testing. If this proved positive, then identification of the patients receiving the products would be made and follow-up pursued.

1234. Positive samples from the RTCs would be sent to Dr Tedder for confirmation and he would receive additional samples when the donor was interviewed. His work was to be supported by the MRC. It would not be known whether routine use of the test was justified until the results of the study had been assessed. However, the implications for routine screening should be considered early as if the results were satisfactory, there should not be undue delay before this took place.

1235. Dr Gunson outlined the further developmental work that would need to be performed in relation to the test reagents and preparation of test kits. He also advised that other issues requiring consideration included that additional staff and equipment would be needed at every RTC to carry out such routine screening. Some would also require additional

space. He noted that he had written at length about the possibilities of developing the test in the UK, since the alternative would be to purchase test kits from a US company and he said that he dreaded to think what the cost would be to the NHS under those circumstances.

1236. Dr Gunson advised that a major decision would therefore be required to proceed to routine screening, particularly when the incidence of positive reactors would probably be very low. However, he doubted it would be possible to resist pressure from various sources when dealing with a potentially fatal condition. He requested that this topic be placed on the agenda for their meeting on 7 August 1984.

1237. I have been shown a letter from Dr Harris, DHSS and Chairman of the Advisory Committee on the NBTS, to Dr Lane dated 31 August 1984 [CBLA0001875]. In that letter he advised that, in view of the recent isolation of HTLV-III which appeared to be causally related to AIDS, and the UK development of a radioimmunoassay technique for the detection of antibody to HTLV-III, it was necessary for a group of experts to consider the implications for the NBTS and he asked if Dr Lane would be willing to assist. If so, they planned to convene the first meeting of the Working Group on AIDS in October under the chairmanship of Dr Michael Abrams, Head of the DHSS's Medical Division dealing with Scientific Services.

1238. I understand that there was a meeting of the Advisory Group on Hepatitis on 9 October 1984 chaired by Sir Robert Williams [CBLA0001904]. Dr Craske provided an update on AIDS and reported that the most significant development in the last six months had been the identification of a retrovirus in the US and France. This virus was the most serious candidate found so far for the aetiological agent of AIDS. A reliable immunoassay procedure had been developed at the Middlesex Hospital and showed a prevalence of HTLV-III antibodies in 17 percent of the homosexuals at risk. The relationship between exposure and infection was not yet known. The incubation period of

AIDS could be up to six years, with the average of about four years. The number of cases of AIDS was rising rapidly, doubling every six months. Cases were mostly in London and among male homosexuals. There was a relatively low prevalence of HTLV III antibodies in intravenous drug abusers, indicating that the retrovirus had not spread widely in this community.

1239. I have been shown a DHSS memo dated 19 October 1984 [DHSC0002323_009]. The memo appears to respond to questions from the CMO concerning AIDS and blood donation. On the question of when no blood/plasma will be donated without prior testing, the memo points out that at that time only pilot studies had been conducted at the North London Transfusion Centre. The note discusses the supply of testing reagents, that an increase of supply is felt to need the agreement of US authorities, and domestic issues in the production of reagents. The memo expressed the hope that by November there would be sufficient reagents to test all blood donors at the North London Transfusion Centre.

1240. It was suggested that there is a danger in making such testing too public in the event that high risk groups start using blood donations as a way of testing for their HTLV antibody status. The memo notes that it cannot be certain when testing of each donation for HTLV-III will be established in the UK, and that it is not known when the American and French tests that are being developed will be available on the market in the UK. The memo notes that the AIDS Working Party of the Advisory Committee on the National Blood Transfusion is being arranged to consider this and make recommendations. The memo also comments on the "*position about blood transfusion/plasma related AIDS in the UK and its controls*". The memo explains that the DHSS were yet to know of a case of AIDS reliably related to blood transfusion (although there were about 40 cases in the US).

1241. I have been shown the minutes of a meeting of the Advisory Committee on the NBTS dated 8 November 1984 [PRSE0004783]. Dr Smithies reported that by the end of October 1984, 88 cases of AIDS had been reported to the CDSC, of which 75% were homosexuals and three were haemophiliacs. None had been associated with blood transfusion. Dr Smithies advised that the Middlesex Hospital and Chester Beatty Laboratory were testing for HTLV-III antibody using a radioimmunoassay method. A survey of 1,000 NBTS donors had revealed no infection, but it was hoped that a larger survey would be undertaken to confirm findings. Pilot screening at an RTC was one of the points to be considered at the Committee's new Working Group on AIDS, which was due to hold its first meeting on 27 November. Dr Cash, SNBTS, advised that in the US, the individual's permission was necessary before screening could be carried out and there were many implications for donor morale.

1242. Dr Lane requested an update on both the Gallo and British isolate availability and was advised by Dr Smithies that the US had been approached for permission to use the Gallo isolate in the UK. Some progress had been made on the British isolate, but the position would be clearer by 27 November. Dr Gunson advised that five American companies were licenced to use the Gallo isolate to develop tests.

1243. In November 1984, a paper was circulated to members of the Advisory Committee on the NBTS's Working Group on AIDS in advance of their first meeting on 27 November 1984, which appears to have been prepared by the Chairman, Dr M Abrams at the DHSS. I have been provided with this paper [CBLA0001934_003]. The paper set out various issues on which the group's views were sought in order to protect the blood supply from the increasing prevalence of AIDS.

1244. In respect of screening for HTLV III antibody, the paper advised that a radioimmunoassay for HTLV III antibody had been developed in the UK. An article in The Lancet described the test and prevalence of

antibody found in 2,000 people. 1,000 blood donors tested were all negative, whereas it was present in patients with AIDS and from high-risk groups. The test had subsequently been used in a limited manner and it had not yet been possible to scale up production as the original isolate used to develop the test was acquired from Dr Gallo in the US on the basis of an exchange between scientific workers in the same field. Five US companies had been awarded licences by the US Government which gave them access to HTLV-III from Gallo's original isolate for commercial development. Tests developed by those companies, which could be used for screening blood donations, were expected to be available in early 1985.

1245. The DHSS had just received authorisation from the US for the wider use of the Gallo isolate in the UK. A British isolate of the retrovirus HTLV III was also now available and it was expected that a radioimmunoassay test using this material would be developed. As it seemed probable that test reagents would only be available on a restricted basis at first, consideration was needed as to how best to use the tests in the NBTS. Relevant factors included whether there was a case for preferential testing (i.e. all whole blood donations, plasmapheresis donations or donations for cryoprecipitate) and whether RTCs in areas with an increased prevalence of high risk groups should institute testing before others.

1246. The paper advised that facilities would be required to confirm the results of any positive tests. As the number of positive results was likely to be small, it was queried whether it might be preferable for confirmation to be undertaken in one place. Once a positive donor was identified, a retrospective survey of previous donations would be required. The extent of the survey would depend on the number of previous donations, how they were used and where they were given. It would probably be necessary to ask the donor directly for the latter information. The surveillance of donors with HTLV III antibody seemed necessary and consideration should be given to whether the current

method used for donors found to be positive for hepatitis B antigen (namely, asking the donor to consult his GP and informing the GP directly) would be sufficient or if other arrangements should be made. It was also queried whether the CDSC should be notified of antibody positive donors in addition to those currently reported with AIDS.

1247. It was noted that the Health Department in the US had issued a statement of informed consent for blood donors, which agreed to a small sample of blood being saved for use at a later date to test for infectious agents (as part of a national research study of 200,000 blood donors). It was queried whether such a study should be initiated in the UK pending the institution of the screening test for all donations. Further, it was queried whether donors should be informed that they were being screened for HTLV-III antibody when the screening test was instituted.

1248. Consideration also needed to be given to the likelihood of Factor VIII and other blood products transmitting HTLV III and how best to ensure such products were free from infection. It was queried whether donations used for blood products might be considered to have screening priority, unless other means were used to inactivate HTLV III. There was some evidence that dry heat treatment of Factor VIII might be effective. Further, it was queried whether methods of heat inactivation be used even if donations are screened for antibody.

1249. I understand that the first meeting of the Advisory Committee on the NBTS's Working Group on AIDS was held on 27 November 1984. It was chaired by Dr Abrams of the DHSS. I have been provided with a report of the meeting from Dr Abrams [DHSC0002251_011]. It would appear that there was a unanimous strong view at the meeting that the antibody test for HTLV-III must be used for all NBTS donors as soon as possible. It was hoped that the Tedder/Weiss test could be scaled up very quickly, although Professor Weiss pointed out some of the problems of doing this.

1250. If test kits were limited initially, it was thought they should be used first in North London where Dr Tedder, Professor Weiss and Dr Contreras could supervise the introduction. There was an inconclusive discussion on whether the kits should be used preferentially, if in short supply, in high-risk donor areas. There should be a central laboratory (or laboratories) to confirm all positive results.

1251. It was noted that donors should be told that HTLV III testing would be added to the other tests performed on their blood. Donors with positive results should be informed, although there was no unanimity on who should do it or how. Follow up of donors and patients, counselling and contact tracing arrangements were being considered by IMCD (this appears to refer to the DHSS Communicable Diseases Division). One suggestion was for a regional immunology service to deal with such issues at special centres. It would also appear that some of the participants raised concerns about how the further research and testing would be funded.

1252. I understand that on 10 December 1984 there was a combined meeting of blood service members with UKHCDO, PHLS, the DHSS and BPL (among others). I have been provided with the minutes, but they are quite difficult to follow [CBLA0001948]. It was noted that testing was likely to be recommended for haemophilia patients and contacts, in addition to the 2,500 haemophiliacs who would require regular testing. The testing of contacts for haemophilia alone would be in the order of 10,000. If one broadened the test to take in the NBTS, it was clear that many thousands of tests would be required each year.

1253. Dr Craske advised that at present, test reagents were only available on a research basis and substantial resources would be required to enable the proposed workload to be undertaken. Limited resources made it impossible to undertake routine tests at the moment. There was some discussion as to which organisation would be best placed to

organise the testing and whether DHSS financial support would be forthcoming. Dr Lane suggested that if resources were available, BPL would help to coordinate the endeavour. Dr Smithies advised that she would take these points back to the DHSS for consideration.

1254. In respect of blood donor testing, it was suggested that either the mass commercialisation of a British test or application of a current commercial test was required. It was confirmed that testing would be introduced at two centres early in 1985 prior to widening availability to the rest of the NBTS. Dr Gunson advised that it would be preferable to test all donors, however if resources were limited it might be better to concentrate testing at the major "*risk*" centres. Dr Cash was concerned that no central organising body was being contemplated for the test programme. This view was confirmed by Dr Tedder, who was concerned that the pace of test advancement was so fast that the scientists were left to introduce a test as soon as possible. Further concern was expressed over the lack of financial support from the DHSS. It was noted that a long discussion took place in respect of whether those found to be positive should be informed and several differing views were expressed. It was agreed that clinicians would decide depending on the facts of each case, but in general information should be provided if asked for.

1255. Professor Bloom summarised the discussion up to that point by advising that testing should be instituted as soon as possible and that information on test results should not be given automatically, but if asked for. Heat treated material should be given preferentially in those cases where concentrate is required. The financial considerations must be considered secondary to the primary aim of treatment.

1256. I understand that there was an RTD meeting on 23 January 1985. I have been provided with the minutes for that meeting [CBLA0001995]. It was noted that the AIDS Working Party had met in November, which was felt by the RTDs in attendance to have been unproductive, there

being as yet no new leaflet, no finance and no positive move towards full donor screening. The DHSS had set up another AIDS Working Party (The Expert Advisory Group on AIDS) of which Dr Gunson and Dr Contreras were members. It is recorded that the RTDs were unhappy that no information had been given to them.

1257. Dr Contreras, RTD, provided an update on the status of HTLV-III testing and advised that as yet, there was no date for availability of tests for a pilot study. The anti-core test would be evaluated at Edgware (North London RTC) on stored samples. Companies were approaching RTDs with tests and it was felt strongly that they should not be pressured by commercial sources to accept a test which was not suitable for NBTS purposes. It was also considered that the DHSS should be pressed to make any test available to the community before its use in blood donor screening, otherwise unsuitable donors would be attracted (attending purely for the purpose of being tested). Dr Lane advised that high purity heat treated Factor VIII would be available in the Spring. He stressed that the Haemophilia Society's anxiety was not for testing but effective heat treatment of Factor VIII.

1258. I understand that the first meeting of the DHSS Expert Advisory Group on AIDS was held on 29 January 1985. I have been provided with the minutes for this meeting [PRSE0002734]. Among a range of other issues, the group discussed the work being carried out to develop a screening test. The Chairman said that DHSS would ensure all tests were evaluated. It was uncertain how soon a screening test would be available. He reminded members that the November meeting of the NBTS Advisory Group on AIDS had concluded that a screening test for all blood donors should be made available as soon as possible, which was generally supported by the group. A subgroup was set up to consider the various aspects of screening tests for AIDS, in particular the best way of introducing the service when the tests became available. The subgroup would be chaired by Dr Smithies and its members included Dr Gunson.

1259. I have been provided with the minutes of a meeting of the CBLA which was held on 1 February 1985 [CBLA0002007]. There was a discussion of HTLV-III testing using RIA Testing. Dr Lane confirmed that BPL could produce an alternative to Chester Beatty's work at a lower cost if provided the antibody. Dr Gunson confirmed the necessity of testing. It was noted that the role of CBLA in the matter was not yet established but there would be related capital requirements for equipment for RIA tests. The Chairman stressed that revenue sparing was as important as saving. Dr Gunson emphasised that enzyme assays were a US test and if the UK needed to convert to this that would be a significant problem for the continuance of RIA testing. Thus, it was thought vital that a British test be developed.

1260. I have also been provided with the minutes of the EAGA Screening Test Subgroup which held its first meeting on 15 February 1985 [DHSC0000425]. The Subgroup's terms of reference were to advise the EAGA on the introduction of an antibody test to the AIDS virus. An update was provided on the availability of a screening test. A paper was tabled describing US kits and their results (entitled FDA Evaluation of HTLV III). The kits had not tested the same serum samples. It was agreed that it was essential to do repeat assessments on the same samples in the UK and that evaluation would also have to incorporate confirmatory procedures. The Chairman confirmed that the DHSS had invited companies developing test kits to take part in an evaluation. Initially tests would be undertaken by PHLS against their existing sera panel, followed by an evaluation in RTC's and laboratories serving STD clinics. The Chairman asked Dr Gunson and Dr McClelland to consider the feasibility of acquiring sufficient samples in RTCs and Dr Pinching from STD clinics.

1261. It was noted that RTDs wanted a common date for the introduction of a test into the NTBS. It was considered that individual RTCs should be dissuaded from implementing tests on a local basis and it was agreed

that tests should be made available for the clinical setting first. The Subgroup noted the need for one or two central Reference Centres for use by District General Hospitals and RTCs. It was proposed that consideration should also be given to the ethics of informing people that their blood was going to be tested. It was noted that Dr Abrams' Subgroup had advised that blood donors should be informed that their blood was going to be subjected to a number of tests. A final decision as to whether sera collected for evaluation tests should be collected anonymously was deferred to the next meeting.

1262. I have been provided with the minutes of the RTD meeting on 23 January 1985 which was reconvened on 18 February 1985 to complete the agenda [CBLA0001995]. It is noted at the end of the minutes that Dr Smithies and Mr Williams, DHSS, informed the RTDs on the DHSS policy on HTLV III testing and counselling, although details of this discussion are not documented.

1263. I understand from a report of the World Haemophilia AIDS Centre [BART0000795] that on 2 March 1985 the FDA approved three test kits for screening HTLV-III. These were the Abbott Laboratories, Electro-Nucleonics Inc and Litton-Bionetics tests. It was reported that the American Red Cross immediately signed an agreement with Abbott and accounted plans to phase-in the assay within days, with nationwide implementation to take 2-6 weeks. It was noted by government officials that the new tests would need to be used cautiously since "*it is neither error proof nor a diagnostic test for AIDS*". The Editor's note attached indicated that "*[r]eaders are cautioned that this antibody test is a good screen for blood and blood products but is a poor test for diagnosis of patients. 'It screens blood not patients'.*"

1264. The World Haemophilia AIDS Centre document also summarised the ABRA Newsletter from March 1985. This included information on the intention to test in the US, and Germany requiring that plasma and

plasma products exported to Germany after 1 October 1985 must be tested. It was thought by April or May a blood/plasma industry standard would have been established. The FDA was expected to call for testing of all such products. The summary then explains the testing and disposal process.

Introduction of HTLV-III testing in the UK

1265. I have been provided with the minutes of the EAGA Screening Test Subgroup from 1 March 1985 [DHSC0000421]. Dr Gunson and Dr McClelland tabled a paper which outlined a proposal for the evaluation of test kits in a field trial of 10,000 specimens collected routinely from blood donors across ten RTCs, which it was hoped would be sufficient to test all the kits found to be reliable in the evaluation undertaken at the PHLS as well as evaluating "second generation" tests. Dr Pinching confirmed that he would be able to collect specimens from about 120 people attending STD clinics and believed to be at high risk, which would provide materials for evaluation of test kits in a population where the number of positives would be expected to be high.

1266. The meeting also discussed a letter to be published in the Lancet from a large number of RTDs in England, Wales and Scotland. The group agreed that the letter, whilst in danger of being misinterpreted in that it might be regarded as recommending open access screening, did point to the concern felt about the early reports of the unreliability of commercial tests produced in the US and the need for their full evaluation before they were introduced into the RTCs.

1267. The Subgroup discussed informed consent. It is documented that the proposed field evaluation would not require the participants' consent because the sera would not be able to be identified with the donors. However, Dr Gunson and Dr McClelland recommended that when tests for blood donations were introduced, donors should be informed that their blood would be tested for AIDS, e.g. through leaflets sent with call up cards or provided at sessions. A lot of donors might not be

prepared to give blood if they knew it was going to be tested for AIDS and efforts would have to be made to recruit more donors. It was agreed that legal opinion should be sought in respect of obtaining informed consent from blood donors. Dr Pinching expressed unease about studies being carried out on samples collected from individuals attending STD clinics who would not necessarily have consented to these investigations. It was noted that such studies provided invaluable information about the spread of the disease, for which there was no other way of finding out. However, it was agreed that the conduct of these studies required further consideration.

1268. The Subgroup considered the re-testing of positive samples. Dr Gunson advocated that the original sample should be referred to the reference centre for confirmation before a donor was recalled. Dr McClelland thought that the donor should be recalled if two tests on the first sample were positive and the second sample taken for confirmation. It was agreed that local practice would differ between RTCs, however all members were unanimous that a positive test on two samples, one of which would have been confirmed by the reference centre, was required before an individual was regarded as being truly seropositive. Dr McClelland considered whether all positive donations, even if not confirmed, should be regarded as inappropriate to use for transfusion and the donor taken off the panel. In view of the current lack of knowledge about the exact significance of the test, it was thought that such a donor might be deferred. Dealing with these donations would depend on the circumstances and be a matter for local judgment.

1269. I have been shown the letter published in the Lancet on 2 March 1985 [PRSE0004824]. The letter advised that current commercial kits for HTLV III antibody tests were likely to give a high rate of false-positive results and they would therefore recommend that careful consideration be given before they were introduced for the screening of all blood donors, *"for the amount and degree of unnecessary stress and*

hardship that a fair number of our donors and their families would thus have to undergo is unacceptable". This in turn could lead to a sizeable drop in the supply of blood and blood products. For the safety of transfused patients, the first priority for HTLV-III antibody tests should be given to patients attending venereal disease clinics and other members of the general public who wish to access these tests. Otherwise, many high-risk people may present at blood donation sessions simply to find out their HTLV-III antibody status. *"We do support, strongly, the screening of all blood donors for HTLV-III antibody testing, but we would advise that this is delayed until test systems have been appropriately evaluated and efforts have been made to give all members of the public access to HTLV-III antibody testing".*

1270. I have been shown a memo that was sent from Dr Smithies to Dr Harris at the DHSS on 11 March 1985 [PRSE0002672]. That memo concerned the evaluation of antibody screening tests and the introduction into the NHS. Dr Smithies advised that all manufacturers known to be making diagnostic reagents had been informed that the DHSS intended to evaluate their kits and advise the NHS of those that were sufficiently reliable to be used in laboratories. Five manufacturers had indicated their willingness to co-operate.

1271. The initial evaluation of the kits would be undertaken at the PHLS Virus Reference Laboratory. The protocol for this evaluation would be agreed by an ad hoc panel of virologists on 18 March 1985. An Expert Advisory Sub-Group had advised that a field evaluation of the kits would also be necessary because of the preliminary results of FDA studies. A protocol for these field evaluations would be considered by an ad hoc panel comprised of the virologists, BTS representatives and a statistician. The field evaluation could not be started until the kits had gained approval in the initial evaluation, however arrangements were being made to collect and store the sera for testing. Kits which satisfied the evaluation would be listed by the DHSS.

1272. I have been shown the minutes of the second meeting of EAGA on 13 March 1985 [PRSE0000456]. The Group discussed draft DHSS guidance papers about AIDS for doctors, which were intended to be annexed to a letter from the CMO. The draft papers were endorsed subject to some agreed amendments. It was acknowledged that the guidance would need to be revised as knowledge about AIDS developed. It was agreed that the CSDC's report on AIDS dated 22 February 1985 should also be annexed to the letter. Dr Smithies, DHSS, provided an update on the two meetings of the Screening Test Sub-Group. The various types of confirmatory tests were discussed at length.

1273. I understand there was a meeting of the EAGA Screening Test Subgroup on 28 March 1985 [DHSC0001571]. The minutes note that due to the great logistical problems in seeking "*informed consent*" at sessions, RTDs should be consulted and devise agreed procedures on providing information to donors. It was agreed that all anti-HTLV III positive donors must be informed of their results because of the danger to their health and that of others.

1274. Dr Mortimer, PHLS, provided an update on the PHLS evaluation of screening tests, which he considered might start in May 1985 subject to obtaining additional trained staff. He thought the evaluation might take 4-8 weeks after a protocol had been agreed. Dr Gunson reported that a sufficient number of regions had agreed to help with the evaluation. Members discussed a draft report setting out the Subgroup's recommendations on the introduction of a test for antibody to the AIDS related virus for the EAGA. A further draft was circulated in early April and the final version was submitted to the EAGA for consideration at its next meeting on 22 April 1985. I have been provided with that report [PRSE0002096].

1275. The Subgroup's report confirms that five manufacturers in the US had been licensed to use the HTLV III virus isolated by Dr Gallo to develop a diagnostic test for the antibody to HTLV III. The Pasteur Institute in France was also known to be developing an antibody test based on the LAV virus isolated by Dr Montagnier. In the UK, Wellcome Diagnostics were developing an antibody test based on Professor Weiss's isolate. It was expected that others would enter the field. The test developed by the US companies had been used in trials to provide data to obtain FDA approval. FDA licences had now been granted to Abbott Laboratories and Electronucleonics, enabling them to market their test kits in the US and abroad. The DHSS had informed all companies known to be developing tests of its intention to evaluate those test kits which were to be marketed in the UK and then advise the NHS on which ones had proved satisfactory. A group of experts had been invited to form an advisory panel and to agree the protocol for evaluation.

1276. Plans for a two stage departmental evaluation of test kits had been made. Firstly, a preliminary assessment of each diagnostic kit would be made at the PHLS Virus Reference Laboratory. Secondly, tests found to be sufficiently sensitive and specific would then be evaluated in a field trial in the NBTS. The same panel of sera should be used for testing all kits, as the evaluations required by the FDA were thought to be unsatisfactory because different sera had been used to evaluate each kit. Sufficient aliquots of the panel of sera were required to ensure they were available when "*second generation*" kits were developed. Positive samples would be subject to confirmatory procedures including the Western blot as they became available.

1277. The Subgroup recommended that testing facilities should be available to clinicians caring for patients in high risk groups for AIDS. The availability of tests in the NHS should be publicised before or at least simultaneously with the introduction by all RTCs of the screening of blood donations. Members endorsed the RTDs decision that the

screening of blood donations should, as far as possible, be introduced at all centres at the same time. Before routine testing commenced, reference centres must also be established, to which positive sera could be referred for confirmation. The Subgroup also identified a need for panels of reference sera to be collected and distributed to laboratories undertaking testing.

1278. Tests undertaken as part of the evaluation studies would not require the consent of donors as the sera would be made anonymous. Tests undertaken on individuals in high-risk groups and others considered to be at risk should be with consent after counselling. Blood donors should be formally notified that all donations would be screened routinely so as to give them an opportunity to withdraw. RTDs should devise an agreed procedure for all centres to follow when informing donors.

1279. All sera obtained from blood donors and found to have a positive reaction should have the test repeated. If the repeat test is positive, a further sample should be obtained from the blood pack and sent to the reference centre. Only if the reference centre confirms the positive result should the donor be recalled, informed and referred for further testing and counselling. If the reference centre does not confirm the positive result, the donation should be discarded. The donor would be screened again at their next visit and steps taken according to the results of the screening test. If the repeat test is negative after a positive initial test, a sample should still be sent to the reference centre for confirmation. If the confirmatory test is positive then the donor should be recalled as above. If it is negative, then that donation should be discarded but the donor should be kept on the panel and tested again at the next visit.

1280. The strictest confidentiality of test results should be maintained and the necessary arrangements and facilities provided to preserve such confidentiality. The Subgroup felt that there would be considerable

costs consequences arising from their recommendations, e.g. on freely available diagnostic testing, reference centres, strict confidentiality etc, that could not be met from within existing resource allocations.

1281. I have been shown the minutes of a meeting of the CBLA Central Committee for Research and Development in Blood Transfusion from 2 April 1985 [CBLA0002113]. The committee discussed the introduction of anti-HTLV III testing. Dr Gunson confirmed that five US companies had been asked to develop screening tests in 1984 and two had now been licensed by the FDA, which meant that exported tests from the US could be used in other countries. However, Dr Gunson highlighted possible problems in introducing the test in the NBTS:

- Obtaining a proper [e]valuation with the US test on the donor population would be difficult and the UK might need to undertake its own.
- The implications of a positive test and transmission to others could not be determined at present.
- Whilst people in high risk groups were currently being asked not to donate blood, some might be attracted to donor sessions in order to be tested if the NBTS introduced the test unilaterally.
- If tests were not introduced simultaneously in the UK, there could be public concern if certain regions fell behind schedule.

1282. Dr Smithies, DHSS, reported that evaluation studies of the tests had been set up. A protocol for the evaluation had been sent to manufacturers and results would hopefully be received by mid-May 1985. The importance of test evaluation was emphasised and it was agreed that an adequate confirmatory laboratory service was also required, especially in view of the high incidence of false positive results. Dr Gunson raised a question about testing in the haemophiliac population and was informed about tests carried out in Oxford and at

Middlesex Hospital. The results had confirmed the importance of evaluation.

1283. I have been provided with the minutes of a meeting of the RTDs on 17 April 1985 [PRSE0002906]. The Chairman commented on how valuable the recent AIDS meeting with Dr Smithies at the DHSS had been to the RTDs, which appears to refer to the reconvened RTD meeting that took place on 18 February 1985. There was support for future meeting invitations to be extended to Dr Smithies and Mr Williams from the DHSS and Mr Armour from the CBLA, which would make them aware of NBTS issues and avoid delay in communication. Dr Gunson outlined plans for the two stage evaluation of anti-HTLV III tests at the PHLS and NBTS. He advised that 1 October 1985 had been suggested as the starting date.

