Witness Name: Dr Lorna Williamson
Statement WITN0643010
Exhibits:WITN0643011 -
WITN0643053
Dated: 21 November 2021

INFECTED BLOOD INQUIRY

SECOND WRITTEN STATEMENT OF DR LORNA WILLIAMSON

I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 19 August 2021.

I, Dr Lorna Williamson, c/o NHS Blood and Transplant, 500, North Bristol Park, Filton, Bristol, BS34 7QH will say as follows:

Section 1: Introduction

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

1. My full name is Lorna McLeod Williamson OBE.

2. My address is c/o NHS Blood and Transplant, 500, North Bristol Park, Filton, Bristol, BS34 7QH.

3. My date of birth is GRO-C 1953.

4. My professional qualifications are BSc, MB ChB, MD, FRCP, FRCPath.

Opening remarks

5. I would like to open my statement with some personal remarks.

6. Firstly, my heart goes out to every single person affected by these awful events. Every one of your stories is different, but I have found all that I have heard to be both tragic and moving.

7. Like all other doctors I have known, I have gone to work every day with the aim of helping the patients who have entrusted their care to me. I have always tried to do my best for them within the resources available. There is nothing worse than a patient being seriously damaged by their treatment. So if it emerges that anyone has been harmed by my actions, whether wrongly judged or taken too late, to you I offer deepest apologies.

8. Everyone affected by this tragedy deserves a full and frank explanation of what happened, something you have waited so long to be told. I am pleased to have the chance to contribute my recollection of events.

9. It is a great pity that this Inquiry did not happen a lot earlier when memories were fresher, and more of my former Blood Service colleagues would have been able to contribute. Inevitably, my recall of events 15-30 years ago is incomplete and may be faulty in places. I have been greatly helped by detailed reading of the 2000 pages of documents provided by the Inquiry. From a combination of memory and reading, I have put together as best as I can a chronology of certain events and have tried to answer the detailed questions put to me.

10. I enclose a copy of my CV (Exhibit WITN0643011) and a chronological list of personal publications (Exhibit WITN0643012).

11. I have already prepared a statement as part of NHSBT's response to an amended Rule 9 request dated 14 August 2020 relating to lookback and

have not repeated here the contents of that statement which should be read in addition.

12. This Inquiry has caused me to look back over my career with reflection. In section 18, under 'Issues', I have tried to put together some thoughts on what improvements have taken place in the National Blood Service over that time, and also the transformation that has occurred in the way that patient safety decisions are taken. I have done this in the hope that, as we move forward, these improvements are not lost. Indeed, it is my hope that they are added to by new insights from the important work of this Inquiry.

13. Many things have changed in transfusion practice during my career, but the one constant has been the loyalty and dedication of blood donors and the staff who take such care of them and their precious donations. So I will end these remarks by thanking all blood donors, past and present. You have given up your time on many occasions to give your blood for a stranger and have saved and improved many lives. That is something of which you can be very proud.

2. Please set out your employment history with dates if possible, including the various roles and responsibilities that you have held throughout your career.

14. I graduated in Medicine (MB, ChB) with Honours from the University of Edinburgh in 1978. I had undertaken an intercalated Honours BSc year in Medical Sciences from 1974-75 (awarded first class). I became interested in haematology in about 1975 and undertook a 4-week elective period in haematology at the Royal Infirmary, Edinburgh, in 1976.

15. I have separated my employment history into training and consultant posts.

a. TRAINING POSTS

- **August 1978-January 1979: Pre-registration House Officer in Surgery, Royal Infirmary of Edinburgh.** I admitted patients requiring surgery, organised tests for them and occasionally assisted in theatre.

- **February- July 1979: Pre-registration House Officer in Medicine, Eastern General Hospital, Edinburgh.** I cared for patients with acute and chronic medical conditions.

- **August 1979-July 1980: Senior House Officer in Medicine, Queen's Medical Centre, Nottingham.** This post included 6 months working for a consultant specialising in liver disease, so I learned a good deal about the major causes of liver disease. I do not recall seeing any patients with haemophilia. I passed the Membership of the Royal College of Physicians (MRCP) examinations in summer 1979.

- **August 1980- July 1983: Senior House Officer then Registrar in Haematology, City Hospital, Nottingham.** These posts provided general training in both laboratory and clinical haematology. I treated patients with various anaemias, leukaemias and other blood cancers such as lymphoma, and examined blood and bone marrow samples in the laboratory. This post did not involve haemophilia care, as the Haemophilia Centre was at the other hospital in Nottingham (Queen's Medical Centre). The training included a 1-week training course at the Trent Regional Transfusion Centre (RTC), Sheffield, which sparked my interest in transfusion medicine.

- **August 1983-July 1985. Research Fellow in Haematology, City Hospital, Nottingham.** This was a full-time research post in the laboratory, working on white blood cells and inflammation. I did not see any patients during that time. This work formed the basis of my

Doctor of Medicine (MD) thesis, awarded by the University of Edinburgh in 1988.

- **August 1985-May 1987 Full-time Senior Registrar in Haematology (Transfusion), Sheffield.** While all senior registrar posts in haematology included a 6-month period of training at an RTC, this rotating post provided extra time at the RTC, and was intended for trainees who wanted to specialise in transfusion medicine. My rotation consisted of:

- **August 1985-July 1986 Royal Hallamshire Hospital** (consultants Professor Eric Preston, Dr Mike Greaves and Dr David Winfield). One of the other senior registrars was Dr Charles Hay. Coagulation and haemophilia were major interests of the department, so although my training involved laboratory and clinical aspects of all areas of haematology, there was considerable discussion about the major issues in haemophilia at that time, ie infection with HIV and non-A, non-B hepatitis, and the provision of virally inactivated clotting factor concentrates. I attended the haemophilia clinic with Professor Preston, and was struck by how many patients were in wheelchairs. As I had had no previous experience in haemophilia, I did not make treatment decisions for individual patients without discussion with one of the consultants, usually Professor Preston. I was not involved in decisions regarding which clotting factor concentrates to use, either in general, or for individual patients. I was very much aware of the previous and on-going research undertaken by the Sheffield team on non-A, non-B hepatitis, and I can recall haemophilia in-patients having liver biopsies. The issue of virus transmission by clotting factor concentrates and blood components was very much to the fore at that time.