1284. I have been provided with the minutes of a meeting of EAGA held on 22 April 1985 [PRSE0001239]. Dr Gunson was absent but Dr Contreras was in attendance. Dr Smithies, DHSS, introduced the Screening Tests Subgroup's circulated report on the introduction of a test for anti-HTLV III (see above). There was general agreement that before any screening test was introduced into the NBTS, there was a need to ensure that it was reliable and proper validation tests and arrangements were available.

1285. The Screening subgroup's recommendation that RTDs should devise an agreed procedure for all centres to follow when informing donors about screening and test results was accepted and it was agreed that a meeting of RTDs should be set up quickly for this purpose. The Subgroup's recommendations concerning the need to set up reference centres before routine testing commenced and for panels of reference sera to be collected and distributed to laboratories undertaking testing were also agreed. In respect of the Subgroup's proposals regarding repeat and confirmatory testing in the event of a positive result, there was some discussion as to the extent to which RTDs would wish the

EAGA to take decisions on the detailed procedures to be operated within the NTBS. However, Dr Abrams explained that the EAGA was expected to give unequivocal advice to the CMO on the principles involved. The Subgroup's recommendations at paragraph 11 were noted to be broadly acceptable, but would be considered further at the next meeting.

1286. I have been provided with the minutes of the fourth meeting of EAGA dated 29 May 1985 [PRSE0002837]. Dr Mortimer provided an update on PHLS's evaluation of available screening tests and it was recorded that three kits were being tested in the next two to six weeks and it was hoped that at least three sets of data would be available for discussion by an ad hoc group of experts in mid July 1985. Further discussion took place regarding how the samples would be tested and validation of the results. Dr Harris said that whilst it was important to introduce a reliable screening test as soon as possible, an effective evaluation was essential and should not be rushed. Professor Bloom expressed his concern at delaying the introduction of a screening test in the BTS and hoped it would be initiated as soon as possible.

1287. I have been shown a letter from Dr Harris of the DHSS to Dr Whitehead of PHLS dated 31 May 1985 asking as to when the evaluation studies would be completed and the service would be ready for the countrywide introduction of the antibody test, with facilities for confirmatory tests [NHBT0000186_032]. The letter emphasised the importance that the DHSS attached to completing the evaluation as soon as possible and to have in hand the further steps that are needed when the tests are introduced. He advised that Ministers must be in a position to announce the steps that the UK has taken, with the background knowledge that countries such as Germany, France, USA and Australia are already testing for the antibody.

1288. I have been provided with a report from Dr Mortimer which appears to be in response to this letter from June 1985 [NHBT0000186_032]. In

summary, he advised that a supply of reliable, commercially produced anti HTLV-III test kits was required, preferably from at least two manufacturers (ideally one from the UK, Wellcome, and one of the several US manufacturers) to cope with screening and confirmatory tests. The first stage evaluation of available commercial kits by the PHLS would be completed in July 1985. The second stage evaluation of these and other kits would then be carried out at BTS laboratories in Edgware and Manchester and by the PHLS. In Autumn 1985, the PHLS would run training courses for laboratory workers in respect of the available commercial tests, confirmation of test results and quality control.

1289. Dr Mortimer emphasised that the serious implications for individuals of a positive finding demands that the tests are accurately performed and all positive and suspect negative findings are repeated by the same test and confirmed by at least one, preferably two, methodologically different assays. Further discussions between the CDSC, NBTS Directors and others involved was also recommended to ensure a confidential and comprehensive reporting system to the CDSC that would identify and distinguish provisional from confirmed positive findings and avoid duplication in order to effectively monitor the spread of infection.

1290. I have been provided with the minutes of a meeting of the EAGA Screening Test Subgroup from 10 June 1985 [NHBT0000186_033]. Dr Mortimer provided an update from PHLS in respect of the ongoing evaluation of test kits which was discussed in detail. In summary, three test kits would be evaluated by the end of June 1985 which would allow the NBTS field trials to go ahead earlier than planned.

1291. Dr Gunson reported that a donation found to be positive would be discarded and the test would be repeated on the pilot tube and donor bag. All positive sera would then be sent for confirmation to the Reference Laboratory. If the positive finding was confirmed, the donor

would be recalled to the RTC for further samples and counselling. Members agreed that it was crucial that NBTS staff were suitably trained for this counselling role. If the Reference Laboratory was unable to confirm the positive finding, the donor would not be informed, but their donor card would be marked and the donor tested again at their next visit. If the next donation tested positive, the donor would be contacted for a further sample and informed of the reason for recall. The name and address of the GP would be sought and results forwarded.

1292. The Subgroup also considered the follow up of earlier positive donations. It was agreed that where long-standing donors were found to be antibody positive, only physicians should be informed (via the haematologist) and it would be for the physician to decide further action.

1293. I have been provided with a report entitled *Effect of AIDS on the Blood Transfusion Service* which appears to have been prepared for a Consultant Advisor Meeting on 14 June 1985 [NHBT0039762_105]. The report summarises the effects that AIDS had had on the NBTS and measures being taken to try and meet *"what is, arguably, the most important challenge that the Transfusion Service has had to face".*

1294. The report states that RTCs in England and Wales were following a common policy with respect to the implementation of procedures designed to increase the safety of blood transfusion and two measures had been put into effect: (1) The distribution of leaflets to prospective blood donors giving facts on AIDS and asking people in high-risk categories not to give blood. Distribution was arranged so that every prospective donor was given a leaflet and donors asked at blood collection sessions if they had read it. (2) Factor VIII concentrates were now heat-treated, which was hoped to inactivate the HTLV III virus. The report refers to an antibody test being developed in 1984 and states that several companies had test kits available. It is

emphasised that this was not a diagnostic test and a positive result only indicated that a person had been exposed to the AIDS virus and did not necessarily mean they would develop AIDS, although this could not be ruled out. Prior to sale of the test kits in the UK, the companies involved had evaluated the tests for the purpose of licensing by the FDA in the US, which had provided some evidence of differing degrees of false positive reactions. Whilst the UK trial of the kits may defer the introduction of routine testing for a short period, it was considered essential to ensure that the most effective and economical screening of donations was put into use.

1295. It had been agreed that, contrary to current policy with respect to tests on donor samples, it would be necessary to inform the donor that anti-HTLV III tests would be carried out on the donation and the donor would be informed of confirmed, positive results. This could only be done with the donor's agreement, and an effective means for contacting and consenting every donor was being worked out. It was uncertain what effect this would have on donor recruitment. An infrastructure would be necessary to handle the work involved and reference centres would be needed to carry out the confirmatory tests resulting from the screening tests at RTCs. There would also have to be appropriate means for keeping the donor's family doctor informed and for the counselling of donors with confirmed positive results. The report stated that these matters were being urgently considered, both within the NBTS and with the DHSS.

1296. Lastly, it was important to ensure the blood supply was not made less safe as a result of introducing the screening test, meaning there should be alternative venues where high risk groups could obtain anti-HTLV III testing, to prevent them ignoring the request not to donate. The danger inherent in such persons donating was that they may be carrying the virus without having developed the antibody and the screening test would then be negative and the donation would be passed for clinical use.

1297. I have been provided with a press release from Mr Kenneth Clarke dated 27 June 1985 [DHSC0001184]. It announced that a test would be introduced within the next few months to screen all blood donations for antibodies to the AIDS virus. Arrangements would also be made for STD clinics to provide a test for people concerned that they may have been exposed to the disease. Mr Clarke stated:

I understand and share the concern to get these tests in use as soon as possible. However we must have tests which are accurate and can be trusted. A number of test kits are already available and in use abroad but reports from those countries suggest that the tests are not entirely reliable. We believe that no test should be introduced in the UK until its reliability has been established. There is no point in introducing a test which often fails to detect antibodies in the blood or detects antibodies where there are none. An evaluation programme is being undertaken by the Public Health Laboratory Service and National Blood Transfusion Service experts as a matter of urgency. It is essential to complete this programme if we are to have a sensible policy that really does protect the public. Contrary to reports in today's press no decisions on choice of test kits have yet been made. We hope that we will be able to introduce a test within four to five months. We are also making arrangements to offer counselling to anyone whose blood is found to be positive. We expect that the number of blood donors found to have antibodies is likely to be very small. The risk of contracting AIDS from receiving a blood transfusion remains extremely small and screening will reduce this risk still further. There is no risk at all to those giving blood of contracting AIDS.

1298. The press release's note to editors confirmed that the Government had provided funds of over £57,000 to enable the PHLS to carry out a full evaluation of all the test kits which were currently available. A further £750,000 would be provided for the PHLS to set up laboratory

facilities to confirm the results of any blood donations found positive and to test the samples taken in STD clinics.

1299. I have also been provided with a background note relating to this announcement from the CMO [DHSC0001501]. The CMO points out that more than two million blood donations are collected each year and it is therefore essential to ensure that any tests introduced on this scale must be known to give consistent results and be specific and sensitive. Whilst the commercial products already on sale had been evaluated elsewhere on an individual basis, no comparative evaluation was available. The PHLS was currently conducting such an evaluation and a field trial (in the NBTS) designed to explore the specificity of the test and operational aspects of its routine use in large scale screening throughout the country would also be essential and enable an informed choice to be made. He states it had been suggested that testing should be introduced immediately, before the reliability of the tests available had been evaluated. However, he explained that early experience of other countries and the considerations outlined in his note had led Ministers to decide that it would be wrong to introduce a screening test until the further evaluations had been carried out.

1300. I have been provided with the minutes of a meeting of the CBLA Central Committee for Research and Development in Blood Transfusion dated 9 July 1985 [BPLL0004117]. Dr Gunson reported that five company tests were now available for anti-HTLV screening. It was his view, however, that until a proper evaluation had been carried out within the PHLS and BTS, the tests should not be used for routine screening of blood donations. By not knowing the prevalence of antibodies in the donor population, the NBTS was yet unaware of the most effective test, especially as far as false positive results were concerned. It was noted that 6,000 donor samples were due to be tested at Edgware and Manchester and results would be analysed as the studies continued. Six PHLS laboratories in addition to PHLS Colindale were being set up as reference laboratories.

1301. Professor Bloom referred to his capacity as Chairman of the Haemophilia Centre Directors and said that whilst he appreciated the need for a proper evaluation of the tests, as a representative of "users" his immediate priority was the protection of Factor VIII recipients. He therefore considered that any undue delay in the introduction of tests would be unreasonable.

1302. I have been provided with minutes of a meeting of the RTDs on 10 July 1985 [CBLA0002212]. At that meeting Dr Gunson provided an update on testing in the NBTS, which it was hoped would begin shortly. It was noted that the PHLS report would indicate the preferred tests and trigger the full evaluation of donor samples in the NBTS. The results would be presented and RTDs would be able to decide on testing procedures. The RTDs agreed that time would be required to establish routine testing as accommodation, equipment and staff recruitment and training would be necessary once it was known which test would be in use. A definite date for initiating testing had not yet been given, but October 1985 was the objective.

1303. Concern was expressed that high-risk members of the general public might be attracted to blood donor sessions in order to obtain testing and it was felt strongly that publicity should be used to deter this from happening. Dr Smithies, DHSS, reassured the meeting that concern was felt centrally on this matter and the message would be reinforced on testing and counselling. Dr Smithies requested nomination of two representatives from each RTC to attend a special counselling course.

1304. I have been provided with a report dated 11 July 1985 prepared by the Working Party of the RTDs' Committee entitled *Screening of Blood Donations for Anti-HTLV III in Regional Blood Transfusion Centres* [DHSC0000406]. The report states that in accordance with the resolution of the EAGA, Dr Smithies, DHSS, consulting with the NBTS on the screening of blood donations for anti-HTLV III, the RTD

Committee had formed a Working Party comprised of six RTDs from the NBTS (including Dr Gunson) and Dr McClelland from the SNBTS. The contents of the report were approved by the Directors of both the NBTS and SNBTS and subsequently endorsed by the EAGA on 30 July 1985 (see below). It would appear that this report laid down the framework for the introduction of routine screening throughout the UK, including a target start date of October 1985. It outlined recommended procedures for informing donors that their blood would be tested, the management of positive results, the care of positive donors and significantly, lookback in respect of recipients of positive donations.

1305. The report recommends that prior to the commencement of screening in the NBTS, there should be the establishment of 1) reference centres for carrying out nationally agreed confirmatory tests on positive sera and 2) alternative venues for anti-HTLV III tests for the general public who were not blood donors.

1306. It was agreed that an evaluation in the NBTS of different test kits should be performed. However, it was recognised that there was a degree of urgency for the introduction of routine screening and RTDs were therefore being advised to make arrangements with their respective RHA's for the initiation of testing whilst the NBTS evaluation was proceeding, the selection of kits for use being made on the recommendations from the PHLS study. As such, long term contracts with a particular manufacturer should be avoided until the results of the NBTS evaluation were available. If these measures were taken, it may be possible to commence screening of blood donations by October 1985 and it was agreed that the introduction of the tests should take place throughout the UK over the shortest period practicable.

1307. The following procedure was proposed for RTCs to follow on receipt of a positive screening test result:

1) If the initial screen test is positive, the donation is not used for transfusion. The test is repeated both on the initial sample and on a sample taken from the actual donation or integral donor line.
2) If one or both of the repeat screening tests is/are positive, a sample of serum and plasma from the donation is sent to the reference centre for confirmation.
3) If both repeat screening tests are negative, the donor will remain on the panel and not be informed. The donor will be recalled for a further donation. The donor records will be flagged so that particular attention will be given to the testing of a subsequent donation. A sample may be sent to the reference centre, depending on local agreements.
    - If screening tests on the subsequent donation are negative, the donation will be made available for use and the flag will be removed from the donor's record.
    - If screening tests on the subsequent donation are positive, the donation will be discarded and a sample of serum and plasma sent to the reference centre for confirmation.
4) If the confirmatory tests on the initial donation are positive, the donor will be suspended from the panel. An interview with the donor will be arranged, where a further sample of blood will be collected and sent to the reference centre where the original confirmatory tests were carried out.
5) If the confirmatory tests on the initial donation are negative, the donor will remain on the panel and will not be informed. The donor will be recalled for at least one further regular donation and their record flagged so that particular attention will be given to testing the further donation.
    - If the screening tests on the subsequent donation are positive, the donation will be discarded and a sample of serum and plasma will be sent to the reference centre for confirmatory tests.
    - If the confirmatory tests on the subsequent donation are negative, this is probably a "non-specific result" and the donor

should be removed from the panel. The donor should be interviewed and advised that his/her blood contains a factor which is not harmful and is unrelated to AIDS, but which interferes with routine testing of blood.

- If the confirmatory tests on the subsequent donation are positive, proceed as paragraph 4.
- If screening tests on the subsequent donation are negative, the donation will be passed for use providing all other tests are satisfactory.

1308. It was recommended that all donors are notified before giving blood that their donation will be tested for anti-HTLV III by being sent or given a leaflet. Donors were to be asked to confirm that they agree to the test by signing form "NBTS 110", which asks donors to tell the doctor in charge if they have any of the listed conditions (e.g. anaemia, cancer, asthma), have visited any places abroad (other than Europe or North America) or have had or been in contact with an infectious disease. It also stated *"Please read the leaflet explaining about AIDS. All blood donations will be tested for the AIDS antibody and other infections. If your donation reveals a positive result you will be asked to attend for further confirmatory tests. Please sign below to show that you have read this notice and that you agree that your blood is tested".* Donations would not be accepted from donors who did not agree to have their blood tested.

1309. On receipt of the first confirmed positive result for anti-HTLV III, the donor would be sent a letter by the RTC. An early appointment would be arranged for the donor to be interviewed by a doctor from the RTC who has been trained in counselling and the significance of a positive anti-HTLV III result would be explained. The donor would be asked for the name and address of his/her GP and every effort would be made to ensure that the results of the tests could be reported to the GP and that the donor receives further medical consultation. A further sample of blood would be collected as outlined above.

1310. In respect of the follow up of recipients of previous donations given by donors found to be anti-HTLV III positive (i.e. look-back), it was recommended at section seven of the report that:

7.1 Efforts will be made to determine the names of any patients who received blood and components from the donations taken during the past five years and the information regarding the known or possible seropositivity of the donation given to the Consultant in charge of the patient [PHEN0000864].

7.2. If plasma from any of the donations was sent for fractionation, full follow-up of all patients receiving coagulation factor concentrates may be difficult or impossible. Since patients suffering from haemophilia A and B are being investigated for anti-HTLV III at present, it is recommended that no additional follow up be carried out.

1311. I have been provided with the minutes of a meeting of EAGA held on 30 July 1985 [NHBT0000186_035]. Dr Acheson commenced by outlining the additional funding that had been provided by the DHSS since the last meeting, including to the PHLS for its ongoing evaluation and provision of test facilities, the NBTS for its field trials and St Mary's Hospital towards counselling training courses.

1312. Dr Smithies provided an update on the two stage evaluation of screening tests. The first stage had identified three kits as being most suitable for diagnostic laboratories, two of which were considered to be particularly suitable for use in the BTS and would now be investigated in the second stage, designed to assess their performance in large scale screening of blood donors. Dr Acheson congratulated all those concerned with the development of this work, particularly for the speed with which it had been achieved.

1313. Members agreed that the timing of the introduction of the tests was crucial and that the BTS should not be exposed to the risk of being the

only free access testing point. It was also essential to have sufficient counselling arrangements set up by the time the tests were introduced. A synchronised introduction of testing arrangements was therefore required in the BTS, GUM clinics and elsewhere. Dr Acheson advised that a letter had been sent out by the DHSS that day to Regional General Managers asking them to provide testing facilities outside the BTS and to plan for the counselling of people found to be antibody positive.

1314. The report by the Working Party of the RTD Committee on the screening of blood donations dated 11 July 1985 was discussed. The Working Party recognised the pressure to introduce routine screening in the BTS as soon as possible and RTDs were therefore being advised to make arrangements with their respective RHAs for the introduction of testing and familiarise themselves with the kits recommended by the PHLS study whilst the NBTS evaluation was proceeding. The evaluation within the NBTS had begun, with two centres each testing 6000 specimens at the rate of 600 tests a day and an analysis should be available by September 1985. The Working Party therefore considered it possible to commence screening in October 1985 and recommended that testing should be introduced throughout the UK over the shortest period practicable. The question of consent was raised and it was noted that the BTS would be informing blood donors that the test would be carried out. On receipt of a confirmed positive result, the donor would be sent a letter by the RTC and an appointment arranged for them to be interviewed by a doctor trained in counselling. The donor would be asked to provide their GP's contact details together with consent to disclose their positive result to the GP and efforts made to ensure that they received further medical advice.

1315. Members agreed that the screening test should be introduced simultaneously throughout the BTS and a date for the introduction should be set for all centres to work to. This would also provide an

opportunity for publicity, which could be linked with advice to blood donors and the general public.

1316. I have been shown a letter of Mr Hart of the DHSS to regional general managers dated 30 July 1985 [DHSC0000593]. Mr Hart referred to his previous letter dated 20 February 1985 asking that financial provision be made for the screening of blood donations for anti-HTLV III in the BTS. He advised that he was now requesting the provision of testing facilities outside of the NBTS and explained that those in high-risk groups had been told not to donate blood, however it was possible that some of those at risk might attend donor sessions when screening is introduced merely to have the test, thus increasing the risk of infected blood donations. STD clinics seemed most suited to offering advice and a test where necessary to the majority of concerned people in high-risk groups, however health authorities would need to consider how to cater for other groups such as organ and semen donors, and haemophiliacs where arrangements for such patients had not been made. The PHLS would perform the test, however, health authorities needed to plan for the taking of specimens and counselling of people found to be positive. Dr Hart asked for up to two nominated individuals from each district health authority to attend a counselling course, commencing in the Autumn.

1317. Mr Hart advised that estimates of demand were difficult to make. At the end of June 1985, 176 cases had been reported in the UK, 88% in homosexual men. 77% had been reported from the four Thames regions, with the rest scattered around the country. Most of the risk in the next year or two was likely to continue to be concentrated in the Thames regions. The number of cases of HTLV III infection was much higher and it was estimated that about 10,000 people were infected, mostly men, and that the large majority were in London. He advised that it was important to ensure that the facilities provided were well publicised and that there was close collaboration with GP Committees so that GPs were aware of the local arrangements.

1318. I have been shown a letter from Dr Harris to all regional, district and special health authority general managers dated 1 August 1985 [BART0000778]. The letter confirmed that the first stage of the PHLS evaluation of commercially available test kits had now been completed and attached a summary of the expert panel's recommendations. The NBTS was now undertaking its own second stage evaluation covering aspects specific to the use of kits in the blood donation screening context. A more detailed account of the PHLS evaluation would be available on request later that month. Dr Harris also advised that the DHSS had funded the PHLS to set up laboratory facilities to confirm the results of any positive blood donations in the NBTS and to test the samples taken in GUM departments or elsewhere.

1319. The report enclosed with Dr Harris' letter summarised the PHLS's evaluation of five commercially available test kits and recommended that the three kits most suitable for use in diagnostic laboratories were Organon, Ortho and Wellcome. The other kits were less satisfactory and produced an unacceptable number of apparently false positive results and generally gave unreliable results with heat-treated sera. The expert working group considered that the Organon and Wellcome kits were especially easy to use and particularly suitable for use in RTCs. These two kits would be the first to be assessed in the second stage of the evaluation, designed to investigate the performance of kits in large-scale screening of blood donations. A full report on the first stage evaluation would be available later in August 1985.

1320. I have been provided with a memo from Dr Williams of the DHSS to all RTDs in England and Wales (copying in Dr Cash) [PRSE0003215]. He provided an update on alternative site testing arrangements, confirming that the DHSS had written to regional and district general managers asking them to provide alternative facilities, outside the NBTS, for anti-HTLV III testing. He advised that the first phase of the PHLS evaluation of screening tests was complete and enclosed the

expert panel's summary advice. The full report would be available later in August and sent to RTDs. The second stage of the evaluation in the NBTS had already started in North London and Manchester RTCs, with the Organon and Wellcome kits being the first to be evaluated.

1321. Dr Williams confirmed that the recommendations of the RTDs' Working Party, which RTDs will have received from Dr Gunson, had been endorsed by the EAGA. He advised that the second stage of the evaluation would take 2-3 months to complete to a formal report stage, although some interim information would be available sooner, and it had been agreed that RTC's could not wait until that report was available before commencing preparations for anti-HTLV III testing. Given the encouraging results of the PHLS evaluation, RTDs should use the next 2-3 months to make preparations to introduce routine screening, using either the Organon or Wellcome kits on an interim basis, with effect from a suggested target date of mid-October 1985. He proposed that RTDs:

- Immediately approach their RHAs (if they had not already done so) for funding and then make the practical arrangements for setting aside the laboratory space involved and training the necessary staff.
- Familiarise themselves and their staff with the two test kits which were being evaluated, with the anticipated assistance of both suppliers and the PHLS.
- Until the BTS evaluation was completed, consider making enquiries about short term contracts with manufacturers to supply the tests until the end of this year.

1322. Dr Williams requested that RTDs keep him informed of their progress in making preparations for screening, in particular if they expect any difficulties meeting the suggested deadline of 14 October 1985.

1323. I have been shown a press release from the DHSS dated 1 August 1985 [NHBT0000186_036]. It announced that the first stage of the evaluation of commercially available test kits to screen blood for HTLV III antibody had been completed by the PHLS. Three kits proved to be most suitable for use in diagnostic laboratories, two of which appeared to be particularly suitable for use in RTCs and were now being assessed in the NBTS. Once the second stage evaluation had been completed, routine screening of all blood donations would be introduced.

1324. I have been provided with a departmental memorandum from Dr Martlew dated 5 August 1985 to a number of recipients including Dr Gunson [NHBT0004253]. The memo addressed anti-HTLV-III testing of plasma donors. Dr Martlew noted that Dr Gunson had asked her to arrange such testing of plasma donors to assist the evaluation of the kits prepared for use in the blood transfusion service. She indicated that it will be necessary to advise donors of such testing, and a new NBTS 110 notice to donors was attached. Dr Martlew proposed that the procedure commence from 12 August 1985. She requested that apheresis donors be asked to sign the new form, and that an extra 10ml of clotted blood be taken for laboratory purposes. NBTS 110 identified AIDS, referred to the relevant leaflet explaining about the disease, notified the donor that testing would be done, and that a positive result would require a confirmatory test. The donor was asked to sign the form to confirm agreement to the testing and to confirm that the notice had been read.

1325. I have been shown an article from the *New Scientist* dated 8 August 1985 [DHSC0000509]. The article was titled *"Ministers delayed launch of AIDS test"* and referred to accusations that the British government was deliberately delaying the introduction of a blood test for antibodies to the AIDS virus. It is reported that six months after such a screening test was introduced in the US, the government had announced its approval of a test developed by the British company Wellcome

Diagnostics last week. Abbott Laboratories, which developed the US test, is said to have accused the DHSS of delaying official approval until a British test was available.

1326. The article states that the DHSS had explained it was waiting for a comprehensive assessment of all screening kits on the market in order to identify the most appropriate one for the needs of the NBTS and had been alarmed by the number of false positives obtained with the currently available tests. The DHSS announced last week that it had now completed the first phase of its assessment and had approved three AIDS screening kits for use in diagnostic laboratories and two (made by Organon and Wellcome) had been chosen to enter the second phase of assessment for daily use at RTCs in Edgware and Manchester.

1327. The article criticises the DHSS's explanation for not standing up to scrutiny. It explains that US research had shown that the six "ELISA" antibody tests currently on the market all produce false positives and a definite diagnosis of AIDS requires a further test, called the Western blot, which is slow, difficult and costly to carry out. Abbot Laboratories was about to launch an alternative confirmatory test that relies on a better marker for the AIDS antibody. "*It seems odd, therefore, that the DHSS insists on looking for the "best" test".* Further, whilst it is acknowledged that false positive results are *"clearly worrying"* for the blood donor, it reports that they are not a problem for the NBTS, whose primary concern is to keep blood free of pathogens. It referred to data from 131 US clinics which indicated that about 0.85 per cent of blood was positive when first tested and only between 0.14-0.29 per cent was positive after further testing. The amount of blood falsely diagnosed as positive was therefore relatively insignificant. However, it states that Wellcome claims its test will produce fewer false positives than other tests on the market, is easier and quicker to use and is confident it can scale up production to screen the NBTS's 2.25 million annual donors.

1328. I have been shown a letter from Dr Williams of the DHSS to all RTDs dated 22 August 1985 [NHBT0004236]. He said that to date, the indication from almost all RTDs had been that no significant problems were anticipated in meeting the target deadline of 14 October 1985 for the introduction of routine screening of blood donations for anti-HTLV III. He also enclosed a press release regarding testing (see below) and advised that the DHSS were reprinting the revised version of *"AIDS – important new advice for blood donors"*, which referred to the new screening tests.

1329. I have been shown a press release from the DHSS dated 23 August 1985 [PRSE0002603][76]. Mr Patten, Parliamentary Secretary for Health, announced that routine screening of all blood donations for antibodies to the AIDS virus should be introduced by mid-October. He advised that the NBTS was urgently carrying out its own evaluation of the test kits following initial evaluation by PHLS and making preparations for the introduction of routine screening, including the provision of laboratory space and staff training. The procedures for handling the test results and counselling those found to be positive had also been agreed. Mr Patten said *"it is important that we reduce the risk of AIDS being spread through blood transfusions and blood products. This risk is already extremely small but screening all blood donations will reduce it still further".* He also advised that health authorities had been asked to make alternative arrangements, outside the NBTS, to provide testing for people who may be worried that they have been infected with the virus.

1330. I have been shown a further letter from the *New Scientist* published on 29 August 1985 [NHBT0000030_012]. The letter was written by Dr John Barbara and Dr Patricia Hewitt at the North London BTC which responded to the suggestion that the DHSS had "*delayed the launch*" of AIDS testing in its article published on 8 August 1985 (see above).

[76].

The letter states that premature initiation of mass anti-HTLV-III screening had been resisted by Directors, as detailed in a letter to *The Lancet* dated 2 March 1985 (see above), and there were several reasons for the "*delay*", which did not include waiting until Wellcome had produced their assay. It is pointed out that few centres actually used Wellcome reagents for their current routine microbiological screening, so there was certainly no pre-existing bias.

1331. The letter explains that assessment is necessary before any test is adopted. American donors differ from British ones in several aspects of donor demography, as reflected in the parameters of transmission of various infections by transfusion, and it would have been irresponsible not to assess how the various tests performed when applied to British donors. The Wellcome test offers a number of potential advantages in the context of British transfusion centres and is also very rapid, with no pre-dilution stage. A further major consideration was that screening of blood donations should not begin until people at risk of AIDS could easily obtain testing at sites other than transfusion centres and donor publicity is aimed at minimising the number of donors likely to be in AIDS-risk groups. *"We do not want to attract high risk donors since there have been reports of virus isolation from the lymphocytes of a few anti-HTLV-III negative subjects".*

1332. I have been shown a further memo from Mr Williams of the DHSS to all RTDs in England and Wales (copying in Dr Cash) [NHBT0096480_027]. The memo informed RTDs of arrangements that had been made for the revision of the existing blood donor leaflet and form NBTS 110 in light of the imminent introduction of routine screening for anti-HTLV III. Mr Williams enclosed the revised text of NBTS 110 for local reproduction, which now included reference to the revised donor leaflet and AIDS antibody test, as produced by the RTDs' Working Party on AIDS. He advised that the Working Party's draft information leaflet (also appended to the report) had been largely incorporated into a revision of the leaflet *"AIDS – important new advice*

for blood donors" (issued in January 1985), now entitled *"AIDS – important information for blood donors".* Initial supplies would be sent to RTCs by 7 October 1985 and it was proposed that no use should be made of the revised leaflet until the date that routine screening commenced (provisionally set for 14 October 1985) to avoid confusion and prevent any irresponsible high risk people attending to donate blood in the period before screening started. He recognised that donors attending for the first few weeks after 14 October would not have received advance notice of the test, except through media publicity. RTCs would therefore need to arrange for them to be given the leaflet as they attended sessions.

1333. I understand that the Council of Europe issued a press release on 23 September 1985 advising that several member states were starting to screen blood donors for AIDS to prevent transmission via blood transfusions [NHBT0010848]. It was noted that the tests could not be regarded as diagnostic and nothing was known about the medical implications of positive results in donors displaying no other symptoms. The Council of Europe's Committee of Experts on Blood Transfusion and Immuno-haematology had considered the information which donors should be given and recommended that all blood donors should be notified about the test, positive results should always be confirmed by more specific tests and advisory services should be established to assist donors with positive results. These proposals were included in a Recommendation (R 85 12) which followed the earlier Recommendation on preventing the transmission of AIDS via blood transfusion, adopted in 1983. It also recalled the basic principles involved in minimising the risk of transmission including the need for national self-sufficiency and to provide all donors with information on AIDS so that persons in risk groups will refrain from giving blood. The need for alternative testing facilities other than transfusion centres and the inactivation treatment of concentrates were also recommended.

1334. I have been shown a press release from 1 October 1985 from the DHSS confirming that from mid-October, all blood donations would be screened for antibodies to the AIDS virus by the NBTS's RTCs [PRSE0003160]. Alternative facilities for providing tests on a confidential basis would become available at GUM clinics at the same time. In addition, all District Health Authorities were making arrangements to carry out tests on patients referred by GPs. Dr Acheson, CMO, had written to all doctors providing information and advice on the new tests. He stated that: "*The synchronous provision of these arrangements is to ensure that people who believe themselves at risk of infection do not donate blood in order to be tested. This is crucial because even a reliable test cannot detect very early infections to which an antibody response has not yet been generated".*

1335. I have been shown a further letter from Dr Acheson of the DHSS dated 1 October 1985 [DHSC0000177]. The letter was sent to all doctors in England enclosing DHSS guidance about the introduction of the anti-HTLV III test, entitled *"AIDS: Booklet 2".* He advised that from mid-October, all blood donations would be screened at RTCs. At the same time, alternative facilities for providing tests would become available at GUM clinics and by arrangement with the patients' GP at certain other clinics, as arranged and publicised by the District Health Authority. The letter reiterated the information provided in the press release that day, namely that the synchronous provision was to ensure that people who believed themselves to be at risk of infection did not donate blood in order to be tested and that health authorities and RTCs would provide counselling services for patients with AIDS and people with a positive antibody test.

1336. I have been provided with the minutes of a meeting of the RTDs held on 9 October 1985 [DHSC0002365_002]. It was noted that training was complete and all RTCs would commence full anti-HLTV III testing by 14 October 1985. The role of the DHSS and press releases over the next few weeks was discussed and Dr Smithies requested the

RTD's advice as there would be much press interest. There was concern that in spite of publicity, high risk people would still come to donor sessions to find out their HTLV III antibody status. Many groups had made it clear that they would not attend STD clinics or GPs and most districts had not made clear arrangements for people to have ready access to testing. Dr Contreras reported her findings that GPs also did not have clear instructions. Dr Smithies, DHSS, referred to the CMO's letter to District Medical Officers (see above). RTDs agreed that although the press statements so far had been accurate, there was still much misunderstanding.

1337. I have been provided with a press release from the DHSS dated 14 October 1985 [NHBT0004299]. Barney Hayhoe, Minister for Health, announced that the NBTS had started the routine screening of blood donations for antibodies to HTLV III, the virus which caused AIDS. Mr Hayhoe said: *"I pay tribute to the efforts made by staff of the NBTS, the PHLS… and others who have made it possible to introduce a fully evaluated test throughout the whole country at the same time. This test will reduce still further the already extremely small risk of transmitting AIDS through a blood transfusion".* He stressed that people in high-risk AIDS groups should not use the NBTS to have their blood tested and advised that alternative arrangements had been made by health authorities for anyone worried that they may have been infected, who should go to a GUM clinic or ask their doctor for advice. He also emphasised that there was no risk of catching AIDS though *giving* blood and appealed to current and prospective donors to donate. He advised that senior staff in the NBTS had been trained to give counselling to the very few expected donors found to be antibody-positive.

1338. The note to editors advised that RTCs were using one of two tests (Organon and Wellcome) found to be particularly suitable for screening blood donations in the PHLS evaluation. Further, if a person

was found to be antibody positive, it did not mean s/he would necessarily develop AIDS but may still be infectious.

HIV-2 Testing

1339. I understand that HIV-2 testing was introduced a few years following the initial introduction of HTLV-III testing. I have provided a brief summary of some of the documents I have been shown which relate to the introduction of this form of testing.

1340. I have been shown a letter from Dr Gunson to Dr Lane dated 27 November 1986 concerning HIV-2 [CBLA0002351_002]. The letter advised that it had come to his attention that two Englishmen (who were not blood donors) had been found to be anti-HIV 2 positive following a visit to Africa. Their sera was unreactive to the current Wellcome test for anti-HIV, which suggested the virus was not detectable with the test most frequently used for screening blood donations. It was important, therefore, to maintain close questioning of donors at blood collection sessions so that those who had visited or lived in Africa south of the Sahara since 1978 and had sexual relations with men or women living there were permanently excluded from giving blood in accordance with the recommendations in the latest AIDS leaflet (issued in September 1986).

1341. I have been shown a letter dated 28 November 1986 from Dr Gunson to Dr Luc Montagnier at the L'Institut Pasteur in France advising that the virus LAV 2 (i.e. HIV 2) had recently been found in two people in England [NHBT0004484]. He sought advice on the incidence of LAV 2 in Africa and recommendations for the exclusion of donors who had been to Africa. Dr Gunson said that at the present time, the BTS excluded those who had visited Africa south of the Sahara and asked if this was sufficient or whether the whole continent of Africa should be included.

1342. I have also been shown a memo dated 28 November 1986 from Dr Martlew sent to all medical officers (copied to Dr Gunson) which referred to the second virus associated with AIDS (LAV2) that the current antibody test for HIV (LAV1) lacked the sensitivity to detect [NHBT0004481]. She stated it was therefore imperative to ensure no donations were collected from individuals who had visited Sub-Saharan Africa since 1978 and had sexual relations with natives of either gender. She enclosed a copy of the latest AIDS leaflet which stated this information and advised that clerical staff had been instructed to ask every donor whether they had visited Africa since 1978 and refer any such people to the medical officers for further advice before being bled. No blood was to be collected from anyone who could not confirm that they had had no sexual relations with men or women living in Sub Saharan Africa during that period. In the event of any doubt, she suggested that the donation be politely declined and that person withdrawn from the donor panel.

1343. I have been shown the response of Dr Montagnier to Dr Gunson dated 26 December 1986 [NHBT0006731]. He said that he would be happy to send Dr Gunson the LAV 2 virus and enclosed the relevant forms for completion. He confirmed the African countries where serological evidence of LAV 2 had been found and advised that they were now conducting epidemiology studies in some of these countries but had no results yet. Some Europeans had got the virus by sexual contact with African women of these countries and approximately 30 percent of these LAV 2 infected individuals did not test positive for HTLV III. He offered Dr Gunson his further assistance if he had any problems with doubtful sera and enclosed a paper on LAV 2 which had been accepted for publication in the Lancet for his information (not attached).

1344. I understand that there was a meeting of the RTDs held on 21 January 1987 [CBLA0002358_001]. Dr Tedder summarised developments which pointed to the emergence of a second virus 'HIV 2' associated

with immune deficiency, with a growing prevalence in West Africa on the "bulge" from Southern Morocco almost to Nigeria where the incidence had risen from a very low level in 1982 to approximately five percent in STD clinics recently. The names LAV2 and HTLV4 had also both been used to describe the new virus/viruses and it remained unclear how similar these were. Professor Weiss offered additional evidence about the behaviour of the new virus and its appearance in Europe and suggested there was a need to act to minimise another epidemic. It was noted that samples from any donors who had visited West Africa would be of value, although it became clear in the ensuing discussion that to take samples on the session from donors who had been rejected because of their social behaviour during a visit to Africa would present problems in some regions. It was agreed that sessional medical officers questioning donors about social activity during African visits should advise those who had had sex to seek counselling and possibly testing.

1345. I have also been shown the minutes of the RTD UK AIDS Working Group on 5 May 1987 [CBLA0002373]. Dr Mortimer, PHLS, gave a brief review of HIV 2 and advised that in common with HIV 1, reliance had to be placed on the detection of antibodies to the virus. Tests had been carried out for anti-HIV 2 at the PHLS on selected groups, which had so far found no positive reactions. It was agreed that on the evidence available, routine screening of blood donations for anti-HIV 2 was not necessary at that time, however it would be desirable to introduce a procedure whereby additional testing of blood from donors who had visited West Africa was undertaken.

1346. The Group discussed how samples from donors who had visited Africa, in particular West Africa, could be submitted for anti-HIV 2 tests. It was agreed that serum samples would be sent to PHLS from donors who had visited Africa since 1977, excluding those countries bordering the Mediterranean, who were not deferred/excluded for any other reason. Such donations should still be used according to current

criteria for acceptability and not withheld because of the anti-HIV2 testing. Donors who were not bled because they admitted to sexual contact with persons living in Africa would be invited to contact the RTC for an appointment, where a history would be taken and counselling given. A blood sample would then be taken and sent to PHLS. The result would later be given (to the donor) and further action taken as indicated.

1347. It is noted that the RTDs present at the meeting would initially send samples for a period of one month to assess the workload. If this proved acceptable, other RTDs would then be asked to participate. The results of the testing would be reviewed after six months and a decision made at that time as to future action. The meeting minutes would be circulated to all UK RTDs prior to the next RTD meeting.

1348. I have been shown a memo from Dr Gunson dated 11 June 1987 to all medical officers and clerks at RTCs concerning HIV-2 [NHBT0004131] He advised that a second AIDS virus had been discovered in Paris which did not always react to the anti-HIV test. The new virus, which could cause an AIDS-like illness, appeared to be carried principally by men and women living in West Africa. There was no evidence that the virus had infected people in this country yet, however it may do so if individuals visiting West Africa have sexual relations with people living there. There was not a current need to routinely screen all blood donations for anti-HIV 2, however it was important to closely monitor the situation. It was therefore proposed to carry out anti-HIV 2 tests on donors who had visited Africa, except for those countries bordering the Mediterranean. Dr Gunson outlined the following procedure to be carried out at blood collection sessions:

1. The Session/Panel Clerks should continue to ask donors who have travelled abroad whether they have visited Africa.

If the visit to Africa (other than to countries bordering the Mediterranean) was within the last six months, the donor should be deferred because of the potential risk of malaria transmission. Arrangements should be made for the donor to be recalled at a suitable time.

If the donor visited Africa between 1977 and six months ago, then he/she should be asked which Country they have visited and the year of the visit. A note of the country and year should be made and the donor referred to the Sessional Medical Officer.

If the Medical Officer is satisfied the donor should be bled, the Country visited and year should be entered in the remarks column of the blood collection sheet.

2. The Sessional Medical Officer should, in an area away from other donors, ask whether the person has had sexual contact with any person living in Africa, as is carried out at present.

If the donor says that they have not had any such sexual relations then they can be asked to return to the session/panel clerk, and can donate.

If the donor admits to having sexual contact with a person living in Africa they should be informed that they may have exposed themselves to the AIDS virus and that it is important that further tests are carried out.

The donor should be told that they can seek advice from a Consultant at the Regional Transfusion Centre within a very short time and that a blood sample can be taken for tests. It should be stressed that the matter will be kept in strict confidence.

The donor should be given a letter from me (specimen attached) [not included in disclosure document] which recommends that they write to, or telephone the RTC to make an appointment to see a member of the Consultant Medical Staff.

A note concerning the donor, the Country and the year of visit should be sent to me.

A blood sample should NOT be taken at the session.

1349. I have been provided with the minutes of a meeting between Dr Gunson, Dr Smithies, Dr Mortimer, Dr Tedder and Mr Lister on 26 February 1988 concerning anti-HIV-2 screening [NHBT0004121]. Dr Gunson described the approach made to blood donors who admitted to having visited Africa. If a donor had visited Africa in the last six months, blood was not taken because of the possible risk of transmitting malaria. After six months, donors were asked if they had had sexual intercourse whilst in Africa with residents there. If not, a donation was collected and a sample sent to Dr Mortimer for HIV 2 testing. If an affirmative answer was given, the donor was offered an appointment for a blood test at the RTC. These specimens were also sent to Dr Mortimer for HIV 2 testing. Four centres had taken part in a pilot trial and all RTD's had subsequently been invited to take part. However, samples had not been received from other RTCs. It was therefore agreed that Dr Gunson should write to all RTDs again inviting them to take part in the scheme and advising them to inform the DHSS in the event of resource issues. It was also agreed that it would be advisable to extend the amount of screening for HIV 2 in GUM clinics.

1350. I understand that on 18 March 1988 Dr Gunson wrote to all RTDs (copying in the SNBTS, DHSS, PHLS and Dr Tedder) in respect of the anti-HIV 2 study [NHBT0003698]. He referred to his previous letter of 31 July 1987 in which he had asked if other RTCs would participate in

the study, however none had yet done so. He advised that to date, sera from 2200 blood donors had been tested in the study and no positives had been found. However, instances of HIV-2 infection had been identified in several European countries and one case of specific HIV-2 infection, i.e. not combined with HIV 1, had been found in the UK. Whilst the need for routine screening of all donations for anti-HIV 2 had not yet arisen, he considered it was essential that donors who had visited the countries in West Africa listed in his (earlier) letter should have an anti-HIV 2 test performed. He was therefore writing to ask RTCs to take part in the scheme.

1351. I have been shown a letter that Dr Gunson wrote to Dr Smithies on 25 March 1998 following reports in the press about the anti-HIV 2 positive donor and his subsequent discussions with reporters [NHBT0003695]. He advised that there was one aspect of the anti-HIV 2 testing programme where the blood transfusion service was vulnerable and pointed out that the tests were carried out at PHLS after blood and products had been used. Whilst plasma found to be anti-HIV 2 positive could possibly be withdrawn, cellular products will have been used and this meant that the first positive result the NBTS find may well have led to transmission of HIV 2 to patients before the result was received. He wondered whether it might be better if Dr Mortimer were able to send kits round to the RTCs, who could carry out the tests in parallel with the anti-HIV 1 test. Any doubtful, equivocal or positive results could then be sent to Dr Mortimer for confirmation and the blood could be withheld pending the result.

1352. I understand there was a meeting of EAGA on 12 April 1988, the minutes for which I have been provided with [MRCO0000003_137]. At that meeting HIV-2 was discussed:

Members noted the position, and – provided that cells from any donor which were to be tested for HIV-2 should either not be used or should be held (as should any separated plasma) pending a negative result

being obtained – endorsed the present arrangements for selective testing as appropriate and satisfactory. It was agreed that routine testing at RTCs for HIV-2 was not at present justified and that testing was best confined to a few central laboratories. However, the position should be kept under review, as should advances in tests for HIV-2.

1353. I have been shown a letter dated 14 April 1988 from Dr Gunson to all RTDs in England and Wales (copying in the SNBTS, DHSS and PHLS) to confirm the RTDs procedure agreed at the previous day's meeting as follows [NHBT0003691]:

1. All RTC's will identify donations from donors who give a history of having visited or lived in the West African Countries which are listed in Appendix I.

2. A sample of serum from the donor of such a donation will be sent to Dr. Philip Mortimer, PHLS Colindale, accompanied by form B1 appropriately completed. Tests for anti-HIV2 will be performed at the PHLS and the results reported to RTC's.

3. Cellular products will either not be used from these donations, or, together with any plasma or cryoprecipitate separated from the donations, will be placed in quarantine in the RTC and will not be issued to hospitals (or BPL) until a negative report for anti-HIV2 is received from PHLs.

4. In addition, those RTC's who wish to do so, may send serum samples for anti-HIV2 tests from donors who present at sessions but who are not accepted for donations because of a history of sexual contact with persons who are living in or have lived in West Africa.

1354. I have been shown a letter that Dr Cash sent to Dr Pickles at the DHSS on 19 May 1988 [NHBT0003677]. He expressed SNBTS's concerns regarding the enforceability of Dr Gunson's instructions about anti-HIV 2 tests. In a subsequent letter I have also been shown dated 21 June 1988 [NHBT0003673] Dr Cash confirmed that after detailed consultation, he would advise that the SNBTS adopt an

interim policy whereby Directors used their best efforts to identify relevant donors and, where operationally practicable, send samples of such donations to the PHLS for testing and not use such donations for clinical purposes until a negative result was received from PHLS. The plasma collected from such donations was not debarred from routine transfer to PFC storage facilities but the PFC would be advised by RTC staff of a positive HIV 2 results from the PHLS.

1355. I understand that the 11th meeting of the Council of Europe's Committee of Experts on Blood Transfusion and Immunohaematology was held on 3-6 May 1988. I have been provided with the meeting report [NHBT0000018_019]. The meeting report documents that Dr Gunson led the discussion on AIDS and presented the data he had compiled from member countries on anti-HIV tests on blood donations and related matters. I understand that those data can be found at [NHBT0004514_001].

1356. The report notes that only a few countries had performed anti-HIV 2 tests on selected donations and no positive results had been found. Table two of Dr Gunson's survey indicates that five countries (UK, France, Germany, Portugal and Greece) had carried out limited anti-HIV 2 tests to the end of December 1987. Professor E Freisleben (Denmark) advised that an investigation by the Select Committee on Automation and Quality Control had found that the present anti-HIV 1 tests also detected anti-HIV 2 and that commercial firms were being urged to provide kits which combined anti-HIV 1 and 2 tests. Dr Gunson pointed out that all batches of anti-HIV test kits could not be guaranteed to detect anti-HIV 2 and the statement that this could be achieved should be treated with caution. Further, combined anti-HIV 1 and 2 tests should not lead to a decrease in the sensitivity of the detection of anti-HIV 1.

1357. I understand that the 12th meeting of the Council of Europe's Committee of Experts on Blood Transfusion and Immunohaematology

was held on 23-26 May 1989 [NHBT0004027]. The meeting report documents that Dr Gunson led the discussion on AIDS. Among a range of other things, there was a discussion in respect of screening blood donations for anti-HIV 2 infection. Dr Gunson's circulated paper summarising replies received from 13 countries to his questionnaire on anti-HIV testing of blood donations confirmed that anti-HIV 2 was not routinely tested for and where it was, no positives had been found. Dr Gunson stated that, in general, it appeared that routine screening for anti-HIV 2 was not justified but that selective screening of donors who had visited countries where there was a significant prevalence of HIV 2 infection was recommended. He concluded that HIV 2 infection should be monitored and it would be interesting to see the results of the evaluation of the combined anti-HIV-1/HIV-2 tests since the sensitivity and specificity for the detection of anti-HIV 1 must not be compromised.

1358. I have been provided with a memo from Dr Rehman at the DHSS dated 3 August 1989 [NHBT0000061_035] to Dr Jones copied to Dr Metters, Dr Pickles, Mr Canavan and Mr Arthur. The memo addressed the screening of blood donations for NANBH and HIV 1 and 2. The Scottish RTCs were being approached by Ortho and Wellcome in relation to screening tests. Prof Cash, Director of the Scottish NBTS, was seeking confirmation that screening of NANBH or HIV 2 was to be a national decision. It had been indicated by the two pharmaceutical companies that Dr Gunson was involved in such screening. The memo records that Dr Rejman confirmed that the ACVSB had decided NANBH was not to be screened for as routine, and that there was no immediate need for HIV 2 screening in the UK.

1359. The remainder of the memo detailed a proposed letter from Dr McIntrye to Prof Cash discussing Chiron testing for NANBH and combined HIV testing. With regard to the latter, it was recorded that Dr Gunson was to meet with Wellcome next week and discuss costs of the test. He was to inform them that the decision will be a UK national

decision. The proposed letter indicates that, per EAGA recommendations, currently any donor who was acceptable under other criteria that has visited West Africa will have a sample sent to PHLS for HIV 2 testing. Blood is quarantined until the result is known. It is recorded that over the last 2 years there have been no positive tests out of approximately 8,000 samples.

1360. I have been shown a letter dated 18 August 1989 that Dr Gunson sent to all RTDs in respect of anti-HIV 1 and 2 tests and anti-HCV tests [PRSE0002340]. He advised that it was important to act in a co-ordinated manner nationally and also with Scotland regarding the introduction of routine screening of donations. Approval would also be required from the DHSS via the Committee on the Virological Safety of Blood, which he noted was next due to meet on 17 October 1989. Dr Gunson did not think there was an urgent need to use the anti-HIV 1 and 2 test since there was no evidence from present selective screening that HIV 2 was a problem. He would be interested in learning if RTDs were approached by firms other than Wellcome (who he was meeting the following week) and the price per test being offered, together with details of how this compared with the cost of the RTCs current anti-HIV 1 test.

1361. I have seen a letter from Dr Reenay to Dr Gunson dated 23 March 1990 to confirm that Ministerial approval had now been received to introduce routine testing of all blood donations for both anti-HIV1 and anti-HIV-2 [NHBT0004168]. The combined test was to be introduced UK wide as soon as possible at a date to be agreed within the NBTS and communicated to the DoH, however P Reenay noted further to a discussion with Dr Gunson that this could not be earlier than the beginning of June for various reasons.

1362. I have been shown a technical bulletin issued by the American Association of Blood Banks on 30 April 1990 in respect of HIV-2 screening [NHBT0004153]. It noted that a HIV-2 test was licensed on

25 April 1990, and the FDA had made recommendations on the use of the test. The document included a summary of the Blood and Blood Products Advisory Committee of the FDA recommendations and relevant data, such a summary being made by the American Association of Blood Banks, the American Red Cross, and the Council of Community Blood Centres. In that summary, it was stated that there was currently no public health need for routine screening of donors of whole blood or source plasma for antibodies to HIV-2. The reason for this was the limited restriction to West Africa, small number of people in the US demonstrating the infection, and the fact that HIV-1 tests will detect the majority of HIV-2 carriers. The FDA required donor deferral procedures for emigrants from countries where HIV-2 infection is endemic already. HIV-2 infection was identified as very rare in the US. It was noted this would be re-evaluated over time.

1363. I understand that the 13th meeting of the Council of Europe's Committee of Experts on Blood Transfusion and Immunohaematology was held on 8-11 May 1990. I have been provided with the report of that meeting [NHBT0000019_020]. Dr Gunson led the discussion on AIDS. In respect of anti-HIV 2 testing, it was noted that only Portugal had instituted routine screening. Combined anti-HIV 1+2 tests were now available and being used in some countries. Dr Gunson commented that the test kits evaluated in the UK had demonstrated that the sensitivity of anti-HIV-1 in the combined test was at least no less than with the specific test for anti-HIV-1 but the specificity may not be as great, which could lead to an increased number of false positive results. It was agreed that consideration should be given to the introduction of routine screening of blood donations with the combined anti HIV 1+2 test.

1364. I have been shown a letter from David Donald at BPL to Dr Gunson copied to all the RTDs dated 11 July 1990 [NHBT0001675]. The letter set out that, in accordance with the Committee on Safety of Medicine all blood donations should include a test for HIV 2 antibodies. This

mandatory requirement would be included in the next revisions of BPL and BPLD Plasma Specifications. However, the letter sought confirmation of when the centre implemented HIV 2 antibody testing in compliance with this requirement, along with details of date and batch/pool number BPL and BPLD will have received plasma routinely tested for the antibody. Until changes in the specifications, plasma dispatch sheets were to be annotated to denote HIV 2 antibody testing had been performed, and the centre was to provide advice on which antibody test-kit was being used.

1365. I have also been shown a letter from Dr Gunson to Dr Lane dated 16 July 1990 [NHBT0001674] to formally confirm that by 1 June 1990, all RTCs had commenced the routine screening of all blood and plasma donations with the combined anti-HIV 1 and 2 test, except for the Bristol RTC who had commenced on 14 June 1990 and the Cambridge, Manchester and Lancaster RTCs who had commenced on 2 July 1990.

Provision of Factor Concentrates rather than Cryoprecipitate

Summary

1366. This part builds on the historic evidence produced in Q18 and Section 8 in respect of plasma supply. I do not repeat all of that evidence, although I do highlight some of the documents that have been provided to me by those advising me.