- **July 1986-May 1987 Sheffield RTC and Sheffield Children's Hospital, Sheffield.** Consultants at the RTC were Dr Bill Wagstaff (Director), Dr Robert Sokol, Dr Virge James and Dr Katy Forman. My

time at the RTC was spent rotating through each department, learning advanced aspects of blood typing and cross-matching, donor recruitment and selection, donor and therapeutic apheresis, donation testing for viruses and other infectious agents, and manufacture of blood components (red cells, fresh frozen plasma, cryoprecipitate and platelets). I took queries from hospitals across the Trent Region regarding individual patients where there were difficulties providing compatible blood. There was a major push at that time to produce more plasma for fractionation at the Blood Products Laboratory (BPL), and the programme of plasma collection by donor apheresis was expanding. HIV was a major issue, with donor testing having started in 1985, and new guidance to exclude high risk donors, e.g. male donors who had had sex with other men. The RTC consultants were very well aware of the virus risks from blood components and clotting factor concentrates. I recall seeing samples of the first virally inactivated clotting factor concentrates coming from BPL. The first ones did not dissolve well, but when virally inactivated concentrates called 8Y and 9A became available, they were well received by hospitals and patients.

- At the Children's Hospital, most of my time was spent caring for in-patients and out-patients with leukaemias and solid tumours, working closely with the paediatric team and the haematology consultants, Dr John Lilleyman and Dr Katy Forman. I sat in on the haemophilia clinic as part of my training, but did not make treatment decisions on individual patients without discussion with Dr Lilleyman. I was not involved in any decisions regarding treatment policies.

- **May 1987- February 1988 Maternity leave.**

- **February- July 1988- Part-time (50%) senior registrar in haematology, Sheffield rotation.** For personal reasons, I reduced my working hours, joining a national scheme for part-time training. I

split my time between the RTC, Royal Hallamshire Hospital and Children's Hospital. The responsibilities were as outlined above.

- During my time in Sheffield, I passed the final examination in haematology for Membership of the Royal College of Pathologists (MRCPath).

- **September 1988- July 1990. Part-time (50%) senior registrar in transfusion, East Anglian Blood Transfusion Centre (EABTC), Cambridge**. For family reasons, I moved my nationally-funded training post to Cambridge. I have given details of this post in Section 2.

b. CONSULTANT POSTS

- **July 1990-January 1991 Maternity leave.**

- **January-March 1991: Locum Consultant Haematologist at EABTC**.

- **April 1991- September 2008: University Lecturer (Reader from approx. 2004) in Transfusion Medicine, Department of Haematology at the University of Cambridge.** This post was allocated nominally 50% time for university work (research and teaching) and 50% time for NHS work as an Honorary Consultant at EABTC.

- **April 1991- 1994 Honorary Consultant Haematologist to EABTC.**

- I have given details of these consultant posts and my responsibilities at EABTC in section 2.

- **1994-1999 Honorary Consultant and Clinical Lead for Blood Components, London and South-East Zone, National Blood Service.**

- **1999-2007 Honorary Consultant and National Clinical Director for Components, National Blood Service (NHS Blood and Transplant from 2005 onwards).**

- **October 2007- May 2016: Medical and Research Director, NHS Blood and Transplant.**

I have set out my roles and responsibilities of these national posts in Section 3, along with membership of NHSBT/UK Blood Services groups relevant to the Inquiry.

3. Please set out your membership, past or present, of any committees, associations, parties, societies or groups relevant to the Inquiry's Terms of Reference, including the dates of your membership.

16. **Early 1990s: Member, Transfusion Task Force of the British Committee for Standards in Haematology (BCSH), the guideline group within the British Society for Haematology (BSH)**. The Transfusion Task Force produced guidance for clinical and laboratory transfusion practice aimed at hospital staff. I chaired a group which produced the first UK guidelines for the Irradiation of blood components, which is done for patients with impaired immunity to prevent the fatal complication of Transfusion-Associated Graft-versus-Host disease. This is discussed further in Section 10, under Serious Hazards of Transfusion.

17. **Early 1990s**: Member, Council, British Blood Transfusion Society (BBTS). BBTS is a scientific society for all staff working in transfusion in blood services and hospitals.

18. **2007-2016: Member, Chief Medical Officer's National Blood Transfusion Committee (NBTC).** This group was established in 2001 to drive optimal transfusion practice at the front line of the NHS. My membership was as NHSBT's Medical and Research Director.

19. **2010-2014: Chair, Royal College of Pathologists (RCPath)Transfusion Medicine Committee.** This group set standards for professionals working in the field and advised on transfusion training for doctors and scientists.

20. **2008-2016: Member, Department of Health Advisory Committee on Safety of Blood, Tissues and Organs (SaBTO).** This group provides advice to the Health Ministers of the four UK home nations. During my membership, I was Chair of three working groups which produced recommendations on donation policies for tissues and cells from men who have had sex with men, pathogen inactivation of platelets, and hepatitis E.

21. **2007-2016: International activities.** As Medical and Research Director of NHSBT, I became a member of the European Blood Alliance (EBA)- an association of publicly funded transfusion services mostly within the EU, and of the Alliance of Blood Operators (ABO)- an association of transfusion services from UK, USA, Canada and Australia. I chaired the ABO Medical Directors group, which produced recommendations on clinical governance for Blood Services ([WITN0672072] and the development of their medical leaders. I was also an invited member of the Canadian Blood Services' Scientific and Research Advisory Committee, which provided me with insights into issues in North-American transfusion practice. I was also a member of the research board of l'Etablissement Francais du Sang (EFS), the French national transfusion service, at a time when they were seeking to restructure their research activities.

4. Please explain how you kept abreast of medical and scientific developments and research in your field in the course of your career.

22. There were a number of ways in which I kept up to date:

23. By regular reading of the medical literature, covering both general journals such as The Lancet and New England Journal of Medicine, and specialist journals in haematology (British Journal of Haematology, Blood) and transfusion (Transfusion, Transfusion Medicine, Transfusion Medicine Reviews, Vox Sanguinis).