1367. I understand that an important feature of the evidence prior to the introduction of heat treatment of factor concentrates was the continued (and increased) use of factor concentrates following the identification of AIDS as a syndrome and its linking with blood products. I understand that some have suggested that, as was the case in some other European countries, a move to prescribing more cryoprecipitate would have been desirable. As appropriate, I have been provided with some documents relevant to this issue.

1368. In summary, it would appear from the evidence that I have been provided with that there was a constant and continued demand for factor concentrates over the 1970s and 1980s. The source of that demand is discussed in my answer to question 18; it was heavily influenced by the demand for factor concentrates to treat people with haemophilia. As a result, there was a consistent increase in the demands made on the blood service to provide plasma to BPL (and other laboratories) for fractionation. Those demands, and the steps taken to meet those demands, are set out in my answer to section 8. As I also explain in that section, it was not until the redevelopment of BPL in the mid to late-1980s that the demand did not continue to outstrip supply.

1369. In my answer to section 7 I discussed the attempts to move to RTCs distributing all factor concentrates, including commercial purchased concentrates, in the late-1970s and early 1980s. As I understand it, this did not occur. In light of this demand for concentrates, and the continued purchase of commercial concentrates, it is unclear to me whether the blood service could unilaterally reduce provision of plasma to BPL and instead process it into cryoprecipitate. From the documents I have seen, the demand was consistently for factor concentrates, and the RTCs were under consistent pressure to supply plasma to BPL for fractionation. If the blood service had reduced its supply of plasma to BPL, such that NHS concentrate production reduced, it is unclear whether treating clinicians would have reverted to increased purchase of commercial product. That is particularly so considering the pro-rata distribution of factor products from BPL at the time.

1370. My tentative view based on the documents I have seen is that this decision was difficult with a number of parties holding very differing views. This is based on the fact that, in order for the blood service to effect change, a clear clinical consensus on the requirements for each

product would have been helpful and, furthermore, an agreement would have been required from all parties before embarking on changes. The reason I think this would have been required was because it appears that doing this would not have been straightforward with a number of 'trade offs' requiring resolution, including some changes required to the BPL plant if the solution needed was cryoprecipitate in a freeze-dried form. Thus, based on the documents I have seen, it seems to me that it would have required a distinct change in the demand for products back to cryoprecipitate for the blood service to adopt such a change. While from the documents it appears that the blood service might have been part of an implicit decision by all concerned not to revert entirely to the use and therefore production of cryoprecipitate, the decision would have had to be taken between clinicians, DHSS, BPL and the blood service, and this was a complicated decision. It is therefore hard for me to conclude that the blood service could alone have been the catalyst to affect a change back to cryoprecipitate.

The 1970s

1371. As I have set out in Q18 and Section 8, there was a significant and continually increasing demand for plasma in the 1970s. At that time, it would appear that the demand for factor VIII could be met through both cryoprecipitate and freeze-dried factor VIII. For example, I have seen the minutes of a meeting between the Haemophilia Centre Directors, RTDs and regional scientific advisors for the supra-regional territory for which Oxford haemophilia centre was responsible [CBLA0000391]. At that meeting Dr Maycock noted that the target of 15 million units of factor VIII per annum would be met through "*both cryoprecipitate and NHS intermediate potency freeze-dried factor VIII*". There was an extensive discussion of target units at that meeting.

1372. I have been shown the minutes of the Expert Group on the Treatment of Haemophilia on 20 March 1973 [PRSE0004706]. Attendance included haemophilia centre directors, Dr Maycock, Dr Rizza, and staff

from the DHSS and SSHD. At that meeting the various advantages and disadvantages of cryoprecipitate and freeze-dried concentrate were considered. In respect of the former it would appear some practical difficulties were discussed; in respect of the latter practical advantages were discussed but "a possible disadvantage arises from the fact that AHG concentrate is prepared from a larger pool of donations, and in theory therefore the risk of hepatitis is greater". There as a discussion of some of the controlling factors for monitoring HBV at the time. The minutes went on to note:

'*At a meeting of the Haemophilia Centre Directors in 1972 there was a consensus of opinion in favour of freeze-dried concentrate, and this was confirmed in a survey, undertaken by Dr Maycock, of the opinions of clinicians. The limiting factors are the capacity for production (and the cost) of this preparation'.*

1373. As can also be seen by my answer to section 8, it would appear that plasma targets were set primarily by reference to the supply of plasma to BPL (and other laboratories). It would appear to me that a consequence of this was that fractionation capacity, and the demand for fractionated products, was the primary driving force behind the pressure on the blood service at the time to increase the number of donations. Failures to meet the requirements of BPL were noted by the government, haemophilia doctors, and BPL.

1374. I have been shown the minutes of a meeting of the RTDs, Haemophilia Reference Centre Directors, and others, at Sheffield on 22 October 1976 [CBLA0000473]. At that meeting:
    a. Dr Biggs gave a presentation and noted "*[t]here is an urgent need to convert as much as possible plasma at present used for cryoprecipitate to a freeze-dried preparation*".
    b. Later in that meeting Dr Jenkins asked the group what was recorded in the minutes as "*[t]arget – Haemophilia Centre Directors – how much freeze-dried and how much cryoprecipitate?*".

Professor Bloom is recorded as having replied "*100% freeze-dried*".

c. In response to Professor Bloom Dr Bevan noted that the phasing out of cryoprecipitate and replacement with freeze-dried Factor VIII would take three years.

1375. I have also been shown the minutes of a report of the Working Group on Trends in the Demand for Blood Products [DHSC0002189_014]. That report is dated December 1977 following it being convened by the DHSS in January 1977. In that report the working group noted "*we believe that the long term aim should be the complete transfer of cryoprecipitate to a fractionated freeze dried concentrate. However, guidance will be needed on a continuing basis from Regional Transfusion Centres on the time scale for such a development*".

1376. I have also been provided with a report from Dr Lane entitled *The Function of Stop-Gap and Phased Redevelopment of the Blood Products Laboratory* dated 31 May 1979 [BPLL0001508]. Among a range of other issues in that report, Dr Lane commented on the principal determinants influencing the future of BPL. The first was "*the continuing pressure, from both the field and the Department, to produce more Factor VIII concentrate. BPL had almost reached the limit of its present production capacity, and, as a prerequisite, RTCs would have to increase the supply of plasma*".

The 1980s

1377. In my answer to question 39 I have noted that in 1981 there was the introduction of pro-rata provision of blood products from BPL to a region proportional to the amount of plasma that was provided by RTCs for fractionation. From that point the amount of plasma that RTCs provided from their region to BPL was directly proportionate to the amount of NHS factor concentrate that clinicians in the region could access. As to the purchase of commercial factor products, I have discussed the lack of control RTCs had in my answer to section

7. It appears to me that, in the most case, RTCs had limited – if any - power to influence the use of such products.

1378. I have been provided with the minutes of a joint meeting of representatives of haemophilia centres and the blood transfusion service on 23 April 1981 [DHSC0002207_019]. Among other things, at that meeting the types of material required for treatment were discussed. In the minutes:

a. *"IT WAS AGREED THAT PROBABLY NO MORE THAN 10 PER CENT OF THE FACTOR VIII-CONTAINING PRODUCTS SHOULD BE IN THE FORM OF FREEZE-DRIED CRYOPRECIPITATE. A SMALL AMOUNT OF FROZEN CRYOPRECIPITATE SHOULD STILL BE MADE FOR USE IN SELECTED CASES".*
b. "*IT WAS ESTIMATED THAT A MINIMUM OF 80 PER CENT OF THE FACTOR VIII REQUIREMENT WOULD NEED TO BE IN THE FORM OF INTERMEDIATE PURITY CONCENTRATE*".
c. "*IT WAS AGREED THAT A MAXIMUM OF 10 PER CENT OF THE TOTAL FACTOR VIII REQUIREMENT WOULD BE NEEDED AS HIGH PURITY CONCENTRATE*".

1379. As I have set out in Q18, plasma targets were set on the basis of the need to provide fresh frozen plasma to BPL (and associated other laboratories). If fresh frozen plasma from a whole blood donation (or plasmapheresis) was provided to BPL for fractionation, there was nothing left to convert to cryoprecipitate at an RTC. From the documents I have been shown, part of the meeting of the increasing demand for plasma to BPL was that cryoprecipitate was not produced. I note in passing, for example, the comment of Dr Gunson at a meeting of the RTDs on 19 May 1981 [NHBT0018340] that at that point "*200,000 litres (assuming no cryoprecipitate production) would be available from approximately 50% of all donations*".

1380. **I have been provided with the minutes of a joint meeting of representatives of the haemophilia centre directors and the RTDs dated 15 September 1981 [CBLA0001448]. At that meeting plasma demands were discussed in light of a demand for 100 million i.u. of Factor VIII by the mid-1980s. There was a discussion of the products within which it was to be produced: *"Directors agreed that they needed to reconsider their original estimated requirement for 10 million international units of freeze-dried cryoprecipitate and 10 million international units of high-purity concentrate. Dr Walford explained that to produce that amount of high-purity Factor VIII concentrate would require a disproportionate amount of plasma, and the costs of production would be very high. Directors agreed that if freeze-dried cryoprecipitate were not available, then frozen cryoprecipitate would be an acceptable substitute. However, if more intermediate-purity concentrate were made available, the need for frozen cryoprecipitate would drop even further. At present, about 1-2 million international units of frozen cryoprecipitate were used to treat von Willebrands disease. Directors thought that the need for high purity concentrate might be substantially less than 10 million international units, but the requirement and supply would need to be kept under careful review. (In view of the above requirements it is likely that the plasma requirement could be reduced to 435,000kg)".***

1381. I have been provided with a copy of the minutes of a meeting of the UK Working Party on Transfusion-Associated Hepatitis which was held on 20 April 1983 [NHBT0000023_003]. At that meeting Dr Gunson commented on AIDS and the possibility of the introduction of a leaflet for risk groups. He went on to note "*because of AIDS the uptake of cryoprecipitate will probably rise in the UK (Dr McClelland thought about fourfold in Edinburgh) and this would mean a drop in supply of plasma to BPL. This would apply especially to patients who had not previously received concentrates*".

1382. I understand Dr Lane wrote a short paper on AIDS dated 22 April 1983 [CBLA0001697] for an upcoming CBLA meeting. In that paper he noted progress with AIDS was being kept under regular survey, and senior BPL management were reviewing laboratory policy. He noted there were 14 cases in the UK, with no reports of AIDS in haemophiliacs. He also noted that the Haemophilia directors had been alerted and were maintaining heightened levels of security.

1383. As to BPL, Dr Lane noted that it would adopt a "wait and see" approach of continued Factor VIII concentrate production with continued attention to research on viral inactivation. As to cryoprecipitate, he noted:

The potential of the laboratory to manufacture small pool freeze-dried cryoprecipitate in significant amounts, as an alternative to large pool intermediate factor VIII concentrate, has been ruled out on logistic production considerations.

Whilst the situation in the UK appears to be under control, it is recognised that a first genuine report of AIDS in a haemophiliac could well bring about a sudden and significant general request for single unit wet cryoprecipitate for a large number of haemophiliacs. Whether this demand could be suppressed is unknown, but it would seriously reduce the efficiency of the current plasma procurement programme to satisfy BPL targets for factor VIII concentrate. An elaborate programme of pooled capture under sterile conditions of regional cryoprecipitate supernatant would have to be introduced to provide starting material for factor IX, immunoglobulin and albumin products.

1384. The report concludes that this accentuates the requirement, recognised by BPL, to have considerable flexibility within production and the importance of properly supported vigorous programs of research. Dr Lane notes that "*[t]he possible impact of AIDS and the high incidence of non-A non-B hepatitis has caused the Director to review the current level of resource set aside for virus inactivation*". He noted further proposals would be put to the Authority if it was felt that expansion of that programme was needed.

1385. It would appear that Dr Lane wrote his paper for a meeting of the CBLA on 27 April 1983. I have been provided with the minutes for this meeting. Dr Gunson reported that the RTD's had considered all the

American literature on this subject and at their next committee meeting, it would be recommended that no further measures be taken at that time, apart from those already being carried out. Professor Bloom reported that he had given a talk on AIDS at the AGM of the Haemophilia Society. His impression was that haemophiliacs were not greatly concerned about AIDS.

1386. I understand that there is a report from Dr Gunson and Dr Barbara dated 28 April 1983 in respect of the work of the RTD Working Party on Transfusion-Associated Hepatitis. In that report AIDS was discussed, and it was noted that the Working Party had carefully followed information from the US in respect of the disease and considered recommendations with respect to donor screening and the use of cryoprecipitate. To date, there had been no cases reported following the transfusion of blood or blood products (in the UK). It had been agreed that until further information was available, the Working Party would not recommend changes to present practices for donor selection or the use of blood products.

1387. I have been shown a letter dated 16 May 1983 that Dr Gunson wrote to Dr Walford to inform her of what happened at the Council of Europe Meeting regarding AIDS [DHSC0000716] (I have discussed what I think are the reports from this meeting below). He discussed the provision of product in Switzerland, AIDS in Belgium, and the upcoming resolutions of the Ministers. He went on to say:

You can see that what they are leading to is the greater use of cryoprecipitate, and we saw two years ago that this tends to be the standard product in many European countries. Although I put forward the UK view of this product the consensus was against us. Like you, I do not think BPL could change to freeze-dried cryo. rapidly and the logistic problems will be considerable. The CBLA is going to have to consider the interim period before the completion of the new plant very carefully and I am not sure yet, until I can give the matter more

thought, what would be the best solution. Fortunately everyone here was in agreement that it was vital to present a balanced view of this problem and to avoid emotive over-reaction (my phrase which will appear in the report of the meeting!).

1388. I have also been shown a letter from May 1983 that Dr Spence Galbraith, Director of the CDSC, wrote to Dr Ian Field at the DHSS [CBLA0000043_040]. He commented that a case of AIDS had been reported in a haemophiliac in Cardiff who had received US Factor VIII and fitted the recognised criteria for a diagnosis of AIDS. He also referred to the three Spanish cases reported in *The Lancet* in April (see above), who had all received US Factor VIII, and the further 11 reported cases in US haemophiliacs in the same issue. He stated: *"I have reviewed the literature and come to the conclusion that all blood products made from blood donated in the USA after 1978 should be withdrawn from use until the risk of AIDS transmission by these products has been clarified".* He appended a paper setting out the reasons for his proposal.

1389. I understand that the Committee of Experts on Blood Transfusion and Immunohaematology of the Council of Europe held a meeting in Lisbon on 16-19 May 1983. Dr Gunson attended as the UK member and Rapporteur. He subsequently prepared a report of the Committee's discussions on AIDS dated 13 June 1983. I have been provided with this report [CBLA0001710]. This followed an informal report which he produced on 19 May 1983. I have also been provided with this report [NHBT0017430]. In the informal report Dr Gunson noted that he would include personal comments which would not appear in the official report. As such, there is some slight variation in the figures, along with some other differences.

1390. He advised that within Europe, most countries reported less than 10 cases and the disease had not reached the proportions described in the US (approximately 1,200 cases by June 1983). The committee was

interested in the possible association of AIDS with the transfusion of blood and blood products (the informal report particularly identifies coagulation factor concentrates given to patients suffering from haemophilia).12 haemophilia patients had contracted AIDS in the US, however the incidence in Europe was much less. At the time of his report, only one haemophilia patient in the UK had symptoms which fulfilled the criteria defined for AIDS and there was one further possible case. Although the disease had not yet reached the severity that it had in the US, committee members agreed that the following recommendation should be put to the Council of Ministers at their meeting on 23 June 1983:

I) To take all necessary steps and measures in respect of AIDS

a) to avoid the use of coagulation factor products from large plasma pools, except when such a product is specifically indicated for medical reasons; this is especially important for those countries where self-sufficiency in the production of such products has not been achieved.

b) to inform attending physicians and selected recipients, such as haemophiliacs, of the potential health hazards of haemotherapy and the possibility of minimising these risks

c) to provide all donors with information on AIDS, so that those in high risk groups will refrain from donating.

II) To pursue rapid and full implementation of recommendations of R(80)5 and R(81)14

1391. Before making these recommendations the informal report noted: "*[t]he significance of AIDS to the Committee was in relation to the effects with respect to the transfusion of blood and blood products, particularly with coagulation factor concentrates given to patients suffering from haemophilia. Absolute proof that AIDS is caused by a transmissible infectious agent is not yet available, but the consensus in the Committee was that it should be regarded as such and that a recommendation should be made to the Council of Ministers at the*

meeting in June to take the necessary steps to minimize the transmission of AIDS by the transfusion of blood products. Since there is not a specific test which can be used to detect potential carriers, the recommendations have to be general."

1392. Dr Gunson advised that whilst these recommendations could be supported in principle, it was important to consider their implementation from a UK context. He explained that the concept of small pools for coagulation factor products concerned the use of freeze-dried cryoprecipitate as the basic product for the treatment of haemophilia. The definition of small pools varied considerably, from 8-12 donations per pool in some countries to much greater amounts in others. However, in these countries, there was no equivalent of the UK national regulatory authority and quality assurance procedures required. He considered that the conversion from the intermediate concentrate of Factor VIII to a small pool freeze-dried cryoprecipitate did not seem to be warranted at that time. The informal report added that implementation of this would cause both logistic problems and possibly practical problems in respect to the capability of BPL to produce such material. He also noted that the claim of higher yields of this material are "*not impressive when quality control tests on each batch prepared from pools of 8-10 litres of plasma*".

1393. Dr Gunson reported that physicians and patients, especially haemophiliacs, were being informed of the risks of AIDS. The RTDs had prepared an informative leaflet on AIDS for donors, which would be published by the DHSS shortly. Additional questions were to be asked of donors in an attempt to dissuade those in high-risk groups from donating. In the informal report he noted that a leaflet had been considered to inform donors about AIDS, but the consensus had been to hold this in reserve for the present. Dr Gunson thought perhaps further consideration should be given to this matter.

1394. R(80)5 and R(81)14 referred to the need for countries to develop self-sufficiency in blood products and minimise the importation of blood products respectively. Dr Gunson advised that the principle of self-sufficiency in blood products had been accepted by the UK Government, who had allocated money to rebuild the BPL, and it was important that allocations of finance to regional centres was adequate for the provision of sufficient plasma to enable the new BPL to function at optimum capacity. He considered there to be little alternative to the importation of plasma products, particularly Factor VIII, at that time. However, he noted that, since the middle of April 1983, US commercial companies had tightened their medical examination of donors providing plasma for the preparation of Factor VIII. The informal report added that the rebuilding of BPL would not be an effective production unit until 1986. He went on to note that he found it difficult to believe that imported plasma products, particularly from the USA, would be difficult to phase out in the near future. This was because the Haemophilia Directors have always maintained that they require up to 100 per cent more Factor VIII for the treatment of haemophilia than can be produced from BPL.

1395. In the informal report Dr Gunson added that "*[i]t is important, I think to avoid emotive over-reaction*" amongst recipients, a phrase which will also appear in the recommendations. The informal report concludes by noting that the implication of AIDS in various aspects of blood transfusion practice kept appearing in the meetings. Dr Gunson noted that this undoubtedly is an important disease with a high mortality rate which has attracted considerable press publicity. It was noted that, while it had not reached the proportions in Europe as it had in the USA, many members of the Committee thought they may be seeing the beginnings of a problem that could escalate if appropriate steps were not taken at this point.

1396. Following on from this report, the AIDS leaflet was progressed. I have discussed this issue already above and do not repeat that evidence here.

1397. I have been shown a letter from the Haemiophilia Society to the DHSS dated 17 May 1983 [PRSE0003827]. The Society confirmed their wish to meet a minister as soon as possible after the election to discuss:*"1. Self-sufficiency in blood products before 1986. 2. No ban on the importation of American concentrates* [in the] *meantime. 3. UK investigations relating to AIDS".*

1398. I have been shown a letter that Dr Gunson wrote to Sir Henry Yellowlees on 9 June 1983 [NHBT0001067] concerning AIDS. He advised that the aetiology of the disease was not known, however there was a strong possibility it was caused by a transmissible infectious agent and had therefore been implicated in the transfusion of blood and blood products. In the US, several haemophiliacs had contracted AIDS, all of whom received Factor VIII concentrate. In England, one haemophiliac fulfilled the US definition of AIDS and one other possible haemophiliac may have the syndrome. Dr Gunson advised that the significance of AIDS with respect to the transfusion of blood and blood products was two-fold:

(1) To ensure that persons in a high risk group with respect to AIDS are not enrolled as blood donors. In order to achieve this aim, the Regional Transfusion Directors, with the agreement of Senior Medical Officers at the DHSS have prepared a pamphlet which gives information to donors on AIDS and asks those persons in high-risk groups not to donate blood. Additional questions are to be asked of donors with respect to their health, but it is unanimously agreed that the sexual practices of donors cannot be questioned directly.

(2) Approximately one-half of the Factor VIII concentrate used in the treatment of haemophilia in England and Wales at present is

derived from plasma imported from the USA. The Press have been keenly interested in this aspect and there is, in my view, no alternative to the continuation of this policy in the short term. As you will appreciate, the commercial companies producing this product in the USA have been subjected to considerable pressures to produce safe material and since April, 1983, restrictions have been placed on donors in high-risk groups with respect to AIDS, and the importation of the product prepared before April, 1983, is being carefully monitored. In the medium term, the Blood Products Laboratory, Elstree, is being rebuilt so that it will have the capability of preparing blood products at a level which will make this country self-sufficient. The necessity of an adequate supply of plasma from our volunteer donors to the new laboratory from the regional transfusion centres cannot be over-emphasised".

1399. Dr Gunson went on to advise that whilst AIDS was not a major problem in this country at that time and it was not known whether it would be in the future, it was being taken seriously in European countries and the Ministers of the Council of Europe were to be asked to approve recommendations designed to minimise the effect of AIDS. He stated that these recommendations were not in general incompatible with the measures that were being taken in this country.

1400. I understand that on 23 June 1983 the Committee of Ministers at the Council of Europe adopted the Committee of Experts on Blood Transfusion and Immunohaematology's recommendation in relation to preventing the possible transmission of AIDS from affected blood donors to patients receiving blood or blood products, with some minor amendments [NHBT0010651_004]. Recommendation No. R (83) 8 recommended the government of members states:

I) to take all necessary steps and measures with respect to the Acquired Immune Deficiency Syndrome and in particular:

- *to avoid whenever possible the use of coagulation factor products prepared from large plasma pools; this is especially important for those countries where self-sufficiency in the production of such products has not yet being achieved;*
- *to inform attending physicians and selected recipients, such as haemophiliacs, of the potential health hazards of haemotherapy and the possibilities of minimising these risks;*
- *to provide all blood donors with information on the Acquired Immune Deficiency Syndrome so that those in risk groups will refrain from donating (an example of an information leaflet for donors is appended);*

II) to pursue rapid and full implementation of Recommendations No. R(80)5 and No. R81(14).

1401. I have been provided with the minutes of a special meeting of the Haemophilia Centre Reference Directors held on 13 May 1983 [HCDO0000003_008]. I have also been provided with a letter that appears to have been sent to haemophilia clinicians from Professor Bloom and Dr Rizza on 24 Jun 1983 [HCDO0000270_004]. In respect of the recommendations from the meeting, the following "*general recommendations were agreed*":

1. For mildly affected patients with haemophilia A or von Willebrand's disease and minor lesions, treatment with DDAVP should be considered. Because of the increased risk of transmitting hepatitis by means of large pool concentrates in such patients, this is in any case the usual practice of many Directors.

2. For treatment of children and mildly affected patients or patients unexposed to imported concentrates many Directors already reserve supplies of NHS concentrates (cryoprecipitate or freeze-dried) and it would be circumspect to continue this policy.

It was agreed that there is as yet insufficient evidence to warrant restriction of the use of imported concentrates in other patients in view of the immense benefits of therapy but the situation will be constantly reviewed.

[…]

The evidence to incriminate factor IX concentrates in AIDS is even less than with factor VIII and it seems logical to continue to use our normal supplies of NHS concentrate.

1402. I understand that on 13 July 1983 there was a meeting of the Committee on the Safety of Medicines. I have been provided with the minutes for that meeting [ARCH0001710]. A large number of people were present, and Prof Bloom, Dr Craske, Dr Galbraith, Dr Gunson and Dr Mortimer were reported as present for item 5 on AIDS as expert advisers. The minutes note that the following conclusions were reached, summarised here:

a. The cause of AIDS is unknown, but an infectious aetiology seems likely. A previously unrecognised agent might be involved, but repeated exposure to known agents may also be. Heightened susceptibility may be important. Transmissibility of the supposed agent(s) appears low.
b. Patients repeatedly receiving concentrates appear to be at risk, but the risk currently appears small. The risk is greatest in blood derived from homosexuals and IV drug abusers resident in areas of high incidence, and in those repeatedly receiving concentrates in high dosages. Balanced against the risks of AIDS and other infectious transmitted diseases are the benefit of their use, in the case of haemophilia they are life-saving.
c. Withdrawal of concentrates and replacement with cryoprecipitate was considered. It was concluded it was "*not feasible in the UK on grounds of supply*".

d. Withdrawal of US preparations was considered. It was concluded it was not feasible on grounds of supply. Further, perceived level of risk does not presently justify serious consideration of such a solution. UK independence from foreign supply is being pursued. This should reduce markedly the risks. The Sub-Committee strongly supported the aim. UKHCDO had also adopted a policy for use of US Factor VIII to minimise risk as far as possible.
e. It was advisable all concentrates from US derived plasma be from donations made post 23 March 1983 when new FDA regulations were introduced. This was recommended notwithstanding the possibility of its practical value may be small. It cannot be taken until supplies of such material can be assured. The step should be introduced immediately once feasible.
f. Treatment to inactivate viruses is a promising future development. When evaluating these products, both safety margin and clinical effectiveness need to be considered. Heat treatment could induce reactions in recipients.
g. Manufacturers were producing advertising material for the UK with apparently unjustified claims of the safety of heat-treated Factor VIII. It was advised this should be stopped, due to the fear that unlicensed material could be used on a named-patient basis without the safety and effectiveness being assessed.
h. Hepatitis B vaccine was considered. It was thought there was no evidence of any risk from material licenced in the UK and it was concluded that the licence should remain unchanged (use in high risks groups only). It was a serious and potentially fatal disease. To be kept under observation. Manufacturers were to be asked to provide ongoing data for product safety in respect of AIDS. The current licensed vaccine was subject to three separate inactivation processes, and any new human blood-derived vaccine should be subject to similar stringent treatment before being licensed.
i. It was thought there was no risk from immunoglobulins and albumins at that time. To be kept under close observation.

j. There are various groups working on AIDS. The Sub-Committee recommended the DHSS make sure adequate arrangements are in place to ensure coordination of activities between these groups.
k. There is a need for research work on AIDS in the UK.

1403. I have been provided with the minutes of a meeting of UKHCDO on 17 October 1983 chaired by Prof Bloom, which also included some attendees from the BPL, SNBTS and NIBSC [PRSE0004440]. Dr Gunson was invited but unable to attend. Dr Craske presented a paper on AIDS which had been pre-circulated to Directors. He also outlined his proposals for investigating cases of AIDS in UK haemophiliacs and suggested a three year follow up of patients who had received "suspect" batches of concentrate. He proposed to look at a control group of haemophiliacs and spouses of haemophilia A patients, who had received concentrates. Dr Craske would send out details regarding his proposals to the Haemophilia Centre Directors as soon as possible.

1404. Dr Chisholm raised the problem of patients refusing to take up commercial Factor VIII because of the AIDS scare and wondered whether Directors could revert to using cryoprecipitate for home therapy. Professor Bloom replied that he felt there was no need for patients to stop using commercial concentrates because at present there was no proof that such concentrates were the cause of AIDS. Dr Chisholm referred to problems in her region obtaining large amounts of commercial concentrates, whereas she could get unlimited supplies of cryoprecipitate. Other Directors reported that they had the same problems. After discussion, it was agreed that patients should not be encouraged to go over to cryoprecipitate for home therapy but should continue to receive NHS or commercial concentrates in their usual way.

1405. I understand that on 14 November 1983 the Secretary of State for Social Services, Kenneth Clarke, was asked about the use of imported Factor VIII concentrate [PRSE0000886]. He responded that:

There is no conclusive evidence that acquired immune deficiency syndrome (AIDS) is transmitted by blood products. The use of factor VIII concentrates is confined almost exclusively to designated haemophilia centres whose directors and staff are expert in this field. Professional advice has been made available to all such centres in relation to the possible risks of AIDS from this material.

1406. I have been provided with a memo produced by Professor Bloom dated 29 March 1984 which was circulated to all Haemophilia Centre Directors reappraising UKHCDO's response to imported heat-treated Factor VIII [CBLA0001831]. The memo advised on the appropriate response to proposals by commercial companies to trial new heat-treated products and listed different types of Factor VIII concentrate available for trial at that time. The memo also noted that all products except those derived from NHS Factor VIII were made from plasma imported from the US and therefore carried a putative risk of transmission of AIDS. The approach to be adopted in dealing with patients who might be appropriate subjects for clinical trials was left to individual practitioners.

1407. I have been provided with an AIDS advisory document from UKHCDO dated 14 December 1984 [HCDO0000270_007]. In that report it was noted:

Options in probable decreasing order of safety from AIDS for Haemophilia A

1. Heated U.K. concentrate (note: still NANB hepatitis risk)

2. Single donor cryo. Or FFP

3. Heated imported conc. (note: still NANB hepatitis risk).

4. Unheated U.K. conc.

5. Unheated imported conc – almost certain to be contaminated.

Note: Heated concentrates may still transmit hepatitis. Some of the distinctions e.g. between 3 and 4 are debatable and the long-term effects (e.g. immunogenicity) of using heated plasma proteins in this way are unknown. Even pasteurised albumin is not given as frequently to individuals as will be factor VIII.

RECOMMENDATIONS

1. Concentrate is still needed; bleeding is the commonest cause of disability and death.

2. Use DDAVP in mild Haemophilia A and vWd if possible.

3) For Haemophilia A needing blood products

(a) "Virgin" Patients those not previously exposed to concentrate, and children use cryo or heated NHS factor VIII (if available).

(b) Severe and Moderate haemophiliacs previously treated with factor VIII use heat treated NHS factor VIII, if available or heat treated US commercial.

4) Haemophilia B

(a) Mild Christmas Fresh frozen plasma if possible (otherwise NHS Factor IX.

(b) "Virgin" Patients and those not previously exposed to concentrate use fresh frozen plasma (or NHS factor IX concentrate if essential)

(c) Severe and Moderate Christmas Disease previously exposed to factor IX concentrate continue to use NHS factor IX.

1408. While the issue may continue past this date, from the documents I have seen it would appear that demand for heat treated concentrates produced by BPL continued at a high level. The demand for plasma is discussed in my answer to question 18 and section 8.

Collection of blood from prisons in the UK

1409. At this point it seems sensible for me to address the question of the historical donation of blood by UK prisoners. I say this, even though it is not an issue specifically raised in this Rule 9 request, because it seems relevant given the terms of reference of the Inquiry (in

particular Issues 76a, 77,78 and 79), and as such it ought to be covered by this R9 Response.

Should the collection of blood from such groups have stopped earlier and if so when?

Difficulty defining the extent of prison donation in the UK

1410. I understand that NHSBT's predecessors collected blood at prisons. I also understand that the practice is likely to have largely stopped by the end of 1983, following guidance from the UK Working Party on Transfusion-Associated Hepatitis. Unfortunately, because of the way in which blood services were organised and managed historically, it has not been possible to evidence fully either the extent of the practice or the exact end date(s).

1411. As has already been noted elsewhere in this response, NHSBT is yet to see many of its documents, which has further made the identification of the prisoner issue difficult. There is also limited if any information in an electronic format. Therefore, finding a final date of collection or estimating the volume of blood collected from prisoners in England and Wales, in the way the information for the Scottish Blood Service was presented to Penrose for Scotland, is unfortunately not possible.

International Practice

1412. I have been provided with an SNBTS paper on the collection of blood in prisons produced for the Penrose Inquiry [PRSE0002164]. At the end of that document, a summary of a questionnaire by the European Blood Alliance (EBA), looking at deferral of prisoners, was provided. I have not seen the original questionnaire but was assisted by the information provided in the summary:

- Some countries never collected blood from prisoners (Denmark, the Netherlands and Eire)

- Some countries introduced a permanent or temporary deferral of blood collected from prisoners in the 1970s (Switzerland, 1970; Belgium, mid-1970s; Finland, 1975)
- Some countries ceased the collection of blood from prisons in the 1980s (England – the document suggests in Wales '*those serving a custodial sentence cannot donate*' and Northern Ireland, both 1983; Scotland, 1984; Luxembourg, 1985; France, 1985-89)
- Other countries did not introduce permanent or temporary deferral of blood donation by prisoners until the 1990s (Portugal, 1990; Austria, 1995; Germany, 1996; Norway, 1997).

Historical Context Nationally and Internationally

1413. The following is a chronology of some of the relevant events based on the documents I have received.

- 1971: The World Health Organisation (WHO) published the "*Guide to the Formation and Operation of a Transfusion Service"* in 1971 [PRSE0002035]. This recommended that countries setting up a donor recruitment scheme should take initial steps to form panels of donors within groups such as the armed forces, the police, large industrial or commercial undertakings, universities, prisons and social or religious foundations.

- 1971: I understand from the Krever report [KREV0000001] that also in 1971, The Canadian Red Cross ceased prison collections after hepatitis B surface antigen testing demonstrated conclusively that prison inmates in Canada had a significantly higher prevalence of hepatitis than the rest of the population.

- 1972: A book by JG Allen [PRSE0003483] suggested "*the risk of serum hepatitis from transfusions derived from prison and Skid Row populations is at least 10 times that from the use of volunteer donors*" and that "*the most practical methods of reducing*

the hazard…are to limit the use of blood… especially by excluding, if possible, all prison and Skid Row or commercial donors".

- 1973: The NBTS figures for*: Frequency of HBAg and Anti-HBAg reported by RTCs New General Public and Frequency Donors and in Donors in Armed Forces and in Prison Borstals and Similar Institutions* finds the incidence of HBAg to be 1:1107 in the general public and factory workers; 1:859 in the armed forces and 1:214 in prisons, borstals and similar institutions. The figures for January to March 1974 were respectively 1:1491, 1:967 and 1:848 [PRSE0004719]

- 1975: I have been shown a letter from Dr Garrett Allen (Stanford) wrote to Dr Maycock warning of the increased risk of hepatitis, including NANB hepatitis from the blood of prisoners) [CBLA0000249].

- 1975: I have been shown a letter from Dr H Yellowlees (CMO) dated 1 May 1975 where he wrote to all Regional Medical Officers on the subject of blood donation and hepatitis that it was not necessary to discontinue the collection of blood in prisons provided that all donations were tested for hepatitis B using a sensitive test [PRSE0000009].

- 1976: ISBT published guidance on "*Criteria for the selection of blood donors"*. It outlined the risk of viral hepatitis and acknowledged the limitations of tests available at the time. Prospective donors were to be excluded if they were "suspected to be parenteral drug addicts" or "inmates of a correctional institution" [DHSC0002179_067].

- 1978: The *WHO "Expert Committee on Biological Standardization"* published a report suggesting that donor populations with a prevalence of acute or chronic hepatitis higher

than that found in the general population should be avoided [PRSE0001264].

- 1978: DHSS/SHHD: Standards for the Collection and Processing of Blood and Blood Components and the Manufacture of Associated Fluids made no reference to prisons [PRSE0003128].

- 1995: In the USA the FDA banned prison donors, although the practice of harvesting prison plasma for clotting factor was believed to have stopped in 1983 based on an informal agreement between the FDA and commercial companies, as documented by Cutter and Armour [PRSE0002164].

Historical context: the UK blood services

1414. It should be noted that the term Australia antigen is synonymous with HsBAg, similarly I take Au positivity and negativity relate to the presence or absence of this hepatitis B surface antigen.

1415. The available documentation on this has been really quite limited. What I have seen can be summarised as follows:

1416. I have been shown the minutes of the RTD meeting on 6 October 1971 [NHBT0015758_001]. Under the heading: "*Prisoners as Donors*" there was a note that, since 1 July 1971, the American Red Cross had stopped collecting blood from donors in "*correctional institutions*" because it is generally accepted in the USA that the incidence of infective but Au-negative donations is higher among those from prisoners than from voluntary unpaid donors and that the incidence of Au-positive donors among prisoners is 10 times greater than among voluntary unpaid donors. The following points were made in discussion:

- All RTCs collected blood in prisons, borstals or other similar institutions.
- Several RTDs did not consider that the association of donations from such sources with cases of hepatitis was any greater than that of donations from other donors.
- Dr Darnborough reported that he had found a greater incidence of Au positive among prisoners than other donors. These results confirmed those of Glasgow.
- There was great difficulty in following up prisoners found to be Au-positive and arranging for confirmatory tests. This was particularly so after prisoners had been discharged. In one prison the names of the donors were not given to the RTC. Dr Grant said it was sometimes difficult to keep any record at all of prison donors.
- It was suggested that prison and borstal governors should be asked to prevent any individuals known to be or to have been a drug user from volunteering as a donor.
- After further discussion the meeting agreed to adopt this suggestion but before considering whether to stop collecting blood in prisons, more information should be obtained about the association of such donations with cases of serum hepatitis.

1417. I have been provided the minutes of an RTD meeting on 7 June 1972 [NHBT0016123]. The risk associated with prisoners, especially drug addicts was reported and discussed. An overall incidence of 1:1500 antigen-positive and 1:1300 antibody-positive donors was reported. No antigen- or antibody-positives were observed among 1449 armed forces donors (including US Air Force personnel). On the other hand, in two borstal institutions and two prisons, antigen and antibody were detected in one in 488 donors (total donations tested, 976). In a discussion on the incidence of Australia antigen in the general and other populations, it was noted that of 107 donations involved in 19 cases of serum hepatitis, the incidence among donors from prisons and borstals was the same as that among all donations collected, 'which might suggest that the risk attaching to blood from such donors

(normally bled only once) was not, in fact, higher than that from new general public donors. Various figures, based on small population sizes, were given for the incidence of Australia antigen in donations from prisoners and members of the public in different regions in England. The minutes note that, '*[i]n view of these discrepancies the meeting agreed that further information should be collected before it was decided to discontinue collecting blood in prison and borstal institutions*'.

1418. Five RTCs had gathered the data on hepatitis rates which showed a significantly higher proportion in the prison population. The incidence varied regionally. Dr Bowley reported that the incidence of antigen positives in new donors as compared with prisoners and inmates of borstal institutions was respectively 1/139 and 1/135 in the Sheffield region. Dr Tovey reported Bristol prison showing 1 in 486 prisoners as antigen positive and I in 973 as antibody positive, compared with 1 in 541 and 433 respectively in the armed forces; the corresponding figures for South London were nil for the armed forces and 1 in 285 in prisons.

1419. I have been provided the minutes of an RTD meeting on 20 September 1972 [NHBT0000086_003]. Those minutes note that in Edinburgh the incidence of Au positive tests in prisoners was no higher than among the general population but that in Glasgow the incidence in prisoners was significantly higher. Edgware and Brentwood RTDs meanwhile made the decision at this point to discontinue the collection of blood from prisons and borstals, noting the increased risk of hepatitis.

1420. I have been provided the minutes from an RTD meeting on 26 September 1973 [NHBT0000086_002]. Opinion amongst the 14 RTDs was split evenly on the issue of prisoner donors:

- 7 RTDs felt receipt of donations from borstals/prisons should stop because the incidence is high.
- 7 RTDs felt that collection from borstals/prisons should continue because current testing was safe enough to detect the higher incidence.

The decision was made that blood collection would continue until the statistical differences between figures in the documents produced had been examined more closely.

1421. The RTD minutes suggest that if collection from prisoners was to be discontinued, DHSS should inform the Home Office before any local action was taken. A principal at DHSS had carried out a study on motivation of prisoners to donate and there was a sense that blood donation played a role in rehabilitation. It is not clear what communication occurred between DHSS and The Home Office on this matter or if this had any influence which delayed making a final decision over deferral of prisoners.

1422. The next document addressing prisoners that has been shown to me appears to come from 1976. It is unclear what became of the discussions with the DHSS referenced above. A document called the *Microbiology Section – Annual Report 1976* (written by a P Nuttall) provides the following numbers for HB Antigen detection:

Total donations: 126,349	Antigens: 37	Frequency: 1: 3145
New donors: 18,855	Antigens: 36,	Frequency 1: 725
General public: 122,796	Antigens 33	Frequency: 1: 3,721
Prison donors: 198;	Antigens NIL	Frequency N/A
Students: 3335	Antigens 4	Frequency 1: 838.

This shows that no infections were detected in prison donors, but it was a very small sample - 198 donations out of a total of 126,349. In this sample, 0.16% of total donations tested were from prison donors.

1423. I have been provided a letter from Dr Brookes from Dundee to Dr Cash dated 23 August 1983 [PRSE0002981]. In that letter Dr Brookes noted that a request had been made to discuss donor sessions at prisons and borstals with English representatives. The letter states that in fact no discussion was necessary since as far as England and Wales were concerned, these sessions had already stopped and it was now 'left to the Scottish regions to decide whether they will do the same."

1424. I have been provided the minutes of a UK Working Party on Transfusion-Associated Hepatitis [PRSE0001299] meeting on 27 September 1983. In those minutes the group noted that it reflected the decision of the group that "*prisons should be considered in the context of a 'high-risk' population in terms of several transfusion-transmitted infections and as such should be avoided as a donor source.*"

1425. It appears that for the purposes of a Scottish Transfusion Directors' meeting of 13 September 1983, the East of Scotland Blood Transfusion Service conducted a telephone survey of England and Wales transfusion centres regarding the use of prisons as a source of donor blood [NHBT0008628_001] in response to which, the following information was received:

- Tooting: Has held no collections in prisons since 1979

- Edgware: Prison sessions were stopped in Dr Cleghorn's time. The Centre reconsidered one year ago and decided against.

- Brentwood: The region has only one prison, too small to be used for donor sessions and in any case the Centre would not look for prison sessions now. They do hold a session in a Military Corrective, but the donors are all fit young men, well-vetted by their supervisors.

- Wessex: It is several years since they stopped using the Isle of Wight prisons because of increasing medical problems among prisoners, particularly related to drugs. The prisons cancelled sessions at 2-3 hours' notice because of prison riots, demonstrations etc. At present they use Winchester Prison, a short stay prison for non-violent prisoners, once a year, but plan to withdraw this session in the near future.

- Bristol: Have been holding prison sessions and will stop at the end of 1983. The reason they have given is the higher incidence of hepatitis.

- Cambridge: Prisons were not used as a donor source for many years, then in 1982, during an acute blood shortage, they held a session at an 'Open' prison, but discovered many inmates were drug-addicts (using heroin, LSD etc) and have not gone back. The policy is not to use prisons but reserve the right to do so in emergency.

- Oxford: Has been easing away from donor sessions for some time, and after the discussion at the Cambridge meeting in Spring 1983 discontinued them.

- Cardiff: Uses Cardiff prison and is actively considering whether and when to stop.

- Birmingham: Has discontinued using prisons this year, partly as a consequence of discussions at the spring Cambridge meeting. They did get help from prison officers with regard to vetting donors.

- Liverpool: They have several large prisons (Walton, Risley, Moss Side) and are concerned that there is no pre-selection of donors for prison sessions, therefore a number of medical problems to look out for and they have a notably higher incidence of HB Ag positive

donors from them. They have been moving slowly because of concern that they may be short of blood over Christmas and holiday times, but are phasing prison sessions out.

- Leeds: The region has large prisons at Wakefield, Leeds and Hull. They tried to withdraw prison sessions and got a very active response from the prisons which asked that the sessions should continue. The session staff get help from prison staff to exclude volunteers who are medically unsuitable. Dr Tovey received a letter from a prisoner asking reassurance that if an abnormal result was obtained on donation testing, the prison donor would be informed. The prisoner considered this to be a valuable service performed by B.T.S.

- Newcastle: Long ago stopped holding sessions in Durham and Northallerton, but continued to use an 'open' prison in West Cumberland which housed 'civil' crime prisoners (bigamy, fraud etc). Latterly they had noticed an increase in incidence of hepatitis B markers and discovered that prisoners from Walton Jail (Liverpool) were being sent there for their pre-release six months. This session has now been dropped so that Newcastle holds no prison sessions.

- Sheffield: The relevant person undertaking the calls did not approach these two Centres for information, anticipating that Dr Gunson and Dr Wagstaff would be at the RTD meeting to speak for their Centre.

- Manchester: Reputedly in the past never used prison sessions for the supply of fresh blood and products, the blood was put to plasma.

1426. Dr Harold Gunson National Director of the NBA wrote to Dr John Cash, Director of SNBTS on 2 December 1983 [NHBT0008624]:

"Since it was at a meeting of the Hepatitis Working Party that the question of holding sessions in prisons was raised, as a result of this I have written to all Directors in England and Wales to ask them whether they still hold sessions in H M Prisons. I have had 9 replies to date and 6 have already discontinued holding such sessions, in addition to Dr I Fraser who has decided to discontinue them, although he currently has them on his programme. In this connection, it might be interesting for you to know that when he did a series of 10,000 anti-HBC positives, he found 72 positives, approximately half of which were from prison donors.' He also notes that there had been a request from the media to the DHSS for clarification of the holding of sessions in prisons.

1427. Mrs Edwina Currie, the Secretary of State for Social Services gave a written answer dated 11 February 1987 to a Parliamentary question [NHBT0057149_087] from Mr Dubs regarding the date when the blood transfusion service stopped taking blood from prisoners in penal establishments as follows:

'*Mr Dubs asked the Secretary of State for Social Services when the blood transfusion service stopped taking blood from prisoners in penal establishments*

Mrs Currie: Collection of blood from closed prisons and borstals in England and Wales stopped at the end of 1984 and stopped from the last open prison in 1986'.

1428. It does seem that prisons collections ceased or were relied on less as the 1970s and early 1980s progressed but may have been relied upon in some regions during holiday periods when there was a shortage of supply, particularly from open prisons.

Estimate from limited data

1429. Very limited data is available to undertake any form of estimate of the amount of blood taken or issues with such blood. I provide this information simply as that which I have come across in reading the documents for this section.

1430. The data attached to the RTD minutes for the 143rd meeting held on 20 September 1972, summarising hepatitis B rates in 5 RTCs during 1971/1972 suggests geographical variation but higher rates in the prison population. The data also shows that taken as a whole between January 1971 and August 1972 out of a total of 373,263 donations collected by the five transfusion centres, 5,903 were collected in prisons – or 1.6%. This varied between regions from 4.2% in Cambridge between January 1971 and February 1972 (976/23,390) and 0.5% in Sheffield between April and October 1971 (278/56,057) [NHBT0000086_003].

1431. The Microbiology Section Annual Report for 1976 [NHBT0074591] shows 198 donations from prisons at a far reduced rate of 0.16%. This is a limited snapshot of a small sample, so the range is broad. It therefore represents only a very rough estimate of the actual figure, but it is a useful reference point in lieu of more complete data.

1432. These figures appear to be reasonably consistent with percentages for SNBTS donors presented to the Penrose Inquiry, which were that on average 1.097% of donations came from prisoners. The number varied over the years from 2.38% in 1975, to 0.11% in 1984. This information is provided in the corporate response to the Penrose Inquiry regarding SNBTS blood collection 1975-1984 [PRSE0002164].

1433. A source of information on this point might be the monthly returns referred to in our response to Question 34 of the amended Rule 9 request of 14 August 2020, sent to DHSS from 1 October 1972. It is not known for how long these were submitted or whether they will be available in DHSC papers when released but this paper attached to

the RTD minutes for 20 September 1972 is the only such return identified by us to date in the papers available.

1434. There may also be returns for further years in the Microbiology Section Annual Reports but searches to date have not produced any further reports like that for 1976.

Did Collections at prisons continue into the 1990s?

1435. A box of 101 cards from sessions carried out at a prison in Bristol has been sourced and searched. It is difficult to ascertain which cards belong to prisoners rather than staff since the 'occupation' section is inconsistently completed, there is also an 'address' field but this is also inconsistently completed. It appears that sessions continued at the prison long after collections ceased from prisoners. For those 101 cards lacking clarity over occupation, with dates that span into the 1990s, I understand that current colleagues, who were working at the time, were asked when compiling this evidence and they felt, with great certainty, that these cards represented only donations taken from prison staff since donation from prisoners had long since ceased. It is, however, very difficult to evidence this in a robust way.

Summary and areas of potential delay

1436. At the time when the risk of transfusion transmitted blood-borne infections became understood, RTCs were acting as separate blood services, with directors making independent decisions about donor selection and testing. The decisions have not been documented in a consistent way or archived on a basis which allows retrieval.

1437. Due to the lack of documented evidence, the exact date for when blood collection from prisoners ceased is not available, nor is an estimate of how much blood was collected from prisoners. The practice appears to have reduced during the mid to late 1970s, partly depending on the levels of infection in different regional prison populations and thus the risk profile and then ceased during the

emergence of HIV/AIDS. Documented clarity was given by the UK Working Group on Transfusion Associated Hepatitis in September 1983. Prisoners should, from that time onwards, have been permanently deferred.

1438. In terms of quantity, the available evidence, such as it is, suggests that in 1971/72 on average about 1.6% of the blood supply In England was donated at prisons; by 1976 this had reduced to 0.16%. This summary suggests areas where action might have been taken sooner including:

- delay in stopping blood collection from prisoners, despite discussions over a potentially increased risk of hepatitis having been noted in 1973. In an international context, the UK was considered to be a low prevalence country and many other countries continued to collect from correctional institutions after the practice ceased in the UK. After discharge from prison, ex-prisoners would be deferred on the same principle as any other donor presenting.
- The lack of accurately archived documentation around donor selection policy for each region.
- The potential role of the DHSS and Home Office relating to an enthusiasm for continued prison collections as beneficial in the rehabilitation of inmates
- The fact that RTCs were run by and accountable to separate regional health authorities.

1439. It is important to acknowledge the impact of this practice on the recipients of blood in England and North Wales. Looking back, it seems that decisions on collecting blood from a higher risk prisoner population should and could have been made in a more coordinated and timely manner, given what we now know. Any infection that might have been avoided by reasonable earlier or different action is one too many. On behalf of the English blood service, I am very sorry for any harm that has occurred as a result.

Conclusion

1440. My answer to this question has been long and involved varied subject matter. I hope I have demonstrated in my answer to this and to question 43 that decision-making in the past and the way NHSBT makes decisions and operates today is very different. The nationally coordinated approach, including the work of JPAC SACCSD and SHOT; the processes and surveillance, the highly regulated nature of the organisation, the focus on the health of both donors and recipients, the horizon scanning and the dynamic response to emerging risks, when taken together mean that lessons from the past are being acted on, so that dangers of any future emerging infection can be more robustly mitigated.

45: How effective are NHSBT's current functions, policies and practices in ensuring the safety of the blood supply in England? Please compare the current approach with the historical approach, highlighting significant differences and developments.

Recent

1441. As described in my answer to Q43 and Q44 NHSBT undertakes a series of measures to ensure the safety of the blood supply and has a series of systems and policies to ensure this happens. My answer here is: how do we assure ourselves these are effective? Some of the answer to this question lies in the systems and policies we have put in place, by that I mean assurance mechanisms I describe in my previous answers such as the reports looked at on adverse incidents in clinical governance and QMS meetings, the management and investigations of adverse and serious incidents, the outcomes of clinical audits and incidents informing our risk management. These will provide some assurance as to how effective the measures are and I do not repeat these here. However, I will describe here the systems that we particularly rely on that collect data across the UK and provide longitudinal and collective information to assure us on the

effectiveness of our measures. I have not here described the systems that we have in place to reduce the risk of future infections which are described earlier: these include horizon scanning for emerging infections and R&D. It should be noted, however, that these also form part of the continuum, and system, to reduce infections being transmitted by blood components.

1442. As described in my answer to question 44 the processes that we put in place to maintain safety include
    a. Selecting donors according to guidelines set by JPAC
    b. Cleaning the donor's arm as required by JPAC
    c. Diverting the skin plug formed through the insertion of the needle into a sample pouch.
    d. Screening blood and blood components for various infections.

1443. The assurance on the overall effectiveness is largely given by two reports. The first is the donor surveillance and the second the recipient surveillance (or haemovigilance). Taken together they cover the four safety processes listed above.

1444. The effectiveness of donor selection is monitored by the annual Safe Supplies report produced by the joint NHSBT/PHE Epidemiology team. This is dependent on the prevalence of infections in the general population, but donor selection aims to prevent donors at a higher risk of an infection from donating blood where we consider the risk to be material. The data is then combined with other published data, using a validated model, to give 'residual' risks of an infected donation entering the blood supply e.g. getting through all our measures.

1445. Bacterial contamination is largely a risk in platelets as these are kept at room temperature rather than in the fridge (red cells) or freezer (plasma and cryoprecipitate). Arm cleaning, the skin plug divert and the bacterial screening of platelets are measures to reduce bacterial transmission and their effectiveness is measured by the number of

bacterial contamination in platelets. These are reported to SHOT and captured in that report.

1446. Similarly, the screening of blood and components for other infections is measured by the annual SHOT report.

Monitoring of blood donors – monitoring infections based on routine surveillance of donors

1447. NHSBT works jointly with PHE[77] to maintain further surveillance systems to monitor that policies on donation testing and donor selection are safe and appropriate. The joint NHSBT/PHE Epidemiology unit produces regular reports for operational use within NHSBT as well as annual reports and peer-reviewed publications.

1448. Currently, infections in UK blood donors are closely monitored and routine surveillance is in place to determine if there are changes or trends which occur over time. NHSBT and the other UK blood services collect extensive data on donors including the type of infection; acute and / or chronic status; donor demographics including country of origin within the UK, ethnicity, and age and sex; donor clinical / donation history; details of donor risk behaviours associated with acquiring an infection; and, donor compliance with donor selection. These data are then provided to the NHSBT and PHE's Epidemiology Unit for surveillance purposes. I have addressed the public availability of the Epidemiology Unit's annual review in an earlier answer in this section.