24. By attending conferences of scientific societies within the UK (BSH and BBTS) and internationally (American Society for Haematology, International Society for Blood Transfusion and American Association of Blood Banks). Early in my career, I was able to attend national society conferences annually and international ones every 2 years. As I became more senior, I could attend at least one international conference/year to present original work, and I was sometimes invited to give lectures internationally.

25. Through membership of international bodies which provided high level information exchange as described earlier, as well as through membership of the BEST Collaborative- an organisation of blood services researchers and industry (see section 15 for details).

5. The Inquiry is aware that you provided a statement in the A and Others v National Blood Authority and another [2001] Litigation ("A & Others"), (NHBT0000032_001). The Inquiry only has an unsigned version. Please provide a signed version. Please review the statement. Does it remain true and accurate? If there are matters contained in this statement that you do not consider to be true and accurate, please explain what they are.

26. My statement to this litigation concerned the status at that time of two techniques for the virus inactivation of fresh frozen plasma (FFP), solvent-detergent (SD) treatment and methylene blue (MB) photoinactivation. I have reread the statement and still believe that what I stated was true at the time (it is dated March 2000). I am sorry I cannot provide a signed copy from the time.

27. The status of both of these technologies has moved on considerably since then, and here I provide a short update on both. This is based on my recall of their status at the time of my retirement from NHSBT in 2016; there may have been further developments since then. As in my statement of 2000, my knowledge of the SD technology is confined to its application to FFP for direct clinical use and not to its use in the manufacture of plasma products. I discuss these products, along with my involvement in their evaluation, in section 13.

Use of fresh frozen plasma (FFP).

28. Most FFP is given to patients with acquired abnormalities of the whole clotting system due to trauma, sepsis, liver disease and other medical conditions. It is also used in plasma exchange procedures for conditions such as thrombotic thrombocytopenic purpura (TTP) and Guillain-Barre syndrome. It is also used for patients with inherited single clotting factor deficiencies where no concentrate is available, e.g. factor XI (eleven) deficiency.

Solvent-detergent FFP (SDFP).

29. As outlined in my original statement, this technology works for lipid-coated viruses (HIV, HBV, HCV) but not for other viruses such as parvo-virus and hepatitis A. In addition, the technology requires pooling of several hundred donations, thus raising the possibility of increased risk of transmission of agents not killed by the process, e.g. the prions causing variant Creutzfeldt-Jacob Disease (vCJD). These two factors taken together meant that licencing by the Medicines Control Agency (MCA, now incorporated into the Medicines and Healthcare Regulatory

Agency, MHRA), and a policy decision to implement SD treatment of UK plasmawere both carefully considered. Ultimately, the product was licensed in 1998 but to be manufactured from non-UK plasma only to minimise vCJD risk, and criteria were set for levels of antibody to hepatitis A. I believe this now also applies to hepatitis E. A further consideration was whether SDFFP would be effective in plasma exchange for TTP. I discuss this in more detail in section 13.

30. Between its licensing in the UK in 1998 and my retirement in 2016, the following evolved:

31. In 2012, BCSH Guidance recommended SDFFP as the preferred product for plasma exchange for TTP (Exhibit WITN0643013)

32. Hospitals in England could purchase SDFFP from the supplier Octapharma, and it became the standard product used in Wales.

33. Incorporation of a prion reduction filter

34. There was research into a 'universal' SDFFP, i.e. a product which could be given to someone of any blood group. I do not think this has been licensed in the UK.

Methylene blue (MBFFP).

35. This technology was provided initially by Baxter and then by Macopharma and was designed for use in a standard blood centre environment with single units of FFP, i.e. no pooling was needed. Therefore, it was of considerable interest to NBS/NHSBT and was evaluated by Dr Rebecca Cardigan and her team at the NBS Components Development Laboratory at the Brentwood transfusion centre. These studies showed that MBFFP contained adequate coagulation factors for clinical use and would also be suitable for plasma exchange for TTP. Parallel studies by SNBTS showed that cryoprecipitate could be manufactured from MBFFP. All of this work was

published in the early 2000s [NHBT0042349] (Exhibit WITN0643014, Exhibit WITN0643015). At some point, Macopharma introduced a filter to remove residual MB from the product, thus greatly reducing concerns about toxicity.

36. Because of the vCJD risk from UK plasma, NBS began to import FFP from volunteer blood donors from the USA to be given to children born after the date by which UK foodstuffs were considered safe from Bovine Spongiform Encephalopathy (1st January 1996). However, NBS did not want vCJD avoidance to be associated with an increased residual risk of viruses from non-UK plasma. Therefore, from the outset of importation in 2004, non-UK FFP was subject to MB treatment in our blood centres. We also manufactured MB-treated cryoprecipitate for the same patient group.

6. The inquiry is also aware that you provided evidence to the House of Commons Science and Technology Committee on 30 April 2014 on blood, tissue and organ screening [TSTC0000047]. Please review the transcript of the committee meeting. Does it remain true and accurate? If there are matters contained in this that you do not consider to be true and accurate, please explain what they are.

37. I gave evidence in 2014 which covered the areas of vCJD testing, prion filtration, and pathogen inactivation of platelets and fresh frozen plasma. Having reread the transcript of my evidence, I believe that what I said was true at the time, and I have no corrections to make.

38. The effectiveness of prion filtration was not covered in open session as the results were commercial in confidence.

39. The current situation, as I believe it to be, includes the following:

40. As reported by the National CJD Research and Surveillance Unit (NCJDRSU), new vCJD cases have fallen away in the UK,, with none

since 2011 (https://www.cjd.ed.ac.uk/surveillance/data-and-reports . There have been no cases attributed to blood components transfused since universal leucodepletion was introduced in 1998.

41. A protocol was produced for assessment of prion assays under the EU In Vitro Diagnostics Directive (led by Professor Marc Turner), but no manufacturer has to date produced an assay which meets these requirements.

42. Prion filtration was considered but not recommended by SaBTO in 2012 and has never been implemented.

43. Leucocyte depletion is still performed on all blood components.

44. Imported FFP from volunteer blood donors was provided for patients born on or after 1st January 1996 (the date by which the UK food chain was deemed safe from BSE). This measure was rescinded by SaBTO in 2019.

45. A study of appendix samples looking for infectious prions challenged the assumption of the start and end dates of the BSE epidemic, with small numbers of positive samples before 1980 and after 1996. This meant that plans to create a pool of young donors who would be lower risk for vCJD ('Club 96') were shelved.