1449. The Epidemiology Unit reports these data on a monthly, quarterly and annual basis to a range of stakeholders including members of the Microbiology Strategy Group, Microbiology Services Clinical Group, and operational teams within NHSBT. Key items reported include the number of confirmed infections by donor characteristics and risk behaviours, along with annual incidence and prevalence rates of any given infection. Each year, these data are used to estimate the

[77] PHE is currently in transition to become the UK Health Security Agency on 1 October 2021.

residual risk that an HBV, HCV and / or HIV infection is not detected on routine screening and thus could enter the blood supply. The risk of non-detection arises when the donation is made in the window period of the tests in use – this occurs very early during an infection when there is enough virus to be infectious to the recipient but not enough to be detected on testing. The calculations are made in the UK for a rolling three-year period and are an important benchmark for safety.

Monitoring of blood donors and recipients - Annual residual risk calculations

1450. Each year, using the data described together with published results from papers and expert opinion collected by the NHSBT / PHE Epidemiology Unit, SACTTI prepares a position statement estimating the estimated residual risk that a donation made in a given infectious window period is not detected on testing, specifically for HBV, HCV and HIV. These residual risk estimates are published on the JPAC website as position statements and are freely available [RLIT0001557].[78] Residual risk is usually described as the estimated residual risk per million donations tested, or up to the estimated number of years of blood donation screening before a potentially infectious donation is not detected. It is important to note, however, that residual risk is not the estimated risk of transmission, since transmission will also depend on the amount of undetected virus in the component which may vary by type of component transfused.

1451. The model used to estimate the residual risks is peer reviewed and was developed and is employed by members of the International Society of Blood Transfusion **('ISBT')** Surveillance, Risk Assessment and Policy working party subgroup. I attach a presentation and a paper addressing the calculation of residual viral risk produced by the joint NHSBT/PHE Epidemiology Unit as relevant examples of such estimates [RLIT0672093] and [RLIT0672094].

[78] [RLIT0001557]

1452. Calculating the residual risk of undetected HTLV, HEV and Syphilis has been considered but is thought not to be relevant to informing blood safety in respect of these infections for the following reasons:

a. HTLV: When testing was first introduced in 2002, HTLV was included in the annual residual risk calculations. However, in 2011 a decision was made by SACTTI to cease calculating HTLV risk given that there was too much uncertainty about the presence and / or duration of an infectious window period and the relevant of the calculation was questioned given leucodepletion of all components had been shown to significantly reduce onwards transmission to patients. On the issue of leucodepletion Dr Hewitt published a paper in 2013 on its positive effects perceived in a HTLV lookback exercise[79].
b. Syphilis: Syphilis infection has never been included in the annual risk calculations to date as the clinical risk to transfusion recipients is very low owing to the fact that the bacteria are very heat sensitive and die rapidly at temperatures below 12 – 15 degrees Celsius. The only components which are not stored below this temperature range currently are platelets and granulocyte concentrates.
c. HEV: residual risk for HEV has been calculated in the past, but due to the very variable incidence among blood donors (from our monthly data) any estimates made retrospectively are unlikely to be relevant to current assessments of blood safety. The most likely source of HEV infection in our donors is from a food source with poorly cooked pork products being the most likely source of infection. Previous research has suggested that incidence of HEV infection may vary throughout the year, possibly in relation to changes in consumption i.e. increased barbeques in the summer months or due to a contaminated batch of meat entering the food chain. In addition, there is some debate as to the length of the infectious window period which may be as short as 7 days.

[79] https://onlinelibrary.wiley.com/doi/10.1111/trf.12105

1453. Most recently, the November 2020 position statement covering the period between 2017 and 2019 estimated the number of potentially infectious window period donations that testing did not detect to be less than one in one million. Estimated risk was highest for HBV at 0.87 (95% confidence interval (CI) 0.35 – 1.7) per million donations tested. Estimated risk was lowest for HCV at < 0.01 (95% confidence interval (CI) 0.00-0.05). Estimated risk for HIV was 0.04 (95% confidence interval (CI) 0.01 – 0.09).[WITN0672141].

1454. In 2005, Soldan et al provided risk estimates for the period between 1996 to 2003. They estimated that the frequency of infectious donations entering the blood supply during that period was 1.66 per million for HBV, 0.80 per million for HCV, and 0.14 million for HIV:[WITN0672095].

SHOT Haemovigilance

1455. Formed in 1996, the Serious Hazards of Transfusion haemovigilance scheme is an independent, UK-wide professionally led haemovigilance scheme which collects and analyses anonymised information on adverse events and reactions in blood transfusion from all healthcare organisations that are involved in the transfusion of blood and blood components in the United Kingdom.

1456. SHOT covers the whole process of transfusion from donors to recipients. Transfusion transmitted infections (TTIs) is a chapter in the SHOT report. In the 2020 report there were 3214 events reported in total of which 1130 were near-miss events. Of the other 2084 errors or adverse events there were no transfusion transmitted infections, in the past five years there have been four and in the past 10 years there have been 16 TTIs across the UK.

1457. NHSBT contributes to the data collected and analysed by SHOT. All transfusion transmitted infections are reported by the clinical

microbiology team as part of our MPDs (discussed below) concerning post-transfusion infections. A member of the joint NHSBT/PHE Epidemiology Unit is the National Infections Coordinator and they collate the SHOT reports related to infectious hazards.

1458. SHOT uses these data to produce recommendations to improve patient safety, which are included in its annual report which is then circulated to all relevant organisations including the four UK blood services (including NHSBT) and the relevant health ministries across the UK. Since 2005, SHOT has operated alongside the MHRA's Serious Adverse Blood Reactions and Events database **('SABRE')** – the MHRA's online system for reporting blood safety incidents. Reporting to SABRE is usually carried out by the NHSBT quality assurance team. Both SHOT and SABRE are described in further detail in the rule 9 response provided on 23 January 2019.

1459. The annual SHOT reports are all available on their website. These show that the last documented transmission of HCV in the UK was in 1997, the last documented case of HIV transmission in 2002 and incidences of HBV transmission have significantly reduced over the years.

1460. In addition, diversion of the skin plug was introduced in 2003, improved arm cleaning in 2007 and bacterial screening of platelets in 2011. Since these changes were introduced there has only been one confirmed case of bacterial transmission (in 2015) with 40 cases in the preceding years reported in the 1997-2009 reports [WITN0672092].

1461. The NHSBT / PHE Epidemiology Unit acts as the National Infections Coordinator for SHOT and collect and analyse data from each of the UK blood services on the number and type of transfusion transmitted infections, which feeds into SHOT's role as an independent, professionally led haemovigilance system focused on learning from adverse events.

1462. As a final comment, there is one additional thing NHSBT would like to do and that is to institute a system whereby the outcomes of all transfusions could be known rather than a system of just reporting adverse events. We believe this would give us new ways of auditing blood use and auditing against clinical guidelines, benchmarking between hospitals and performing research. Such a system has never been set up in this country and is very uncommon worldwide. The SCANDAT (Scandinavian Donation and Transfusion) system is the best example of this. In England this would involve enormous datasets and a paper-based system or one that involves someone in a hospital registering the outcome with us is not feasible. However, with technology we believe this should be feasible by linking between datasets. We have recently agreed funding to start working out how this could be best done in England.

vCJD

1463. In my response to Question 44 above, I have provided the details of the various measures taken to ensure the safety of the blood supply in England (and indeed the United Kingdom) in relation to the risk of vCJD contamination. As will be noted from that answer, these are collaborative measures taken by numerous stakeholders, not simply or even principally NHSBT. These stakeholders include PHE, NCJDRSU, DHSC, JPAC and SaBTO.

1464. As will be clear from my previous answer, the approach to ensuring the safety of the blood supply in England in relation to vCJD is necessarily a precautionary one owing to the lack of understanding of the disease and indeed the experience of HIV and HCV earlier in the 20th Century. I provided the details of all presumed and probable transfusion-transmitted infections of vCJD in answer to Question 44 a above.

Comparison

1465. I have no personal knowledge of the historic position; I have been working from papers throughout this section. In addition, for the various reasons explained elsewhere in my response, the nature of the blood service has changed significantly since the 1980s. As such, it is very difficult to undertake any meaningful comparison of the current and historic positions, and I do not think it is appropriate for me to do so. I would however make the following observations

a. The numbers of infections in the population as a whole, which is the potential donor pool, has reduced over time.
b. The systems for recording, investigating incidents and sharing data and knowledge through education continue to improve each year
c. The laboratory technologies for screening and detecting infections have improved markedly over the years
d. The surveillance systems are more robust now than they have ever been in the past and they continue to improve with education, knowledge and IT systems
e. The SHOT Annual Reports show reductions in the numbers of infections related to HIV, and HCV. Hepatitis B continues to be of some concern and there is ongoing work by SaBTO currently to improve the knowledge of this risk and to make recommendations on this.
f. New infections continue to emerge, and we have the processes in place to react quickly if the risk is assessed as requiring action by policy bodies. With recent emerging transfusion transmitted infections, we have introduced rapid donor travel deferrals when this will contain the risk (e.g. Zika and Ebola), screening where the infection is endemic and this is possible (e.g. Hepatitis E) and implementing donor deferrals and other measures where a screening test does not exist (e.g. vCJD).

1466. Thus, as I have tried to explain throughout section 9, the current systems in place are more effective in maintaining the safety of the blood supply than ever before, but this is not a zero risk, nor is it

necessarily the lowest risk possible. Whilst the precautionary principle is rightly used when the risks are not known, for example with decisions made when vCJD first arose, decisions when risks are known require judgement. This judgement requires a weighing of the risks and benefits and of the cost effectiveness of both implementation and omission, as is true of all decisions in healthcare and blood services are no different. It is not possible to introduce every beneficial healthcare intervention and choices always have to be made. Decisions on the extent to which a risk can and should be reduced are considered by SaBTO according to a number of calculations and perspectives including health economics and risk tolerability. These may include cost effectiveness calculations (incremental cost effectiveness ratios, ICERS or quality adjusted life years, QALYs), modelling, sufficiency calculations, as well as absolute risk and other considerations such as equality. Therefore, as explained earlier, they are considered within a formal risk-based decision making framework. As such they are taken with the context of the NHS as a whole.

1467. As the SHOT reports show, there are many adverse events that can happen during the process of transfusion and TTIs are small in number and also small in proportion to the total events. I should make it clear that to make transfusion ever safer, we look at the report each year and will adjust our internal processes or work of our education and patient blood management team as appropriate.

1468. I hope I have demonstrated that we are always striving to maintain and improve safety wherever possible but within the context of the NHS in which we work. Modern day blood services work closely together to share knowledge effectively and quickly.

Section 10: Identifying risks associated with blood and blood products

46. Please explain NHSBT's approach to ensuring its staff keep abreast of medical and scientific developments and research in blood and transfusion-related matters. Does NHSBT delegate this responsibility to its staff members entirely, or does it maintain some control over this process? Has this changed over time?

Current

1469. Currently, keeping abreast of medical and scientific developments and research in blood and transfusion-related matters is an obligation shared by NHSBT and individual staff members. Various frameworks are in place for NHSBT to provide information, training, and guidance to staff. Staff are also obliged personally to keep abreast of such information from the perspective of appraisal, validation, professional regulation, and the requirements of Continuous Professional Development or CPD schemes that individuals belong to. Thus, these frameworks and processes are formal for doctors, nurses and registered scientists. Similarly, there are formal in-house processes for non-registered staff who perform NHSBT business which keep staff up to date and trained on our policies and processes. An annual Personal Development and Performance Review **('PDPR')** process also takes place between every manager and employee which includes organisational and personal development and objectives and compliance rates of this are monitored on a monthly basis.

1470. NHSBT has a wide education remit and programme across the NHS together with other bodies. This includes a well-attended education programme, a pivotal role in examining for the Royal College of Pathologists, a role in guideline development with the British Society for Haematology, the development of international guidelines with the International Society of Blood Transfusion

1471. NHSBT remains very active in R&D and horizon scanning of academic publications. NHSBT academics and consultants are authors on around 200 publications each year and frequently attend and present

at conferences nationally and internationally. There are formal processes for agreeing attendance at conferences and funding this for all colleagues at NHSBT.

Formal National Requirements for Doctors, Nurses and state registered Scientists

1472. Medical staff are the subject of annual appraisal and revalidation (license to practice) as set out by the General Medical Council. In undertaking that appraisal, they are required to provide evidence of keeping up to date with medical developments and training requirements. Staff are subject to minimum requirements for continuing professional development. Evidence of training completed as is provided by doctors is reviewed by a third-party appraiser and any concerns with a specific staff member from that appraisal are escalated firstly to the lead appraiser and then as appropriate to the Responsible Officer (I currently hold this role).

1473. Similarly, Nurses working within NHSBT also undergo appraisal and revalidation in accordance with requirements set out by the Nursing and Midwifery Council and this includes meeting CPD requirements.

1474. The Health and Care and Professions Council also has standards and requirements which will be met by our state registered scientists who comprise the majority of scientific posts within NHSBT (but excluding academic scientific posts).

Formal NHSBT processes to meet regulatory requirements

1475. All individuals who join NHSBT follow a training programme suited to their role. All colleagues working on processes that are part of the collection, manufacturing and issuing of blood components included under the regulatory framework of Good Manufacturing Process are trained in these processes. A training matrix with defined training for each role with mandatory and optional training requirements needs to be completed and reviewed annually. Staff maintain a task-based

training record (signed and dated as appropriate). Such training will be overseen by their line manager. This includes modules of mandatory training for all employees. Training records are subject to quality assurance review and MHRA inspection. All new colleagues working within the GMP environment are also trained on how to use the Quality Management System, appropriately for their role, before they are allowed to start working.

1476. Updates on controlled documents within the Quality Management System (eg Policies; POLs, Management Process Descriptions; MPDs, Standard Operating Procedures; SOPs, and Information leaflets; INFs) are circulated by quality assurance to all staff on a predefined circulation list, according to their roles, to keep people informed of current NHSBT practices with a formal process of acknowledgement and training associated with this. Authors of these documents will routinely include new scientific knowledge and evidence in these documents.

1477. A training programme is given to all new members of the clinical and scientific workforce according to their role. Such training is accompanied by a rationale, so colleagues understand the reason why specific actions or rules are part of their training. Clinicians, particularly the Clinical Support Team (CST) to the Blood Supply Directorate which includes both doctors and nurses, follow processes as described above.

1478. The training that new nurses and donor carers receive is regularly reviewed and updated to reflect the best evidence and practice related to blood donor selection and collection. Within our current programme, we have a process called 'Continuous Observation, Development and Education' which requires each donor carer and nurse to demonstrate on an annual basis that they are following the correct rules and guidelines. In that assessment they are observed to ensure they are competently undertaking the clinical element of their role. They are

also asked to answer a series of questions to demonstrate their knowledge.

1479. For nurses and donor carers there is also a process called 'Hot Spots and Insights' whereby if an incident has taken place, staff review that incident to ensure that lessons are learned and shared with all collection teams. This serves as both a refresher of their current knowledge or as a reminder of the correct processes to follow. Such staff are also required to undertake CPD as appropriate. An aspect of CPD management is that each month clinical scenario questions are sent out to clinical staff to test and maintain their knowledge.

Formal Education Programmes and Resources

1480. NHSBT also run specific educational activities within teams. Examples include CST educational activities and Patient Blood Management educational days. NHSBT runs various courses at basic, introductory, specialist and advanced level for scientists and doctors within NHSBT and the wider NHS to keep employees up to date and to train new employees. For further details see for clinical: https://hospital.blood.co.uk/training/clinical-courses/ and for scientific: https://hospital.blood.co.uk/training/scientific-courses/. These courses are delivered by senior medics and scientists in NHSBT who routinely include new clinical evidence from scientific papers and new guidelines in their teaching materials.

1481. NHSBT Patient Blood Management teams runs the Blood Assist app with educational content on blood use for adult patients and Blood Components app with indication codes for blood usage in adults and children together with best laboratory practice

1482. The PBM team also runs the https://hospital.blood.co.uk/ website which has a lot of information and educational information to support the hospital transfusion community

1483. All colleagues are required to undertake a PDPR with their line manager on an annual basis and compliance against this process is monitored monthly by senior management teams. This includes personal development objectives and education. There is a formal process where individuals can apply for funding to attend relevant conferences and educational events. For example, there are a number of funded places at the British Blood Transfusion Conference each year. There is also free attendance at the annual SHOT Symposium.

1484. A part of their professional development, colleagues are also encouraged to be members or chairs of leading international and national bodies (ISBT, BBTS, ABO) either as an expert or as part of their role and to bring back information for discussion within the institution. Similarly, people are encouraged to be examiners for the Fellow of the Royal College of Pathology exams which involves setting and marking questions and oral exams.

1485. NHSBT consultants deliver training and education on behalf of a number of organisations and bodies that we collaborate with, including the Royal Colleges of Pathologists and Physicians, academic institutions, the British Blood Transfusion Society and other bodies.

1486. Haemovigilance is detailed elsewhere in my rule 9 response, in section 9 above. However, an important part of undertaking those steps is that information is fed back to staff to improve care for donors and patients. SHOT holds an educational meeting each year to coincide with the publication of the Annual SHOT report. NHSBT colleagues are able to attend this in agreement with their line manager. SHOT also produces educational resources (SHOT bites – which includes easy to read documents and videos) which are available online, along with the annual reports. There is also a SHOT app with educational content. SHOT also provides regular updates more generally on donor and patient transfusion safety incidents. Haemovigilance is a standing issue on the Blood Supply CARE

committee **('BSCARE')** agenda and education and alerts are sent to all staff.

1487. The joint NHSBT/PHE epidemiology team publish an annual report on the PHE website highlighting the risks of infections in donors. They also share information using infographics highlighting potential new threats and challenges to the blood supply relating to new viruses and infections should this be published. This information will be provided in both internal and external communications.

1488. NHSBT runs transfusion education talks (TxED talks) which are held online as webinars to communicate new findings to a wide audience (using accessible language). Webinars are also used as a method, alongside news updates, to cascade relevant information through the institution.

1489. As has been noted elsewhere, JPAC provides professional and technical advice to the four blood services of the UK. As part of issuing change and safety notifications **("CNs")** and other relevant documentation, it provides scientific, medical, and technical information for staff training. JPAC is significantly interlinked with NHSBT, and various staff members sit on and/or chair several of its standing advisory committees. There is a formal process for horizon scanning for emerging infections. Similarly, the role of all committees is to scan for emerging clinical evidence in the form of peer reviewed papers that will inform the regular changes and updates in guidance and advice to UK Blood Services.

1490. JPAC issues these as CNs which are similarly circulated to all relevant staff. CNs are reviewed by each team and training records created. Such information is also shared with rationale and supporting evidence so that staff understand the reason for a notification and change and are able to engage with the underlying information and technical issues.

R&D and Horizon Scanning

1491. NHSBT maintains the Transfusion Evidence Library and the Stem Cell Evidence Library. Both provide access to evidence-based publications which are articles pre-selected for clinical relevance and methodological quality. They are fully searchable and updated monthly. They also have filtering to help focus searches. These libraries are curated and produced in partnership with Evidentia Publishing and are fully funded by the four UK blood services. See: www.transfusionevidencelibrary.com and www.stemcellevidence.com. See the information slides which I provide [WITN0672097].

1492. The Transfusion Evidence Library covers systematic reviews since 1980 and randomised controlled trials from 1950. The information provided includes: blood and donation practice; fractionated blood products; management of anaemia; red cells, platelets, FFP, granulocytes, cryoprecipitate; transfusion adverse events; transfusion alternatives; us of blood components; and Covid-19. The website also provides population, intervention, control, and outcomes **('PICO')** summaries of important documents.

1493. In addition to the libraries themselves, monthly evidence alerts are provided to staff with 10 selected publications provided. As examples I have provided the transfusion evidence alert for July 2021 [WITN0672098] and the stem cell evidence alert for July 2021 [WITN0672099].

1494. Staff are, through these websites, provided with free access to relevant journals covering transfusion and transplantation. The NHSBT library can also provide specific access to journal articles which are not otherwise freely accessible to our staff. The NHSBT Library and Knowledge service sends out subject alerts and content alerts from key journals every month. The Research and Development team sends out a list of new publications where there is one from an author

in NHSBT. NHSBT doctors and scientists are authors of around 200 publications per annum. In an ABO R&D benchmarking review in 2017-2018, NHSBT were amongst the best rated blood services in terms of numbers of publications, impact and PhD theses completed.

1495. The Alliance of Blood Operators has produced a formal Horizon Scanning Document that the Medical Directors and team have provided input to. This is widely disseminated and considered by relevant groups in NHSBT [RLIT0001559]

1496. Until one was missed recently because of the pandemic, NHSBT has continued to have a triennial scientific conference described below.

1497. NHSBT has an active clinical and applied research programme; as part of the R&D function until 2020 there were Research Strategy Groups which had a horizon scanning function for emerging academic evidence. This is now led by the medical directors together with colleagues in the new strategy function going forward.

Information Sharing

1498. Various other information is shared from NHSBT's active clinical and applied research programmes, and from haemovigilance programmes and bodies such as JPAC (see below). Each specific area of NHSBT will also have meetings to allow for the dissemination of such knowledge. At these meetings there will often be case-based discussions with evidence review.

Historic

1499. While the documents do provide evidence of the training and keeping up to date that staff did at the blood service, the documents available do not appear to be a complete record. It may be this is because of the autonomous nature of the RTCs, with each adopting their own approach to such training and professional development. As individuals who worked at various RTCs are being called to give

evidence, it is likely they will have the best evidence on steps taken to do this, and who held responsibility for this work. It is difficult for me to provide much information in this regard.

1500. Medical and other staff working in the blood service historically, as is the case now, would have been regulated by their own professional regulators. As the regulators thought appropriate, they would have set training and professional development requirements for the people that they regulated.

1501. I cannot provide granular detail of the historic position. What I can point to in the documents I have been shown are a few occasions of steps taken at a high level by the blood service to keep staff trained or abreast of medical and scientific knowledge.

1502. **Training for clinical staff:** I have been shown a 1977 letter from Dr Gunson, Oxford RTC, to the Secretary, Royal Commission on National Health Service, with memorandum entitled "*The National Blood Transfusion Service: Its Present Status and Proposals for Reorganisation*" [CBLA0000612] which shows that the question of training was essential to the organisation and functioning of the blood services. In reference to staffing the note emphasises that "*it is important that consideration is given to the training of specialists in blood transfusion to maintain the medical staffing of RTCs, since it is essential that NBTS remains clinically orientated.*"

1503. I have been shown a set of minutes from a meeting of the RTDs on 19 February 1975 [NHBT0016487]. At that meeting it would appear that there was a discussion of the expanded role of nursing staff at RTCs, and the introduction of head and deputy head nurses. It was noted in that meeting that "*the Head Nurse and her deputy were responsible for training the donor attendants and maintaining a high standard of proficiency in this staff. This duty was in itself a considerable one*".

1504. I have also been shown the minutes from a meeting of the RTDs on 8 December 1976. At that meeting there was a discussion of arranging training for, and keeping RTCs functioning in the absence of, medical laboratory technicians. Also in that meeting Dr Tovey explained discussions with the Royal College of Pathologists concerning the MRCPath exam and approach to transfusion testing as part of that exam [DHSC0105496_010]. I have been shown minutes where there were further such discussions of the training to be afforded clinicians, particularly in respect of time spent in RTCs: see for example the RTD minutes of 6 July 1977 [DHSC0200019_002].

1505. Discussion of the MRCPath and the requirements of that examination for transfusion specialists was an ongoing discussion in the 1970s:

a. In the RTD Meeting on 3 March 1977 [NHBT0016473] various views were expressed on the practical context of the final MRCPath exam for senior registrars in the BTS. Particularly in respect of interpreting test results or conducting practical laboratory tests.

b. There was further discussion in the meeting on 4 May 1977 [DHSC0002367_012] and the view was expressed by several RTDs that any senior registrar seeking a consultant role should be required to have spent some time in an RTC. Dr Tovey confirmed that Royal College of Pathologists examiners would expect candidates to have some such experience.

c. I have been shown the minutes of an RTD meeting on 20 September 1982 [CBLA0001623]. At that meeting there was a discussion of the MRCPath. The RTDs were concerned to retain the MRCPath in place of the alternative MRCP and retain the special final examination in blood transfusion. RTDs agreed that an MRCPath examination for science graduates was inappropriate.

d. There was a further discussion about the MRCPath at the meeting of the RTDs on 18 May 1983 [CBLA0001707]. It was noted that nothing more had arisen and Primary MRCPath would continue. There had not been a review of the slanted exam or mention of a specific training program for the BTS. A meeting with the examiners to discuss alterations was still awaited.

e. Other discussions of training took place at the 194th meeting of Regional Transfusion Directors in January 1985 [CBLA0001995]. The key question was the extent to which specialist training was needed for blood transfusion medicine, topics of discussion included the possibility for specialist diplomas, the need for jobs within the field, difficulties recruiting "Senior Registrars to Blood Transfusion posts" and the problem that "*transfusion is not a popular speciality for recruitment*".

1506. **Transfusion handbooks:** it would appear that there was available to clinicians in the blood service various texts relevant to the appropriate approach to blood transfusion:

a. I have been shown the minutes of an RTD meeting from 22 March 1972 [NHBT0016125] where there is a discussion about revision and publication of the next edition of *Notes on Transfusion*. The urgency of publishing the revised text was discussed at the next meeting on 7 June 1972, the minutes for which I have also been provided [NHBT0016123].

b. I have been shown the minutes of an RTD meeting on 28 November 1973 [NHBT0016498]. It would appear from those minutes that there was a book entitled *Using the Laboratory* that also gave guidance on blood transfusion and use of laboratories.

c. I have seen the minutes of the RTD meeting on 20 September 1982 [CBLA0001623]. Those notes include a discussion of an

upcoming revision of *Care and Selection of Donors* and *Notes on Transfusion*. It was thought that *Notes on Transfusion* should be the definitive document of the Transfusion service and not be sent to other groups because of delays. It was also said that, this being so, the booklet would be published by the RTD Committee and not associated with the DHSS. The contents were to be aimed at junior medical and nursing staff.

d. I have been provided minutes of a meeting of the RTDs on 10 October 1984 where issues with corrections to *Notes on Transfusion* were discussed [CBLA0001905]. The need for a revised edition was noted and it was commented that the errors in the current version reflected very badly on the service.

e. At the meeting of the RTDs on 18 January 1989, the minutes for which I have been provided, it was proposed that the handbook would be reviewed and revised every 2 years [NHBT0018188]. It would appear that the matter was to be pushed along with Dr McClelland.

1507. As has been discussed elsewhere, the development of these handbooks culminated in the publication of the Red Book and the existence of JPAC. JPAC and its work is discussed elsewhere.

1508. **Journals:** Many of the doctors in the blood services are clinical academics, qualified doctors who also maintain research and teaching responsibilities. Many of those combining clinical practice and academic work, alongside others focused on clinical practice, will have kept abreast of medical developments through accessing relevant medical journals.

1509. More generally, it would appear from the documents that the RTCs took journals, and distributed articles of interest around themselves. I have been provided the minutes of the RTD meeting on 17 April 1985

[PRSE0002906]. At that meeting under the heading "*journals taken by the blood transfusion centres*" it was noted "*it had been suggested that a central list be circulated. The Northern Division considered the availability of photocopies of articles of interest would be useful*". The minutes also note that "*a list of rarer journals taken should be sent to Dr Fraser by all interested parties. Dr Cash agreed to circulate copies of Dr Pepper's current contents scan*".