46. Pathogen inactivation of platelets is not implemented in the UK. Bacterial contamination is prevented by: enhanced skin cleansing, diversion of the first part of the donation (used for routine testing), bacterial testing, and visual testing of the platelets for clumping and loss of swirling. There has been only one bacterial transmission reported to the Serious Hazards of Transfusion (SHOT) haemovigilance scheme since 2009.

7. Apart from your involvement in A & Others, please confirm whether you have provided evidence or have been involved in any other inquiries,

investigations, criminal or 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. Please provide details of your involvement. You may find PRSE0000189 of assistance.

47. The inquiry has drawn my attention to an email from the Penrose Inquiry **in** 2011 as per document [PRSE0000189], which asked whether I could provide the name(s) of colleague(s) who could give an account of the introduction of HIV screening in 1985. I am afraid I cannot recall how I answered that request. However, I have also been provided with document [PRSE0004758], which indicates that at some point, I responded, "one person who might be able to help is Professor John Barbara, who was a senior virologist at the NW Thames RTC in Colindale at the time".

48. I have not provided evidence to, or been involved in, any other inquiries, civil or criminal litigation in relation to infections transmitted by blood transfusion.

Section 2: Your role at East Anglian Blood Transfusion Centre

The Inquiry understands that the East Anglian Blood Transfusion Centre ("EABTC") was alternatively referred to as the Cambridge Blood Transfusion Centre. Is this correct? For the avoidance of doubt, this request will refer to the EABTC throughout, even where the supporting documents refer to the Cambridge Blood Transfusion Centre.

8. Please give the time periods and describe the roles, functions and responsibilities you had at the EABTC during your period and explain how these changed over time.

49. **Note on name of the centre:** When Transfusion Centres were part of each Regional Health Authority (RHA), each was named after its region, so it was the East Anglian Blood Transfusion Centre (sometimes shortened to Cambridge) until the creation of the National Blood Authority in 2004. The NBA took over the running of all previous RTCs in 1995, bringing them together as the National Blood Service. At some point after that , the local name was changed to the Cambridge Blood Centre.

a. Senior Registrar in Haematology/Transfusion Medicine;

50. For family reasons, I moved my nationally-funded training post to Cambridge in 1988 and resumed my training at EABTC. The consultants were Dr Jack Darnborough (Director), Dr John Blagden and Dr Tom Gibson. All three were close to retirement. When Dr Darnborough retired, the RHA appointed Dr Morton McDougall, a Public Health doctor, as Acting Director until Professor Allain arrived in 1991 (see para 47).

51. I worked solely in the EABTC, although I attended haematology departmental meetings and educational events in Addenbrooke's Hospital, Cambridge. I did not have direct responsibility for any patients in the hospital, though I took transfusion queries from hospitals across East Anglia. I continued my training by acting as the doctor at blood donor sessions throughout East Anglia and rotating through different departments in the EABTC. With a colleague, Dr Angela Rankin, I was given the task of establishing a panel of HLA typed (tissue typed) platelet donors. Platelets from such donors are used for patients who develop HLA antibodies (HLA alloimmunisation), which can arise either through transfusion or pregnancy, and which lead to platelets from unselected donors failing to work. This led to a research interest in alloimmunisation and investigation of whether it could be prevented by removing white blood cells from blood components using specific commercially available filters, a process known as leucocyte depletion. This interest

later became relevant when we were investigating ways to reduce the risk of vCJD from blood components (see section 17).

b. Consultant Haematologist;

52. **As Locum Consultant Haematologist at EABTC. January-March 1991.** I had medical and managerial responsibility for blood component processing and the issues department. I replaced Dr Blagden, who had retired. My time in this post was largely taken up with organising EABTC's contribution to blood provision for the combat phase of the first Gulf War (Operation Desert Storm, 17th January-28th February 1991).

53. **As Honorary Consultant Haematologist to EABTC April 1991- 1994 (50%), alongside my post as University Lecturer in Transfusion Medicine, Department of Haematology at the University of Cambridge (50%).** In my NHS consultant role at EABTC, I had medical and managerial responsibility for the blood component manufacturing and issue departments. This included line management responsibility for the scientific and technical staff and ensuring the components met the specifications laid down in the national Guidance for Transfusion Centres ('Red Book'). I attended liaison meetings with the senior blood collection staff to ensure that blood collected across East Anglia could be processed into components (red cells, platelets, FFP and cryoprecipitate) within the required time frames.

c. Management Group Member; and

54. From 1992-1995, in the absence of Professor Allain, I also took on managerial and medical responsibility for the donation testing laboratory, but not for donor health or lookback.

d. Acting Director

55. I would like to clarify this role. To cover for Prof Allain's absence in France from 1992 onwards, Dr Morton McDougall from the East Anglian Regional Health Authority (EARHA) was again appointed Acting Director of the EABTC and attended all meetings RTC Directors were involved. At that point, I had been a consultant for only two years and could not have taken on the role of Acting Director. However, as Dr McDougall was a Public Health doctor, and since I was a qualified haematologist, I sometimes gave him advice and help. In 1994, the NBA formed and would take over the running of RTCs from 1995. At the end of 1994, Dr McDougall returned to the EARHA as it had no longer a responsibility for running EABTC. I was given the title of Acting Director for a few months during the transition to zonal management within the NBS. In essence, this was a caretaker role, as EABTC was no longer in a position to make significant decisions requiring funding.

56. The National Blood Authority took responsibility for the RTCs in 1995, forming the National Blood Service, initially in 3 geographic zones, then under a national structure. My NHS responsibilities were then part of the London & South-East (LSE) zonal structure from 1994-1999, then under a national structure from 1999 onwards.

9. Please describe the organisation of the EABTC during the time you worked there, including: You may also find NHBT0010585_002 of assistance in answering these questions.

a. its structure and staffing and in particular to whom you were accountable;

Organisation and staffing of EABTC.