1510. **Scientific Meetings:** The documentary evidence shows that there was a triennial scientific conference run in the blood service. I have been shown the minutes of [NHBT0017095] where discussion of a new annual scientific meeting was put off as a result of the triennial conference at Tooting to be held on 17, 18, and 19 September 1976 [NHBT0017095].

1511. In the RTD meeting minutes on 6 October 1976 it was explained that the Tooting meeting had been a success with attendance of 200 staff with 175 from other RTCs. In those minutes it was proposed that Dr Wagstaff would undertake to organise a symposium on quality control and standards in NBTs in early 1977 [NHBT0016475].

1512. I have been shown the minutes for the RTD meeting on 19 May 1981 [NHBT0018340]. At that meeting there was agreement that there would be once yearly NBTS scientific meetings in conjunction with RTD meetings held at transfusion centres. The first was proposed to be held in 1982. In addition, it was proposed that a British Society of Blood Transfusion might be set up, as it was thought many people involved with blood transfusion in hospital service might be eager to join.

1513. I have also been shown the minutes of the RTD meeting on 7 October 1981 [NHBT0018339]. At that meeting Dr Gunson reported on discussions concerning the introduction of scientific meetings. The

proposals, which were to go on for further discussion by a steering group, were that:

1. Regular scientific meetings should be held on blood transfusion.
2. That steps be taken to form a British Society of Blood Transfusion.
3. And the RTD Committee should institute a steering group to further this aim. The steering group should be representative of consultants, medical and senior scientific and MLSO[80] staff working in blood transfusion with the power to co-opt a suitable professional advisor.
4. Constitution should be given by the steering group to form a British Journal of Blood Transfusion which would be the official organ of the future society.
5. It was proposed that the inaugural general scientific meeting of this society should take place in the autumn of 1982.

1514. I have also been shown the minutes of the meeting of the RTDs on 20 September 1982 [CBLA0001623]. At that meeting Dr Gunson "*pointed out that MRC had disbanded its Blood Transfusion Research Committee. This advisory function could possibly be undertaken by the newly formed Society of Blood Transfusion. It might be valuable if this Society could establish a link to the Chief Scientist's office to facilitate provision for financial support of projects deemed worthwhile*". It was proposed that further investigations for replacing the committee would be done.

1515. I have been provided the minutes of the 210th RTD meeting held on 18 January 1989 [NHBT0018188]. I understand that this shortly followed the establishment of the National Directorate. There was a discussion following which "*it became clear that any managerial role for the RTD Meeting was regarded as superfluous. It was agreed that there was value in meeting once a year for a one-day scientific symposium and it was agreed that this should be quite a separate thing from the BBTS Meetings and indeed should take place in the Spring*". This discussion

[80] Medical laboratory scientific officer

concluded with the meeting unanimously agreeing that the current RTD meetings be replaced by "*an Annual Meeting open to all NBTS Consultants with a Scientific Agenda*".

1516. **Other conferences and institutions:** I have noted in my answer to Question 18 some of the various other institutions that clinicians would be members of. It would also appear from the documents that I have been shown that symposiums and scientific meetings were a relatively common occurrence. To take a few examples from the documents I have been shown in the course of producing this answer from the 1970s:

a. In the RTD meeting on 3 July 1974 [NHBT0016495] there is reference to a symposium on frozen blood to be run at the London Hospital Medical School on 3 October 1974. From the minutes on 9 October 1974 it was recorded that this was a well-attended meeting [NHBT0016494].
b. In the RTD minutes from 21 June 1976 there is a reference to the 13th European Course in Blood Transfusion being held in Bristol on 18-29 April 1977. Nominations for 3 UK participants were asked for [NHBT0017095].
c. In the RTD meeting on 8 December 1976 there was agreement for an NBTS/PHLS symposium on CMV and blood transfusion in spring 1977 [DHSC0105496_010].

1517. Throughout my answer to this rule 9 request there are various other examples of where such training, symposiums and conferences by others have been run.

47. What external advice, if any, does NHSBT seek to identify and assess the risks of infection associated with the use of blood and/or blood products?

Recent

1518. Far more detail relevant to this question is provided in my answer to the section 9 questions addressed above. I do not propose to reiterate that evidence here but will briefly summarise a few core bodies that provide relevant external advice.

1519. The principal external advice sought by NHSBT to identify and assess the risks of infection associated with the use of blood and / or blood products comes from SaBTO and JPAC, including their standing advisory committees, of which SACTTI is the most significant for the Inquiry's purposes.

1520. The nature and membership of SaBTO is described in Section 9 of this response. In summary, SaBTO in its terms of reference is described as advising the Health Ministers in England, Wales, Scotland and Northern Ireland; the UK Health Departments; the UK Blood services and Transplant service, and the NHS more widely on the most appropriate ways to ensure the safety of blood, cells, tissues and organs for transfusion / transplantation. Its remit includes providing advice on the microbiological safety of gametes and stem cells, in liaison with the relevant regulatory authorities. The Committee will provide independent advice on risk management for Ministers, UK Health Departments, UK Blood and Transplant Services and the wider NHS to consider [RLIT0001563].[81] This includes giving advice and making recommendations both on matters of a "routine" nature and on any specific matters referred to the Committee by the Department of Health or by the health departments of Wales, Scotland or Northern Ireland. The meeting papers and minutes of SaBTO are available publicly online

1521. The nature and membership of JPAC and its standing advisory committees, including SACTTI, is described in Section 9 of this response. In summary, however, SACTTI has within its remit advising on the epidemiological basis for targeting or avoid particular groups as

[81] SaBTO Terms of Reference: [RLIT0001563]

potential donors – in respect of both recognised and emerging transfusion transmissible agents. SACTTI prepares these recommendations using data collated by the NHSBT / PHE Epidemiology Unit. These recommendations are then published in position statements by JPAC.

1522. Other particularly relevant bodies that I discuss in my section 9 answer include the MHRA and the CHM. Of course, to a large extent these bodies go beyond advice and deal with the actual approvals and requirements for production of medicines and treatments in the UK. NHSBT also has a strong relationship with PHE which is also explored in my answer to section 9, and extends to the joint NHSBT/PHE epidemiology unit.

1523. As part of NHS R&D provision, the National Institute of Health Research (NIHR) funds Blood and Transplant Research Units. The upcoming round in 2022 includes a call for five units one of which is in Transfusion and Transplantation Transmission of Infections, these will be co-funded by NHSBT. The successful unit in TTTI will be an academic unit lead by experts in the field who will work closely with NHSBT in this field and the academics will be working closely with NHSBT to provide knowledge and information on the risks of infection from our components and products.

1524. NHSBT has bilateral agreements with both the ABO and EBA to share information and ask questions of both the organisation and of individuals within it. The mechanism for asking for advise where required both exists, and is used, on a frequent basis.

1525. Consultants in NHSBT hold roles in many external organisations where they will work with international peers and will be able to informally ask for advice from these committees or their members. The network of relationships between NHSBT Consultants, scientists and their international peers is deep. For example, I am a member of the

Canadian Blood Service Scientific and Research Advisory Committee and the ABO Chief Medical Officers group. Other examples are provided in my answer to section 3.

48. What internal advisory and/or decision-making structures are in place at NHSBT to identify and assess the risks of infection associated with the use of blood and/or blood products?

Recent

1526. I have already discussed the Good Manufacturing Practice principles and framework at NHSBT for QA in section 9 and do not propose to repeat them here.

1527. NHSBT employs a risk-based decision-making framework for blood safety. This approach, developed by the Alliance of Blood Operators (ABO), is embedded into the risk management framework and comprises two elements: Policy Foundations and Decision Making Framework [WITN0672100]. This was adopted by the board in 2015 [WITN0672101]. This was a move from the previous system 'ALARA' or as low as reasonably achievable to one where there is a concept of risk tolerability within the health service it is being used within. SaBTO has a current working group who are considering risk tolerability in more detail with many stakeholders and patients on the group.

1528. The primary mechanism for the maintenance of blood safety are set out in the answer to Question 42, part of section 9. This comprises a quality management system and safety system responsibility for which is shared between NHSBT, DHSC, PHE and MHRA.

1529. Additional decision-making structures, as set out in the answer to section 47, are contained within JPAC which publishes the 'Red Book' the guidelines for all materials produced by the United Kingdom Blood Transfusion Services for both therapeutic and diagnostic use. These guidelines provide an expert view of current best practice and provide

product specifications. As set out in the JPAC constitution[82], while the blood services are the primary financial contributor to JPAC, they are separate organisations with lines of accountability from JPAC running to DH [RLIT0001558][83].

1530. The NHSBT Therapeutic Product Safety Group is an important group for internal advisory and decision-making issues related to blood safety. I have provided the terms of reference of the group as an exhibit [WITN0672102]. The aims of the group are:

To ensure that NHSBT is coherently engaged in the developing safety agenda within and beyond NHSBT; including 1) shaping the safety agendas of external bodies (e.g. SaBTO, JPAC); 2) responding to emerging threats to safety; 3) providing advice to CARE and external stakeholders on safety matters 4) communicating safety matters to stakeholders and the public 5) proactively seeking and considering safety measures relevant to NHSBT.

1531. The group meets in advance of the CARE committee. The key external relationships of the committee are with SaBTO, JPAC and the UK Forum of Blood Establishments, the Department of Health analytics team, and donors and patients. Internally it has a key working relationship with the CARE Committee and the senior management teams.

1532. NHSBT board minutes demonstrate the implementation of SaBTO recommendations by NHSBT [WITN0672103, 15_86, e-mail 10 August 2021] on HEV universal screening recommendations.

1533. A central feature of internal advice at NHSBT is the CARE committee. I provide the most recent terms of reference for the CARE committee [WITN0672104]. This committee is the Clinical Audit, Risk and

[82] [RLIT0001558]
[83] Ibid – see page 6

Effectiveness Committee. Its purpose is to provide the Executive Team, ARGC, and the Board, with information on all elements of clinical effectiveness, and thus provide assurance of maximum patient benefit and safety, as well as management of clinical risk. The terms of reference were most recently modified in November 2020, and the changes included adding a Digital Data and Technology Services and Information Governance representative to the committee.

1534. An important non-executive sub-group of the national CARE committee is BSCARE. I provided the most recent terms of reference for this body for May 2021 [WITN0672105]. The role of BSCARE is to provide the national CARE committee with information on all elements of clinical effectiveness within Blood Supply and thus provide assurance of maximum donor and patient safety, as well as management of clinical risks. Its role and responsibilities are extensive:

- *To assure itself that the Blood Supply's operational services are achieving clinical effectiveness, through monitoring clinical governance issues.*
- *To ensure there is a robust process for serious incidents and near miss reporting and that effective review leads to directorate and organisational learning. The Committee should have an overall understanding of the incident, gain assurance of the actions being taken to address this, and challenge where there are concerns regarding actions or next steps. The Committee should provide assurance to the CARE Committee that clinical complaints and Serious Incidents are managed in accordance with national guidance whilst ensuring that, where possible, trends are identified and appropriate action is taken, including shared learning to enable clinical and service improvement.*
- *To gain assurance that clinical risks are managed as set out in NHSBT's Risk Management Manual. To have oversight of the BS risks with a clinical risk impact, and to review and challenge the*

actions and controls for those risks. To raise any areas of concern to the CARE Committee.

- *To develop overarching BS clinical governance policies and procedures and monitor review of clinical governance policies in line with their set review date.*
- *To provide scrutiny to the management of the BS clinical claims process.*
- *To ensure that systems are in place for reviewing NICE and other national guidance and for ensuring compliance with relevant recommendations.*
- *To ensure that practice is evidence-based and supported by a robust process of clinical audit.*
- *To prioritise the BS clinical audit work plan, to review clinical audit findings (notably the recommendations and their implementation) and to approve the final report for publication.*
- *To ensure that clinical care is provided by appropriately trained and skilled professionals with the competencies required for service delivery.*
- *To provide the CARE Committee with regular clinical effectiveness updates and exception reports.*
- *To monitor alerts received via the Central Alerting System and review any actions taken in response to any relevant alerts.*
- *To monitor compliance with all relevant Care Quality Commission (CQC) and Medicines and Healthcare products Regulatory Agency (MHRA) outcomes and the organisation's overall preparedness for inspection.*
- *To oversee and advise on any issues related to the Caldicott principles.*
- *To approve research proposals that relate to BS.*
- *To disseminate learning from research findings reported to the group.*
- *To gain assurance that children and adult safeguarding processes are in place and are effective.*

1535. NHSBT's Microbiology Strategy Group provides expert advice and support to directors via the Blood Supply Senior Management Team. It aims to be the forum in which representatives of research, development, operations and clinicians can discuss microbiology testing and provision for NHSBT as a whole. It considers changes to clinical care, scientific developments, the political landscape, and actions of competitors that impact on NHSBT's products or service provision. It is responsible for the development of a strategy for the delivery and maintenance of a standardised NHSBT microbiology screening portfolio. The group provides a forum for key stakeholders to input into priority setting for systems development and provide clinical and operational assessments in support of key initiatives, including provision of data to SaBTO where appropriate. The group is an integral part of management quality review.

1536. Where issues have arisen, I have seen examples of NHSBT reviewing particular practices and procedures to improve safety. For example, following concerns raised about hepatitis B transmission following a donor whose screening tests were negative, a review was conducted into nucleic acid testing for hepatitis B [WITN0672106].

1537. I have described the functions and nature of the NHSBT / PHE Epidemiology Unit in Section 9 of this response. In summary, the Unit monitors and reports numbers and rates of infections in donors which assists in identifying and assessing the risk of infection associated with the use of blood and / or blood products. As described above, these data are then sent to SACTTI to prepare recommendations in respect of the same, which are published in position statements by JPAC. The NSBT / PHE Epidemiology Unit moreover acts as the SHOT National Coordinator for Infectious Diseases.

49. Please describe the enquiries and/or investigations, if any, that NHSBT carries out or causes to be carried out in respect of the risks of the transmission of blood borne infections.

vCJD

1538. I have previously described NHSBT's involvement in any other inquiries, investigations or criminal/civil litigation in relation to vCJD in blood and/or blood products in my answer to Question 7 and section 9 of my answer.

1539. I have further described the various enquiries and/or investigations that NHSBT carries out or causes to be carried out in respect of potential vCJD infection in my answers to Questions 44 a – c above, namely through collaboration with NCJDRSU through the TMER and by participating in public health follow up activities alongside PHE and other bodies, as I have described above.

1540. In terms of how a potential transmission event is investigated I lay out the general principles below that will apply to all infections including vCJD.

Recent

1541. NHSBT has implemented several 'Management Process Descriptions' **('MPDs')**, being documents which provide practical guidance on how NHSBT policies or functions are to be carried out. A number of these MPDs relate to the enquiries and / or investigations that NHSBT carried out in respect of the risks of the transmission of blood borne infections.

1542. I provide the below MPDs as exhibits to this answer. I have included old versions of these documents for information for the Inquiry. Please note that, as a result of the requirements of governance and document management, the old versions of these policies must be destroyed once they have served their purpose for the inquiry.

1543. MPD577 is the Management Process Description for the '*Management of Donors with confirmed Positive Microbiological Markers*', which

states as follows: '*it is the policy of NHSBT to inform donors with a confirmed positive microbiological marker of their test results and implications to their health*'. Where a donor has a confirmed positive microbiological marker of their test results, clinicians undertaking the post-test discussions will inform that donor of the risks of transmissions to other and risks associated with any future donations. It is standard practice for an epidemiology Infected Donor Surveillance Form to be completed for every confirmed positive donor. I have provided this template form as an [WITN0672107, WITN0672108, WITN0672109, WITN0672110, WITN0672111, WITN0672112, WITN0672113, WITN0672114, WITN0672115].

1544. MPD591 is the Management Process Description for the process '*to Identify the Recipients of Possibly Infected Blood*', which states as follows: '*it is the policy of the NHSBT to trace the fate of possibly infected blood components in order to offer advice / testing to recipients*' [WITN0672116, WITN0672117, WITN0672118, WITN0672119, WITN0672120, WITN0672121, WITN0672122, WITN0672123, WITN0672124, WITN0672125, WITN0672126].

1545. MPD596 is the Management Process Description for '*the Investigation of Suspected (Non-bacterial) Transfusion Transmitted Infection*', which states as follows: '*it is the policy of the NHSBT to investigate possible cases of transfusion transmitted infection*' [WITN0672127, WITN0672128, WITN0672129, WITN0672130, WITN0672131, WITN0672132].

1546. MPD578 is the Management Process Description for '*the Investigation of Suspected Bacterial Contamination of Blood Components*', which states as follows: '*it is the policy of the NHSBT to document and investigate any suspected bacterial contamination of blood components*' [WITN0672133, WITN0672134, WITN0672135, WITN0672136].

Historic

1547. Details of the various lookback patient notification exercises and awareness campaigns conducted by NHSBT are dealt with in extensive detail in three answers provided in response to the amended rule 9 request dated 14 August 2020.

Section 11: Public awareness

50. Once the risk of transmission of blood borne infections relevant to the Inquiry's terms of reference was known within NHSBT:

a. What, if any, actions did NHSBT take to reduce the risk to patients of being infected?

b. What, if any, actions did NHSBT take to:

i. identify patients who may have been infected through treatment with infected blood or blood products?

ii. make patients who had been treated with blood or blood products aware of the risk of infection?

1548. As I have previously explained, I have very limited first-hand knowledge of the periods of time primarily in issue before the Inquiry.

1549. Insofar as I have been able to provide first-hand evidence, or evidence by going through documents provided to me, the answer to this issue has been provided in sections 8-10 above. In addition, I refer to the three statements provided in response to the amended rule 9 dated 14 August 2020, which have information relevant to this question. This statement is already extremely lengthy and I do not think it would assist to repeat that information here.

c. What, if any, arrangements were made to provide patients infected through blood products with medical treatment for their condition?

d. What, if any, arrangements were made to provide patients infected through blood products with counselling, psychological support, social work support and/or other support?

1550. Historically and currently, the blood service's primary relationship is with the donor. The donor is the cornerstone of the entire service. As such, the vast majority of interaction that the blood service would have with members of the public is as donors and not as patients.

1551. As I understand it from the documents I have been provided in the course of providing this evidence, the blood service has had limited contact with patients who received blood products. It was and is treating clinicians that were primarily responsible for caring for, and arranging treatment for, patients. That would extend to making arrangements for patients to access counselling, psychological support, social and other support. I understand that Dr Hewitt addresses this issue in some detail in her response to the amended rule 9 dated 14 August 2020.

1552. I am unaware of circumstances in which the blood service historically would have arranged or provided such treatment or support to blood or blood product receiving patients. It may be that clinicians working in the 1980s onwards for the blood service have first-hand knowledge of this information. I have not found anything significant in the documents I have reviewed in the course of providing this evidence.

51. Do you consider that the decisions and actions of NHSBT in response to any known or suspected risks of infection were adequate, appropriate, and proportionate to the risk and severity of infection? If

so, why? If not, please explain what you believe could or should have been done differently.

1553. As I have stressed throughout this document, I have been working from the documents provided to me for most of the blood service's history. I have no independent knowledge of what happened in the past and have not been able to obtain and read every document on these subjects. As such, I cannot have a complete picture. In those circumstances it seems to me that I am not appropriately placed to provide such commentary on the events of the past, which are indeed the subject of the Inquiry. Where I can make comment or observation I have done throughout this document. What I can say, however, is that from reading the papers I think, on occasions, the blood service acted more slowly than it should have done, and than it would do today. On this I am, in particular, also thinking about the introduction of the HCV lookback, which is not part of this statement. For these I, NHSBT and the Board apologise.

52. Did NHSBT encounter any difficulties in obtaining sufficient funding for the identification, notification and / or treatment of people who were infected with blood borne infections relevant to the Inquiry's terms of reference?

1554. I have addressed funding as appropriate throughout this response. It has also been dealt with in the responses to the amended rule 9 request of 14 August 2020. As can be seen from this, there are occasions when it would appear that the blood service had difficulty obtaining funds to undertake certain steps. To take one example, there were the issues with the funding of HCV testing (see Dr Robinson's response to the rule 9 request of 14 August 2020). However, I do not propose to repeat the evidence and commentary that I and others have provided elsewhere in our answers.

Section 12: Financial support

1555. It is important to stress that I have no first-hand knowledge of any relationship between NHSBT and the trusts and funds, and I am therefore working from documents provided to me to identify those points of interaction between NHSBT and the trusts and funds that may be of interest to the inquiry. Therefore, the answers below reflect my and NHSBT's best efforts to describe the nature of those relationships that did exist, based on the documents that I have been shown.

1556. My answers to the questions in this section are based on a review of some historical documents which have been shown to me, relating to the relationship between NHSBT and the trusts and funds. I have principally relied on the correspondence between Dr Hewitt and others concerning the trusts and funds [NHBT0015104], [NHBT0015105]. In addition to those primary documents, I have also drawn from the following sources:

a. Documents that demonstrate Dr Hewitt's involvement with the trusts and funds: e.g. [WITN1125009], [WITN3101005], [NHBT0015096_002], [NHBT0015097], [NHBT0015098], [NHBT0059589];
b. Correspondence indicating some role for NHSBT in assisting by providing information to assessment panels or identifying individuals through lookback: e.g. [NHBT0015108] and [NHBT0015106], possibly also [NHBT0015101]; and,
c. Examples where NBTS through lookback flagged the possibility of claiming under the HIV scheme to clinicians: [NHBT0059589] and [NHBT0092313].

1557. In general, very limited documentation has been available to me that indicates that NHSBT and its predecessors were involved in establishing these trusts and funds. The only document I have seen,

which addresses the matter very briefly, is an undated press release for the Skipton Fund [BART0000511_003]. The relevant passage from that document is:

What consultation has been undertaken?
To ensure the scheme is a success and user-friendly, officials from the four UK health departments have consulted with patient and expert groups representing the entire UK over the last few months. In England, voluntary organisations such as the Haemophilia Society, Hepatitis C Trust and Manor House Group have joined in our discussions. Expertise has been sought from the National Blood Service, Macfarlane Trust and leading hepatologists and haematologists. Comments have also been invited from many other patient groups and individuals.

I have no information about what expertise had in fact being sought, and it may only extend to some of our staff having personal roles on such trusts.

53. What if any involvement did NHSBT have with the different trusts or funds (the Macfarlane Trust, the Eileen Trust, the Macfarlane and Eileen Trust, the Caxton Foundation, the Skipton Fund, EIBSS) that were set up to provide financial support to people who had been infected through infected blood products?

1558. On the basis of the evidence that I have seen, the relationship between NHSBT (and its predecessors) and the trusts and funds listed in this section was limited.

1559. To the extent that there were links between NHSBT or its predecessors and the listed trusts and funds, these were primarily through those hospital consultants who had responsibility for individuals who were eligible for payments; and the Department of Health which has overall responsibility for the care of patients in

England. For example, I have been shown historical documents that demonstrate that the Department of Health requested support from the RTCs to help identify possibly infected blood and required that donation numbers enabling identification of previous donations be sent to the consultant haematologist at the hospital concerned.

1560. NHSBT's core function is to provide critical products and services direct to NHS hospitals, and while NHSBT and its predecessors work collaboratively with NHS hospitals and the Department of Health, neither NHSBT nor its predecessors had much of a direct relationship with the trust and funds, nor did they have direct responsibility for notifying the CMO / DH about individuals who were eligible for payments. As far as I am aware all policy and guidance in respect of the trusts and funds was set by DH.

1561. There were a number of ways in which NHSBT and its predecessors were involved, informally, with the different trusts and funds. However, there were no fixed, institutional arrangements in place between NHSBT and the trusts and funds, and no direct relationship with eligible patients.

1562. I have been shown a letter from Dr Gunson to Dr Hewitt dated 29 May 1992 [NHBT0015104], alongside a number of other sources which I note below, from which I think NHSBT's areas of involvement can be broadly summarised as falling into four primary categories.

1563. First, in scenarios in which one of the RTCs identified the name of an infected recipient, for example through a lookback exercise. Depending on the situation, the RTC would inform the treating clinician or the Department of Health. In respect of the latter case, the Department of Health requested that any such notifications should be submitted in the form contained within the CMO letter which I have been shown [NHBT0015104]. The expectation that RTCs communicated this information to the Department of Health was

extended to patients who had died subsequent to transfusion, to ensure that no potential beneficiaries, including spouses and children, risked being overlooked [NHBT0015108].

1564. Second, the letter suggests that where one of the RTCs had previously notified the consultant haematologist of the donation numbers of blood or blood components that may or may not have been infected, that the blood services were not subject to any further obligations. However, in those scenarios where further information was required, that the RTCs should treat these cases on an "*individual basis*" and may provide further information.

1565. Third, in those circumstances where the patient had died and where, for payment to be made, the Department of Health required evidence that the patient was either confirmed seropositive prior to death, or that the blood or blood components received were seropositive, the blood services assisted in the provision of information to assessment panels. The blood services' ability to assist in cases such as these was contingent on the availability of stored samples, and these were not always available, for example, for patients transfused prior to 1985. I have been shown examples of such assistance that include NBTS giving advice on whether to contact BPL concerning access to plasma of a particular age for testing [NHBT0015101], and requests for frozen stored samples [NHBT0015106].

1566. Fourth, the letter suggests that if the blood services had further information capable of assisting patients or their relatives in obtaining payment, that this should be sent to the Department of Health [NHBT0015104].

1567. I have had provided to me and reviewed a number of documents that confirm that NHSBT was involved with the Trusts and Schemes in this way. Examples include NHSBT providing information to Skipton fund about the likelihood of hepatitis C infection in recipients of

intravenous immunoglobulin [WITN3101005], correspondence between the Department of Health and the RTCs concerning the provision of donor details and CDSD records to ensure applicants are able to achieve payment under HIV and Blood Transfusion / Tissue Transfer Payment Scheme, and records of RTCs writing to DH, alongside the relevant consultant haematologist and the consultant paediatrician, to identify an individual infected with HIV through blood transfusion in order to flag that they may be eligible [NHBT0059589].

1568. Dr Hewitt in her rule 9 response to the amended request of 14 August 2020 expands on the issue of investigations for the purposes of qualification for support from trusts and funds.

54. To what extent did NHSBT inform patients about the different trusts or funds?

1569. This is addressed by Dr Hewitt in her statement in response to the amended Rule 9 request of 14 August 2020.

1570. NHSBT did not have direct responsibility for patients; patients that received transfusions were under the care of a hospital consultant. As such, the information about different trusts and funds provided directly to patients was generally from their treating clinicians. Insofar as NHSBT and its predecessors did have access to information that could assist patients in their access to trusts and funds, efforts were made to inform the relevant hospital consultant. I have identified a number of examples where, through lookback NBTS flagged the possibility of making a claim under the scheme for clinicians to the relevant paediatrician [NHBT0059589], and consultant haematologist [NHBT0092313].

1571. It is worth nothing that, as the blood services did not hold information about most individual transfused patients, there were significant difficulties tracing donors who have not returned to donate after the

introduction of testing for HIV and HCV. Insofar as lookback was possible to assist in informing patients about different trusts and funds, that has been addressed in the statements provided in response to the amended Rule 9 request of 14 August 2020.

55. Did the NHSBT have any policy or any guidance for staff members in relation to referring patients to the trusts and funds for support?

1572. NHSBT and its predecessors did not have direct care of patients and were not responsible for referring patients to trusts and funds for support. The practicalities were such it was for patients and Haematologists to notify the CMO in respect of those who qualified for payments [NHBT0015106].

1573. On 11 May 1992 Dr Gunson, National Director of NBTS wrote to all RTCs to state that RTDs should identify those donors who have been found to be confirmed to be antibody positive, using information from 'look-back' programmes and to provide the list of the donation numbers, together with dates of delivery to the Consultant Haematologist. This was in order to assist the Department of Health in ensuring that no potential beneficiaries were overlooked [NHBT0015108].

1574. Despite this general requirement to update hospital consultants in respect of information that could be relevant to the provision of funding, NHSBT and its predecessors did not have organisational policies or guidance in relation to involvement with trust and schemes. Policy and guidance was set by the Department of Health and NHSBT and its predecessors followed that guidance. As per the answer to question 53, where the Department of Health directly communicated its policies by correspondence to NHSBT and its predecessors, the blood services followed such instructions.

56. What kind of information, if any, did the NHSBT provide to the trusts and funds about, or on behalf of, patients who were seeking assistance from the trusts and funds?

1575. As set out above, NHSBT did not have direct care of patients or provide any information about, or on behalf of, patients who were seeking assistance. In relation to other information provided, the general position at NBTS, as far as I can ascertain from my review of the documents, is that RTCs were required to notify consultant haematologists of the donation numbers of blood and blood products which may have been infected [NHBT0015104], who would then notify the CMO and provide any additional required support. As identified elsewhere the RTCs did not operate as a single central service. Consequently, individual RTCs may have taken different approaches however, I do not have any evidence that this was the case.

1576. NHSBT and its predecessors on at least one occasion [WITN1125009] provided clarification about the particular risks to identified groups of patients on the basis of whether that group had been treated with clotting factor concentrates, both NHS and commercial. This assistance to Department of Health was in relation in its determination of eligibility for the Skipton Fund.

1577. In respect of any information provision to NHS in general NHSBT was sensitive to the fact that there were confidentiality considerations in relation to many of the possibly infected donors [NHBT0015098]. However, where such confidentiality considerations prevented the identification of infected, but not yet identified individuals, NHSBT made efforts to identify the risks that such recipients may have been excluded from payments as a consequence of a failure to share information between government bodies.

57. Did NHSBT act as a gateway for determining or advising whether a particular patient met the eligibility criteria for the receipt of assistance from any of the trusts and funds? If so, please explain who set the criteria, what they were, how they were applied, and by whom. Was NHSBT or any of its staff involved in determining applications made by patients for assistance from the trusts or funds? If so, please describe that involvement.

1578. Generally no. NHSBT is a provider of specialist products and associated services and did not act as a gateway for determining, nor did it advise on, whether a particular patient met the eligibility criteria. NHSBT and its staff were not involved in determining applications made by patients for assistance from trusts and funds (although such staff could hold roles with the trusts and funds on a personal basis). The onus was on the patient and the haematologist to notify the CMO of those persons who might qualify for payments.

1579. The exception to this (although I do not think that this means that NHSBT and its predecessors can reasonably be described as having acted as a 'gateway'), are those circumstances described above where the blood services did write to clinicians to tell them about patients picked up in a lookback exercise. Here while NHSBT and its predecessors identified relevant patients as potentially eligible, as far as I am aware the blood services did not have any influence over whether DH or the trusts/funds themselves subsequently determined any identified patient as eligible for assistance from the trusts and funds.

1580. In cases where patients had died of their primary illness and evidence of HIV seropositivity or that they would have received seropositive products prior to death was necessary, a special panel would adjudicate. NHSBT and its staff was not involved in these special panels (save and insofar as people were part of them on a personal basis), but on occasions NHSBT and its predecessors may have

been asked to identify and provide stored samples from donation where there were available.

1581. For completeness, my current understanding of the personal involvement of blood service employees in relation to trusts and schemes funds is set out below.

1582. The individuals themselves must be the primary source of information, however. I am aware that Dr Hewitt has made a statement on behalf of the England Infected Blood Support Scheme **('EIBSS')** [WITN3101004] in her capacity as a member of the Appeal Panel relating to the (absence of) infectivity of intramuscular (as opposed to intravenous) anti-D immunoglobulin. This statement also refers to her having been a member of the Skipton Fund Appeal Panel, when it was first set up. The document I have referred to above [WITN3101005] is an exhibit to that statement.

1583. I am also aware that Dr Vanessa Martlew, who was a former Director of the Mersey and North Wales RTC, later on in her career became a Trustee of the Macfarlane Trust. I am aware through those advising me that she has provided a statement to the Inquiry, but I have not seen it and am not aware of its contents.

58. To the extent that you feel able to answer, do you consider that the trusts and funds achieved their purposes? Were there difficulties or shortcomings in the way in which they operated or in their dealings with beneficiaries and applicants for assistance?

1584. I have listened to the evidence of some of those infected and affected, much of which is distressing, including the difficulties they encountered in accessing financial and other assistance and support. It is impossible to hear their evidence without being moved and upset by it. I do not believe that is appropriate either for me, or more generally for NHSBT as an institution to provide an answer to this

question. As I have set out clearly above, NHSBT did not work closely or in any direct way with the trusts and funds. Following a review of the material documents on the relationship with the trusts and funds, there is insufficient evidence available for me to provide an informed or helpful review of whether the funds achieved their purposes or on the quality of their operations.

Section 13: Other issues

59. Please explain, in as much detail as you are able to, any other issues that you believe may be of relevance to the Inquiry. To assist, we have provided a list of issues (attached).

1585. As detailed at the beginning of this statement, I acknowledge that the events relating to the Inquiry have had a huge impact on many people. It is clear that things should have been done differently in the past. As an organisation and as a Board we are sorry that they resulted in the transmission of infections that they did and for our part in events. I hope this statement helps bring some clarity on what happened at the time.

1586. We hope that we can demonstrate that we have learned from the historical events considered by this Inquiry and whilst blood transfusion is not, and never will be, without risk of an adverse event, we hope that events such as these will never happen again.

1587. The reasons we believe this are because, as seen with SARS-CoV2, today scientists and doctors are much more aware of emerging infections and tests and vaccines are rapidly developed and implemented. Blood services collaborate internationally and learn from each other. In the UK we can rapidly develop and implement policy changes. Furthermore, NHSBT is effectively managed and led across England, we are a national organisation with consistent policies and

processes, we have good communications with hospitals and good education programmes. We have guidelines and advice from expert committees and bodies, many of which have donor or patient representatives as members. These, in addition to the assurance mechanisms, such as audits, inspections and external reporting, check that processes are working as we think they are and provide us with external scrutiny. Finally, as a system, we have surveillance in place with both Public Health England and SHOT, to horizon scan for emerging infections and to monitor infections in donors and patients. The governance of the system is therefore strong both within NHSBT and with external oversight.

1588. We will, of course, also welcome the recommendations of this Inquiry and will consider carefully how best to implement any recommendations made that are relevant to us.

1589. Throughout this document I note that the organisational structures and thus the 'system' that people worked in, seemed far from ideal. Much has been written on the potential impact of suboptimal organisational structures which cause ambiguity, confusion, poor decision-making and unclear accountability amongst other things. I have been working in the NHS for over three decades and almost without exception everyone I have met has come to work to do a good job. That doesn't mean that things don't go wrong; poor decisions are made but that is often a failing in the systems and structures within which the individuals have to work, rather than the individuals themselves. When this happens, we must make sure that we have a 'just culture' for those working within these systems.

1590. The other thing that impacts on results is the 'culture' within a system. I know, from my own experience, that three decades ago the medical culture was very different from today in terms of the way we (as a whole) treated people. This is also clear from reading the documents that have been provided to the Inquiry. I believe it has now changed significantly, I see now efforts made to acknowledge different opinions

and perspectives, and the care taken to consult and collaborate with and consent patients. I hope as healthcare professionals, we listen to the testimonies and read the documents of this Inquiry and understand the impact of the actions and the way we worked in the past.

1591. I would like to finish where I began, by paying tribute to those infected and who have been adversely affected, who are trying to understand the events of past.

Statement of Truth

I believe that the facts stated in this witness statement are true.

Signed GRO-C

Gail Miflin

Name

19.10.2021

Dated

Table of exhibits:

Section 1: Question 3-4

Date	**Notes/ Description**	**Exhibit number**
	NHSBT Family Tree	WITN067 2007
5 September 2018	GM First Statement	WITN0672001
2019-2020	NHSBT Annual Report 2019 – 2020	WITN067 2009
March 2019	NHSBT standing orders dated March 2019 ('the	WITN067

	Standing Orders')	2010
March 2014	Framework Agreement between the Department of Health and NHS Blood and Transplant 2014	WITN067 2011
March 2020	Scheme of Delegation ('SoD')	WITN067 2012
5 February 2013	Harris Review	WITN067 2013
July 2004	Code of Conduct and accountability of NHS Boards	WITN067 2014
March 2021	Standing Financial instructions	WITN067 2015

Section 1: Question 5

Date	**Notes/ Description**	**Exhibit number**
	NHSBT Family Tree	WITN06 72007
April-September 2005	NBA Report and Accounts from 1 April 2005 to 30 September 2005	WITN06 72016

Section 1: Question 6

Date	**Notes/ Description**	**Exhibit number**
	Table of individuals who held decision making roles in NHSBT from 1970 to present	WITN06 72017

1995	NBA Annual report - 1995	WITN06 72018
1996	NBA Annual report – 1996	WITN06 72019
1997	NBA Annual report – 1997	WITN06 72020
1998	NBA Annual report – 1998	WITN06 72021
1999	NBA Annual report – 1999	WITN06 72022
2000	NBA Annual report – 2000	WITN06 72023
2001	NBA Annual report – 2001	WITN06 72024
2002	NBA Annual report – 2002	WITN06 72025
	NBA Annual report - 2005	WITN06 72026

Section 1: Question 7

Date	**Notes/ Description**	**Exhibit number**
	N/A	

Section 2: Questions 8-13

Date	**Notes/ Description**	**Exhibit**

		number
5 September 2018	Statement of Gail Miflin with exhibits	WITN067 2001
	GM 3 (Exhibit 3 in GM's original statement)	WITN067 2004
14 November 2019	SPN1042/2	WITN067 2027
25 November 2019	SOP4292	WITN067 2028
	GM/3	WITN067 2029
27 November 2006	Pulse specification PSPEC004	WITN067 2030
14 November 2019	MPD1407	WITN067 2031
8 October 2020	SPN189	WITN067 2032
22 November 2011	MPD287	WITN067 2033
7 January 2019	SOP1381	WITN067 2034
September	Data Security Protection Incident Reporting	WITN067

2018	Guidelines (DSP IR September 2018)	2035
3 March 2015	Minutes of the Clinical Audit, Risk and Effectiveness (CARE) Committee for 3 March 2015	WITN067 2036
12 February 2015	SOP13/2 Review/Destructions of Paper Records Places in Offsite Storage	WITN067 2037
	Data Protection Impact Assessment **('DPIA')** for the STRIDES project	WITN067 2038

Section 3: Questions 14-17

Date	**Notes/ Description**	**Exhibit number**
8 December 2016	All Wales Blood Service Project Report	WITN067 2039
	NHSBT Family tree	WITN067 2007
December 2019	The 2019 UK Forum constitution	WITN067 2041
March 2018	JPAC Constitution March 2018	WITN067 2042
	Presidents or Directors of the British Blood Transfusion Society, The American Association of Blood Banks, The International Society for Blood Transfusion	WITN067 2043
2015	Davison KL, et al.: Getting personal with blood donors - the rationale for, methodology of and an overview of participants in the UK blood donor survey. Transfus Med 2015	WITN067 2137

2015	Davison KL et. al. Getting Personal with UK blood donors – the findings from a large scale anonymous survey to assess understanding of and compliance with donor selection guidelines.	WITN067 2138
March 2021	Davison KL, et al; UK Blood Donor Survey Steering Group. Blood donation by men who have sex with men: using evidence to change policy. Vox Sang. 2021 Mar;116(3)	WITN067 2139

Section 4: Question 18

Date	**Notes/ Description**	**Exhibit number**
	NHSBT Family Tree paper	WITN067 2007
2019-2020	NHSBT annual report and accounts 2019 to 2020	WITN067 2044
30 April 1998	30 April 1998 meeting of the Committee on the Safety of Medicines	WITN067 2045
8 and 9 October 2020	Meeting of Commission on Human Medicines ('CHM')	WITN067 2046
24 November 2020	Letter to Betsy Bassis on funding for NHSBT plasma, 24 November 2020	WITN067 2047
19 February 2021	Letter to Betsy Bassis on funding for NHSBT plasma, 19 February 2021	WITN067 2048
17 March 2021	Letter to Betsy Bassis on repurposing of plasma collection, 17 March 2021	WITN067 2049
24 June	Letter to Betsy Bassis on approval of plasma	WITN067

2021	business case	2050

Section 4: Questions 19-22

Date	Notes/ Description	Exhibit number
	N/A	

Section 5: Questions 23-25

Date	Notes/ Description	Exhibit number
2014	2014 Framework Agreement	WITN06 72051
September 2015	NHSBT Triennial Review	WITN06 72140
March 2021	March 2021 Scheme of Delegation	WITN06 72052

Section 6: Questions 26-28

Date	Notes/ Description	Exhibit number
1987-88	Wessex Regional Transfusion Service Annual Report 1987-1988	WITN06 72053

Section 7: Questions 29-34

Date	Notes/ Description	Exhibit number
	Copy of IBE	WITN06 72054
	MPD 148/13.1	WITN06 72055

26 November 2020	INF965 (Non-clinical Issue ("NCI") Customer Guide)	WITN06 72056
14 September 2020	POL273	WITN06 72057
30 November 2020	MPD565	WITN06 72058
January 2021	NHSBT Procurement Procedures Manual 1.1 Procurement Policy	WITN06 72059

Section 8: Questions 35-40

Date	**Notes/ Description**	**Exhibit number**
2019-2020	NHSBT Annual Report 2019-2020	WITN06 72060
5 July 2021	NHS Business Plan 2021/2022	WITN06 72062
March 2020	NBTC - A Plan for NHS Blood and Transplant and Hospitals to Address Red Cell Shortages	WITN06 72063
November 2020	NBTC – A Plan for NHS Blood and Transplant and Hospitals to address Platelet Shortages	WITN06 72064
	NHSBT Family Tree	WITN06 72007
2014	Annex D to the Framework Agreement between the English Department of Health and	WITN06

	NHSBT	72065
February 2021	NHSBT Board Performance Report February 2021	WITN06 72066
April 2021	NHSBT Board Performance Report April 2021	WITN06 72067

Section 9: Questions 41-45

Date	**Notes/ Description**	**Exhibit number**
2019-2020	Annual report 2019-2020	WITN06 72068
September 2014	SaBTO	WITN06 72069
May 2020	Emerging Infections Report **('EIR')**	WITN06 72141
January 2021	Horizon Scanning – Management Process Description: Preparedness for emerging infectious agents (2021).	WITN06 72070
27 August 2021	Internal Audit Team (Government Internal Audit Agency) review of the adequacy and effectiveness of the current NHSBT and JPAC processes for horizon scanning for emerging infections	WITN06 72071
2015	ABO Medical Directors Group paper 2015	WITN06 72072
8 February	POL132	WITN06

2021		72073
14 October 2016	MPD772	WITN06 72074
31 March 2021	Risk Management Manual – MPD 1336	WITN06 72075
25 November 2019	Quality Risk Management Documents – MPD 1094	WITN06 72076
April 2021	NHSBT Board Performance Report	WITN06 72077
	Safe supplies 2018, blood safety timeline – viral	WITN06 72078
	Safe supplies 2018, blood safety timeline – bacterial	WITN06 72079
	Donor consent for blood donation – INF1571	WITN06 72081
	Donor consent for platelets and plasma donation booklet - INF1572	WITN06 72082
	Welcome booklet – INF234	WITN06 72083
	SACTTI Risk Assessment Form	WITN06 72084
16/03/2011	Consent to exchange information about test results form - FRM1516	WITN06 72085
	SaBTO Report	WITN06 72086

	Fair conclusions appendixes	WITN06 72087
November 2020	Statement on vCJD produced by the Joint UKBTS Professional Advisory Committee	WITN06 72088
2019	CJD annual report 1990-2019	WITN06 72089
October 2019	Risk assessment of the transmission of vCJD by blood components	WITN06 72090
April 2021	CJD biannual update (April 2021)	WITN06 72091
	Information for people who have an increased risk of CJD	WITN06 72092
1 February 2005	Estimates of the frequency of HBV, HCV, and HIV infectious donations entering the blood supply in the United Kingdom, 1996 to 2003	WITN06 72095
	SHOT Report 1997-2009	WITN06 72092

Section 10: questions 46-49

Date	**Notes/ Description**	**Exhibit number**
	Libraries information slides with alerts	WITN06 72097
July 2021	The transfusion evidence alert for July 2021	WITN06 72098
July 2021	The stem cell evidence alert for July 2021	WITN06

		72099
26 November 2015	NHSBT Board – A risk-based decision-making framework for blood safety	WITN06 72100
26 November 2015	Minutes of NHSBT meeting	WITN06 72101
April 2018	NHSBT Therapeutic Product Safety Group (TPSG) –Terms of Reference.	WITN06 72102
26 November 2015	Implementation on the Supply of Hepatitis E Virus (HEV) Tested components	WITN06 72103
November 2020	CARE committee terms of reference	WITN06 72104
May 2021	BSCARE terms of reference	WITN06 72105
29 November 2012	HBV NAT paper for Board Nov 2012	WITN06 72106
5 November 2007	MPD577v1	WITN06 72107
19 May 2010	MPD577v2	WITN06 72108
25 March 2011	MPD577v2.1	WITN06 72109
27 September	MPD577v2.2	WITN06 72110

2011		
29 October 2012	MPD577v2.3	WITN06 72111
28 November 2013	MPD577v3	WITN06 72112
10 July 2014	MPD577v4	WITN06 72113
14 September 2015	MPD577v5	WITN06 72114
29 January 2016	MPD577v6	WITN06 72115
18 October 2007	MPD591v1	WITN06 72116
16 November 2009	MPD591v2	WITN06 72117
30 April 2010	MPD591v3	WITN06 72118
13 July 2011	MPD591v3.1	WITN06 72119
6 April 2012	MPD591v4	WITN06 72120
22 August 2012	MPD591v5	WITN06 72121
24 February	MPD591v6	WITN06

2014		72122
30 March 2015	MPD591v7	WITN06 72123
6 June 2016	MPD591v8	WITN06 72124
17 July 2017	MPD591v9	WITN06 72125
1 October 2018	MPD591v9.1	WITN06 72126
29 February 2008	MPD596v1	WITN06 72127
20 April 2011	MPD596v1.1	WITN06 72128
18 December 2013	MPD596v2	WITN06 72129
11 March 2015	MPD596v3	WITN06 72130
5 May 2017	MPD596v4	WITN06 72131
17 July 2018	MPD596v4.1	WITN06 72132
3 January 2007	MPD578v1	WITN06 72133
8 February 2011	MPD578v2	WITN06 72134

30 July 2012	MPD578v3	WITN06 72135
27 November 2012	MPD578v3.1	WITN06 72136

Section 11: Questions 50-52

Date	**Notes/ Description**	**Exhibit number**
	N/A	

Section 12: Questions 53-58

Date	**Notes/ Description**	**Exhibit number**
	N/A	

TABLE OF ACRONYMS

1. Table of Acronyms that appear in the Statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 26 February 2021 of Gail Miflin.

Term	Acronym
Acquired Immunodeficiency Syndrome	AIDS
ABO blood group system	ABO
Alliance of Blood Operators	ABO
Advisory Committee for Transfusion Transmitted Diseases	ACCTD
Advisory Committee on Dangerous Pathogens	ACDP
Advisory Committee on Transfusion Transmitted Infections	ACTTI
Advisory Committee on Virological Safety of Blood	ACVSB
anti-human globulin	AHG
Arm's Length Bodies	ALBs
Antimicrobial Resistance and Healthcare Associated Infections Reference Unit	AMRHAI
hepatitis B core antibody	anti-HBc
Audit, Risk and Governance Committee	ARGC
Advisory Committee of the Safety of Blood	AVSCB
British Blood Transfusion Society	BBTS
Blood Centres	BC
Blood Group Reference Laboratory	BGRL
Blood Products Laboratory (later Bio Products Laboratory)	BPL
Blood Products Laboratory Diagnostics	BPLD
Blood Supply CARE committee	BSCARE
bovine spongioform encephalopathy	BSE
British Society of Haematology	BSH
Blood Safety and Quality Regulations (SI 2005-50)	BSQR
Central Blood Laboratory Authority	CBLA
Centers for Disease Control and Prevention	CDC

Communicable Disease Surveillance Centre	CDSD
Component Development Laboratory	CDL
European Committee on Blood Transfusion	CD-P-TS
Commission on Human Medicines	CHM
Creutzfeldt–Jakob disease	CJD
Chief Medical Officer	CMO
cytomegalovirus	CMV
change and safety notifications	CNs
Central Planning Team	CPT
Care Quality Commission	CQC
Donor Experience Team	DET
Donor Health Checks	DHC
Department of Health and Social Care	DHSC
Department of Health and Social Security	DHSS
Department of Health	DoH
Department of Health	DH
Data Protection Impact Assessment	DPIA
Expert Advisory Group on AIDS	EAGA
European Blood Alliance	EBA
England Infected Blood Support Scheme	EIBSS
Emerging Infections Report	EIR
Enzyme-linked Immunosorbent Assay	ELISA
For the Assessment of Individualised Risk	FAIR
Food and Drug Administration	FDA
Fresh Frozen Plasma	FFP
Factor IX (nine)	FIX
Factor IX Concentrate	FIX
Fellowship exams of the Royal College of Pathology	FRCPath
Factor VIII	FVIII
Factor VIII Concentrate	FVIII
Gastrointestinal Bacteria Reference Unit	GBRU
Hepatitis A (Infectious Hepatitis)	HAV
hepatitis A Virus	HAV

Hepatitis B Core Antigen	HBc
Hepatitis B Surface Antigen	HBsAg
Hepatitis B (Serum Hepatitis)	HBV
Haemophilia Centre Director	HCD
Hepatitis C Virus	HCV
hepatitis E Virus	HEV
Human Immunodeficiency Virus	HIV
human leukocyte antigen	HLA
Her Majesty's Stationery Office	HMSO
Health Protection Agency	HPA
Human Platelet Antigens	HPA
Human T-cell lymphotropic Virus	HTLV
Human T-cell lymphotropic Virus-III	HTLV-III
International Blood Group Reference Laboratory	IBGRL
immunoglobulin	Ig
International Society of Blood Transfusion	ISBT
Integrated Supply Planning	ISP
intravenous	IV
Intravenous immunoglobulin	IVIg
Joint Management Committee	JMC
Joint UKBTS Professional Advisory Committee	JPAC
Multi-disciplinary team	MDT
Medicines and Healthcare Products Regulatory Agency	MHRA
Minimum Inhibitory Concentration	MIC
Medical Laboratory Scientific Officer	MLSO
Management Process Descriptions	MPD
Medical Research Council	MRC
Specialist exam for membership to RCPath	MRCPath
Microbiological Safety of Blood and Tissues for Transplantation	MSBT
Microbiology Services Laboratory	MSL
Non A Non B Hepatitis	NANBH
National Blood Authority	NBA
National Blood Authority (Establishment and Constitution)	NBA (Amendment)

Amendment Order 1994 SI No 589	Order 1994
National Blood Authority (Establishment and Constitution) Order 1993 SI No 585	NBA Order 1993
National Blood Transfusion Committee	NBTC
National Blood Transfusion Service	NBTS
Welsh Blood Services	NBTS (Wales)
National Blood Transfusion Service / Central Blood Laboratory Authority	NBTS/CBLA
Non Clinical Issue	NCI
National CJD Research & Surveillance Unit	NCJDRSU
National External Quality Assessment Service	NEQAS
National Health Service (NHS) Blood and Transplant	NHSBT
NHSBT National Clinical Governance, Audit, Risk and Effectiveness group	NHSBT CARE
NHSBT (Establishment and Constitution) Order (SI 2005 No. 2529)	NHSBT Order 2005
NHSBT (Establishment and Constitution) Regulations (SI 2005 No. 2531)	NHSBT Regulations 2005
NHSCord Blood Bank	NHS-CBB
NHS England	NHSE
National Institute for Biological Standards & Control	NIBSC
Northern Ireland Blood Transfusion Service	NIBTS
National Institute for Health Research	NIHR
National Management Committee	NMC
Notification of infectious diseases	NOID
Organ Donation and Transplant	ODT
Principal Accounting Officer	PAO
Polymerase Chain Reaction	PCR
Personal Development and Performance Review	PDPR
Plasma Fractionation Centre	PFC
Scottish Protein Fractionation Centre	PFC
Plasma Fractionation Laboratory	PFL
Public Health England	PHE

Public Health Laboratory Service	PHLS
Publlic Health Laboratory	PHLS
population, intervention, control, and outcomes	PICO
Plasma Protein Solution	PPS
Quality Management System	QMS
Royal College of Pathologists	RCPath
Regional General Manager	RGM
Regional Health Authority	RHA
Regional Health Board	RHB
radioimmunoassay	RIA
Blood test for HCV	RIBA
ribonucleic acid	RNA
Regional Transfusion Centre	RTC
Regional Transfusion Director	RTD
Respiratory and Vaccine Preventable Bacteria Reference Unit	RVPBRU
Serious Adverse Blood Reactions and Events	SABRE
Advisory Committee on the Safety of Blood, Tissues and Organs	SaBTO
Standing Advisory Committee on Blood Components	SACBC
Standing Advisory Committee on Care and Selection of Donors	SACCSD
Standing Advisory Committee on Clinical Transfusions Medicine	SACCTM
Standing Advisory Committee on Immunohaematology	SACIH
Standing Advisory Committee on Information Technology	SACIT
Standing Advisory Committee on Tissues and Cellular Therapy Products	SACTCTP
UK Standing Advisory Committee on Transfusion Transmitted Infection	SACTTI
saline-adenine-glucose-mannitol	SAGM
Senior Departmental Sponsor	SDS
Special Health Authority	SHA
Serious Hazards of Transfusion	SHOT
Scottish National Blood Transfusion Service	SNBTS
Scheme of Delegation	SoD

Standard Operating Procedure	SOP
Single Plasma Pack	SPP
?	SPSS
Secretary of State for Health and Social Care	SSHSC
Transport Development Group	TDG
Transfusion Medicine Epidemiology Review	TMER
Transfusion-transmitted Infections	TTI
transfusion education talks	TxED
University College London Hospital	UCLH
UK Blood and Transfusion Service	UKBTS
UK Haemophilia Centre Directors (now Doctors) Organisation	UKHCDO
UK Health Security Agency	UKHSA
variant Creutzfeldt–Jakob disease	vCJD
Von Willebrand's Disease	vWD
Von Willebrand's Factor	vWF
World Health Organization	WHO