57. In the late 1980s, it was realised that all 3 consultants at EABTC were about to retire. Therefore a plan was developed by the Professor of Haematology (Professor Robin Carrell) and the Regional Director of Public Health (Dr Michael O' Brian) to create an academic Division of Transfusion Medicine within the University Department of Haematology,

as a joint activity between the University and EARHA. This involved converting the EABTC Director post into a University Professorship, with 50% time for research and teaching and 50% time as an Honorary NHS consultant and Director of EABTC. The other 2 consultant posts were converted into 50:50 University Lecturer/Honorary Consultant posts. Funding for these posts came from the RHA and was given to the University. I believe this was covered by a Memorandum of Understanding. In around 1989, Dr Willem Ouwehand was appointed to the first University lecturer post. In autumn 1990, I was appointed to the second University Lecturer post, to begin in April 1991. Professor Jean-Pierre Allain took up his post as Professor of Transfusion Medicine/Director of EABTC in 1991. I believe that these developments also had the support of Dr Harold Gunson, who was national Medical Director at that time.

58. In 1990, an additional consultant post was created focusing on donor health in preparation for the start of HCV donation screening in 1991. Dr Elizabeth Caffrey was appointed to this post, which later included responsibility for the HCV lookback.

59. For my NHS work, I was initially accountable to Professor Allain as Director of the EABTC, then to Dr McDougall. For my University work, I was also accountable to Professor Allain, and through him, to Professor Robin Carrell, Head of the University Department of Haematology.

b. how the EABTC was funded and how this changed over time;

60. **EABTC funding.** Until 1994, EABTC was funded by the EARHA. I am not aware of the details of how the funding was calculated. The funding was transferred to the National Blood Authority when it assumed responsibility for Blood Centres in 1995. At some point, cross-charging to the hospitals was introduced, with hospitals reimbursing blood centres for the components and diagnostic services they received against a national tariff.

c. its remit, including the geographical area it covered and the hospitals within its area;

61. **Remit of EABTC.** The remit of EABTC was to collect blood across East Anglia, test and process it into components, and provide these blood components and medical advice on transfusion to hospitals in East Anglia, i.e. Cambridgeshire, Norfolk and Suffolk. We undertook testing of certain patients for whom the hospital could not find suitable blood. In common with some other RTCs, we also undertook blood grouping and antibody screening for all pregnant women in the region, and distributed plasma products supplied by BPL but not by commercial suppliers. Additional functions were the manufacture of blood grouping reagents for the hospitals and HLA (tissue) typing of patients and donors who had become unresponsive to donor platelets. We had no remit for the running of transfusion laboratories in the hospitals we served, nor for the direct treatment of any patients.

a. The hospitals were:

b. Cambridgeshire: Addenbrooke's Hospital and the Rosie Maternity Hospital, Cambridge; Hinchingbrooke Hospital, Huntingdon; Papworth Hospital (a specialist chest hospital); Peterborough General Hospital.

c. Norfolk: The Norfolk and Norwich Hospital, Norwich, James Paget Hospital, Great Yarmouth; Queen Elizabeth Hospital, Kings Lynn.

d. Suffolk: Ipswich General Hospital; West Suffolk Hospital, Bury St Edmonds.

d. its place in the National Blood Transfusion Service ("NBTS") together with information as to whom the centre was answerable to at the NBTS, if anyone. When answering this question, please refer to paragraphs 4-16 of Dr Harold Gunson's statement in A & Others and explain whether you agree with what is said there (NHBT0000026_009)

62. **Place in NBTS.** I think the statement of Dr Gunson in NHBT0000026_009 is correct, i.e. the primary accountability of EABTC before the formation of the National Blood Authority (NBA) was to the RHA, I think through the Regional Director of Public Health. The National Directorate could try to influence RTC Directors, but they remained largely autonomous until the NBS was formed.

e. whether the EABTC was associated or linked with other Regional Transfusion Centres ("RTCs") and, if so, how and for what purpose. In particular, please explain the extent to which the EABTC collaborated with the Brentwood RTC in the 1990s and the purpose(s) of this collaboration (see NHBT0041409_002, NHBT0041398, NHBT0035813, DHSC0004239_017, NHBT0041413, NHBT0041418);

63. **Linkages between EABTC and other centres.** As discussed further in Section 10, EABTC was part of the Eastern Division of RTCs, along with the centres in Brentwood (North East Thames), Colindale (North West Thames) and Tooting (South Thames). There were quarterly meetings of Executive teams to discuss regional matters of interest and, importantly, to be a conduit to and from the National Directorate.

64. Separately from the Eastern Division, EABTC and Brentwood consultants met in the early 1990s to consider whether small-scale activities could be rationalised between the two centres. These discussions were superseded by creation of the NBA and the centralisation which then occurred.

f. The EABTC's relationship with Cambridge University and whether and if so how this changed over time;

65. As I have described in para 47, the academic Division of Transfusion Medicine was established in 1989 within the university Department of

Haematology (head, Professor Robin Carrell), through an agreement between the University and EARHA. Although certain scientists and consultants elsewhere in England held honorary academic positions, these were the first substantive academic posts to be created. There was a written agreement covering this, whereby the EARHA undertook to fund the posts and transfer the money to the University, who became the substantive employer.

66. The academic cadre was expanded in the early 1990s through the reorganisation of EABTC (see Q11 below). When Professor Allain returned from France, he continued as the Professor of Transfusion Medicine. When the NBA was created, the arrangement continued, the funding now coming from the NBA. Over the years, Dr Ouwehand was promoted to Professor, and I became Reader in Transfusion Medicine. This remained unchanged until I became NHSBT Medical and Research Director in 2007 when I rescinded my academic post and was replaced by Dr (now Professor) Cedric Ghevaert.

g. whether the EABTC was subject to any form of regulation and if so, what;

67. When Crown Immunity was removed from RTCs, I think in the late 1980s, they became subject to licencing by the MCA (later MHRA) and inspection by the DH Medicines Inspectorate. We held a Manufacturing (Specials) licence for the premises to cover all the activities associated with blood collection, processing, testing, storage, and distribution. The '(Specials)' refers to blood components since they are not licenced medicines. Because we distributed BPL plasma products, we also held a Wholesale (Dealers) licence. We were inspected in 1988 and 1990, and I think every 2 years after that.

h. the EABTC's relationship with the Blood Products Laboratory ("BPL") and any other laboratory involved in the production of blood products or processing of blood; and

68. Like all RTCs, EABTC sent an agreed volume of plasma to BPL every year for fractionation. I discuss this further in Section 5. EABTC also distributed BPL, but not commercial, plasma products. This is discussed further in Section 6.

69. The only relationship between EABTC/Division of Transfusion Medicine with another manufacturer of blood products was with Octapharma in the 1990s, to cover only a clinical trial of their virus inactivated FFP Octaplas. We did not discuss clotting factor concentrates with them. This is discussed in detail in section 13.

i. the approximate number of donations collected each year (you may find page 3 of NHBT0006237 of assistance).

70. In 1990, we were collecting around 90,000 donations/year. I think this gradually rose to around 120,000/year after NBA took over, as it was realised that East Anglia had greater donation potential than its hospitals required, so we arranged to send around 30,000 units/year of red cells to Brentwood and other centres in the London and South-East Zone .

10. Please describe the reorganisation of the EABTC in 1990. You may find DHSC0004239_017 and NHBT0041282_003 (page 1) of assistance.

71. I have addressed this in response to Q11 below.

11. The Inquiry understands that you attended regular meetings of the EABTC's Management Group as well as meetings of the EABTC's Executive Committee. Please see the attached schedule for copies of the minutes the Inquiry holds of meetings you attended from 1990 to 1994. Please explain:

a. What were the respective roles of the Management Group and the Executive Committee at the EABTC during your tenure? How did these groups differ?

b. Were the Management Group and Executive Committee set up as a result of the reorganisation of the EABTC in 1990? (see question 10 above)

c. How long were the Management Group and Executive Committee in existence for?

d. Were the Management Group and/or Executive Committee responsible for making policy decisions for the EABTC during your tenure?

e. As far as you are aware, were similar groups in existence at other RTCs?

72. Here I answer Q10 and Q11 together. It would be fair to say that in 1990 the centre was not a driving force of innovation. Although there was a new manufacturing suite and donation testing laboratory, many activities were outdated, and modern technologies were not employed. In 1989, Dr Ouwehand, who joined us from the blood service in the Netherlands (Sanquin), wrote an excellent visionary document setting out the changes which were needed to make EABTC a leader in service delivery and research over a 10-year period [NHBT0010585_002]. The retirement of a senior scientist and the existence of long unfilled technical vacancies in the laboratories provided an opportunity to restructure the centre staff, the aims being (1) to create a small, nimble decision-making group responsible for strategic direction and financial stewardship - this was the Management Team which met weekly (sometimes minuted as the Executive Committee which is unfortunate) (2) to involve a broader range of staff in discussing key issues - this was the Senior Staff Committee, which met monthly (3) to foster cross-fertilisation across different departments, by creation of a Medical Staff group and a Scientific staff group. In common with many RTCs, the medical staff were also responsible for line management and the budget in their area of expertise/responsibility.

73. Before the creation of the NBA, the Management Team could make decisions regarding major activities in the centre, provided that (1) they were in line with national regulations and guidance, e.g. UK Guidelines for the Transfusion Services ('Red Book') (2) funding was agreed with EARHA.

74. Once the NBA took over management and funding in 1994, RTCs ceased to function as such and became Blood Centres within firstly a zonal than a national structure. The Management Team at Cambridge continued to meet to resolve local issues within our responsibility. Professor Carrell then attended at least some of these meetings.

75. Other RTCs of which I had most knowledge (Sheffield, Brentwood, Colindale) had similar management teams.

Section 3: My roles at the NBTS and NHS Blood and Transplant

12. The Inquiry understands that you held the following roles during your tenure with the NBTS and later NHS Blood and Transplant ("NHSBT").

Please outline the periods you held these roles and describe the functions and responsibilities of the roles and how they differed.

a. Honorary Consultant;

b. Lead Consultant on Components; and

c. Medical and Research Director of NHSBT.

76. I was an Honorary Consultant to the NBS/NHSBT from 1991-2008, in parallel with my holding the substantive post of University Lecturer (then Reader) in the University of Cambridge.

77. The National Blood Authority took responsibility for the RTCs in 1995, forming the National Blood Service, initially in 3 geographic zones, then under a national structure. My NHS responsibilities were then part of the London & South-East (LSE) zonal structure from 1995-1999, then under a national structure from 1999 onwards.

78. **1994-1999 Clinical Lead for Blood Components, London and South-East Zone.**

79. **1999-2007 National Clinical Director for Components.**

80. The major focus of these roles was to investigate ways in which the safety and quality of blood components could be improved and provide advice to the Medical Director. The biggest concern for much of this period was vCJD, which was first described in 1996 (Will RG et al, Lancet 1996; 347:921-925), and, as discussed in section 17, shown in 1997 to be the human form of BSE, commonly known as mad cow disease. The infectious agents for these disorders are known as prions and were present in the blood of infected animals. This raised the spectre that vCJD could be transmitted on a large scale through blood transfusion, so as a top priority, resources were channelled into exploring ways of minimising the vCJD risk from blood components. vCJD risk reduction is discussed in detail in Section 17. I was a member of various groups within the National Blood Service exploring options to deal with the vCJD as follows:

81. Provision of fresh frozen plasma and cryoprecipitate from countries considered low-risk for BSE (this work did not include plasma for fractionation, which was a BPL responsibility). Because non-UK plasma potentially carried a higher risk of HIV and hepatitis, we chose to investigate and implement pathogen inactivation of all imported plasma.

82. Exploration of Leucocyte Depletion (white blood cell filtration) of all blood components as a vCJD risk-reduction step. We provided information to

the Department of Health's Microbiological Safety of Blood and Tissues committee (MSBT) in February 1998. Once the Secretary of State had decided in July 1998 that universal leucocyte depletion should be undertaken, I was a member of the implementation group. Leucocyte depletion of all blood components was introduced in 1999.

83. Removal of as much plasma as possible from cellular blood components (Safer Plasma in Components) group.

84. We were also concerned about the risk of bacterial contamination of platelets, and I advised on pathogen inactivation techniques.

85. I also had responsibility for the Component Development Laboratory in the Brentwood Centre. There were similar laboratories in Bristol and Birmingham. After a national review (I think by Professors Marcela Contreras and David Anstee), it was agreed that there should be a single laboratory for the NBS and that Brentwood should be the location. The laboratory was initially headed by Dr Jerhard Seghatchian. On his retirement, I appointed Dr Rebecca Cardigan as national Head of Component Development. On the closure of the Brentwood Centre, the laboratory, still headed by Dr Cardigan, moved to the Cambridge Centre.

86. I was also a member of various safety groups under the combined remit of the UK Blood Services:

87. **1993-1998 Member/Secretary Joint Professional Advisory Committee (JPAC) Standing Advisory Committee on Transfusion Transmitted Infections**. I acted as secretary in 1997-8. I stood down to take up the chair of SACBC.

88. **1994-1999. Chair, Working Group, Serious Hazards of Transfusion (SHOT).** In 1994, I was asked by Dr Angela Robinson to convene a group to develop a UK-wide reporting system for collation of infections and other serious side effects of transfusion of blood components (red

cells, platelets, FFP and cryoprecipitate). As these are not licensed medicines, the systems for reporting drug side effects did not apply. The remit did not cover fractionated plasma products, as these are licensed medicinal products covered by the MHRA. The public health systems in different parts of the UK had some data on infections transmitted by blood transfusions, but this was not collated UK wide. There was also ongoing research on transfusion errors in hospitals and increasing awareness of serious immunological reactions to blood components, but no comprehensive reporting system which brought them all together.

89. Therefore I established a group whose first actions were to investigate transfusion reporting systems in other countries (in Europe, only France had such a system), and investigate incident reporting systems in other areas of health in the UK. We were aided by a parallel initiative between the NBA and the Public Health Laboratory Service Communicable Disease Surveillance Centre (PHLS CDSC) in England to share data on infections in donors and recipients. We recommended basing a transfusion reporting system on the UK Confidential Enquiry model already in place for maternal deaths and perioperative deaths (NCEPOD).

90. We launched the UK's first haemovigilance system, the Serious Hazards of Transfusion (SHOT), in 1996. Its first annual report, covering 1996-7, was published in 1998. SHOT remains an integral part of the transfusion environment in the UK and has been the model for haemovigilance systems in several other countries (see section 10 for details).

91. **1998-2007 Chair, JPAC Standing Advisory Committee on Blood Components.** We wrote the specifications for all blood components produced by UK Blood Services.

92. **1998-2016: Member, UK Blood Services JPAC.** As discussed in more detail in Section 10, this is the main group producing guidance for the 4 UK Blood Services (Guidelines for the UK Transfusion Services, 'Red

Book'), covering donor selection, testing and manufacture of blood, stem cell and tissue products, and also overseeing production of the Handbook of Transfusion Medicine. I was initially a member as Chair of SACBC, then from 2007, as NHSBT's Medical Director.

93. **2004-2011 Chair, UK Blood Services Prion Reduction Working Group (PRWG).** This was established to examine emerging technologies for the removal of infectious prions from blood components. There was a parallel group on prion testing chaired by Professor Marc Turner, SNBTS.

94. My other main responsibility in this joint University/NHS post was research. I had 2 research interests:

95. Neonatal alloimmune thrombocytopenia. This is an immune condition of newborns resulting in low platelets. It is not relevant to this inquiry and not discussed further.

96. Development of blood components to improve efficacy and safety. This dovetailed with my NBS responsibilities. Some of my research findings were made available to decision-making groups within NBS (later NHSBT) or at the UK level through JPAC or MSBT (later the Advisory Committee for the Safety of Blood, Tissues and Organs, SaBTO). These research studies included:

a. a clinical trial on leukocyte reduction to prevent alloimmunisation (Exhibit WITN0643016), and laboratory studies on removal of viruses (HTLV I and II and cytomegalovirus) by white cell filters (Exhibits WITN0643017 and WITN0643018)

b. studies on virus-inactivated blood components, e.g. solvent-detergent or methylene blue treated fresh frozen plasma ([NHBT0005103_009], Exhibits WITN0643019, WITN0643020, WITN0643014 (pages 253-254) and WITN0643015 , NHBT0042349)

c. analysis of haemovigilance data from SHOT to see whether white cell removal from the blood supply reduced the risk of serious immune complications such as transfusion-associated graft-versus-host disease and post-transfusion purpura (Exhibit WITN0643021).

97. Analysis of haemovigilance data from SHOT to see whether provision of fresh frozen plasma from male donors reduced the risk of transfusion-related acute lung injury (Exhibit WITN0643022).

98. I co-founded, with Professor Mike Murphy, the NBS Clinical Studies Unit, which undertakes national trials, with ethics approval and donor/patient consent, to improve the evidence base for the use of blood components.

99. **October 2007- May 2016: Medical and Research Director, NHS Blood and Transplant.** Clarification: Dr Angela Robinson, Medical Director and Professor Marcela Contreras, Director of Diagnostics, Development and Research, retired at about the same time in 2006. The research portfolio was combined with the Medical Director role, with Dr Tim Wallington acting as Medical and Research Director until October 2007. It should also be noted that my post did not cover BPL, which had a separate Medical Director (Dr Clive Dash).

100. In the Medical and Research Director role, I had 4 main broad areas of responsibility:

a) As a member of the NHSBT Board and Executive team, a shared responsibility for corporate decisions.
b) For the medical workforce - developing new posts and appointing new consultants, and ensuring annual job planning, appraisal and revalidation of all doctors as required by the GMC.
c) Governance and safety of clinical services within NHSBT. It should be noted that major policy decisions on blood safety were taken by DH, the latter usually following advice from SaBTO.
d) Oversight and organisation of NHSBT's research programme.

Specific roles relating to blood safety.

101. **Chair, Clinical Audit Risk and Effectiveness (CARE) Committee, and Lead Director for Safety, Risk and Clinical effectiveness**. I completely restructured the arrangements for clinical governance to ensure a systematic review of risks and solutions. The meeting agendas included review of any untoward incidents, whether donor/patient harm occurred or not, approval of any changes to practice, e.g. as recommended by JPAC, and review of any new external guidance. I also reported on clinical safety at every meeting of the Governance and Audit committee of the Board, chaired by a Non-Executive Director.

102. **Chair: Francis report review group**. This group produced the action plan following the Francis report and updates to the Board.

103. **Member, Transplant Policy Review Committee of the Board.** This group was responsible for UK patient selection for organ transplantation and the organ allocation policies.

104. **Caldicott Guardian** for data protection, working closely with the Senior Information Responsible Officer on information governance. There were a number of incorrect beliefs about data sharing. As clarified in 2014, in the second iteration of Dame Fiona Caldicott's principles for the use of data in the health and social care settings, (https://www.gov.uk/government/publications/the-caldicott-principles), I was keen to ensure that there was clarity that sometimes the duty to share data was as important as withholding it, e.g. as part of a patient's care.

105. **Please set out your membership, past or present, of any committees, associations, parties, societies or groups relevant to the Inquiry's Terms of Reference, including the dates of your membership and the nature of your involvement.**

106. I have listed here the membership of non-Blood Service UK bodies relevant to the Inquiry.

107. **Early 1990s Member, British Society for Haematology's Transfusion Task Force**. I chaired a group which produced the first UK guidelines for the Irradiation of Blood Components [BSHA0000003_023]. This is done for patients with impaired immunity to prevent the fatal complication Transfusion-Associated Graft-versus- Host disease.

108. **2007-2016: Member, Chief Medical Officer's National Blood Transfusion Committee.** This group drives optimal transfusion practice at the front line of the NHS.

109. **2010-2014 Chair, Royal College of Pathologists Transfusion Medicine Committee.** This group set standards for professionals working in the field and advised on training for specialist doctors and scientists.

110. **2011-2016: Member, DH Advisory Committee on Safety of Blood, Tissues and Organs (SaBTO).** This group provided advice to the Health Ministers and health departments of the four UK home nations. I was Chair of three working groups producing recommendations on: donation policies for tissues and cells by men who have had sex with men; pathogen inactivation of platelets; and hepatitis E. I discuss SaBTO further in section 18, under 'Issues'.

13. Who did you report to as a consultant to the NBTS, and later NHSBT?

111. My reporting lines changed as the organisation evolved, as follows:

a) 1991-92 to Professor Jean-Pierre Allain, Director EABTC
b) 1992-94 to Dr Morton McDougall, Acting Director, EABTC

c) 1994-1999 to Mr Peter Garwood, Director of Processing, Testing and Issue, London and SE (LSE) Zone, with professional accountability to Dr Sue Knowles, Clinical Director, LSE Zone.
d) 1999-2007 to Dr Angela Robinson, Medical Director NBS (NHSBT from 2005)
e) 2007-2015 to Lynda Hamlyn, Chief Executive, NHSBT.
f) 2015-2016 to Ian Trenholm, Chief Executive, NHSBT.

14. The Inquiry understands that consultants to the NBTS held annual meetings (see for example NHBT0007051_004). What was the purpose of these meetings? Did consultants meet more regularly in other forums?

112. The annual consultants' meetings were a mixture of education, information transfer from the Board via the Medical Director, and an opportunity for consultants to raise concerns and share problems. There was also a social element, with time to mingle in the breaks and over lunch. The meeting mentioned in the question took place in June 1998, at a particularly critical time for NBS. There was a new Chairman, and a new Chief Executive was about to be appointed. vCJD had appeared as a possible threat to the blood supply, and we were anticipating the Secretary of State's announcement on universal leucocyte depletion, which came in July 1998.

113. Over the years, there were different consultants' fora in addition. In the 1980s, the country had been divided into three divisions, and there were regular meetings of the consultants within each division. This was when all RTCs had a medically qualified Director in charge and when consultants also acted as line managers of the nursing, scientific and other laboratory staff in the centre.

114. When we moved to zonal management in 1995, I recall meetings of the consultants in the London and SE zone. Once consultants became more specialised, there were also zonal, and later national, meetings by

function, e.g. consultants and other doctors specialising in donor work, in microbiology, in components etc.

15. What was "The Blood Club"? Was this a purely social club or was it professional? Who were the members and what was its role? (NHBT0041282_003, page 4)

115. The 'Blood Club' referred to in the minutes of the EABTC Management Team on 8th April 1991 [NHBT0041282_003] referred to the East Anglian Blood Club, which was a meeting of all consultant haematologists in East Anglia, plus the medical staff from EABTC. The meetings, held two or three times/year, lasted for an afternoon, and were followed by an informal meal. The meetings were usually sponsored by a pharmaceutical company, which would have a stand but would not give a presentation. There would be educational talks, interesting cases presented by haematology trainees and an opportunity to discuss the issues of the day. EABTC usually had a slot to discuss forthcoming developments, either local or national. I found it an invaluable opportunity to develop good relations with colleagues around the region and hear any concerns they had about our service to them.

Section 4: Blood collection at EABTC

16. Please explain the system for blood collection at the EABTC during your employment there and how it changed over time.

116. When I arrived at EABTC, there was a donor clinic in the EABTC itself for the collection of apheresis platelets and whole blood. There were also three blood collection teams who went out from Cambridge to collect blood across East Anglia, sometimes staying away for a night or two. On each team, there would be donor attendants (as they were then called), one or more qualified nurses and a session doctor.

117. Between 1988 and 1990, I sometimes acted as the session doctor. At that time, only a doctor could insert the needle into the donor's arm and was also there to answer donor questions, make the final decision as to whether an individual donor should give blood on that day, and support the nurses if a donor became unwell. I always enjoyed these days out meeting donors, who in some places were willing to queue round the block to give blood.

118. Once the donor was greeted, a member of staff (nurse or donor carer) would give the donor an information pack, donor questionnaire, which is in tick box format and consent form and would ask the donor to read, fill in and sign. There was no routine verbal questioning of donors. The member of staff would then check the questionnaire, and if any boxes were ticked which might indicate health concerns or high-risk behaviour, the donor would have an interview with a member of staff. We tried to make this as confidential as possible, i.e. behind a screen, but not all venues could provide a sound-proof location. This interview might result in permanent donor exclusion or temporary suspension from donation while more information was sought, with the donor's consent, from the GP.

119. If the member of staff was happy that the donor met the health criteria, the donor's haemoglobin level was checked on a finger prick sample, which was dropped into a copper sulphate solution of known density. If the sample sank, the haemoglobin level was adequate for donation. If it floated, the donor was asked to defer and a venous sample taken for measurement of the haemoglobin on a blood counting machine back at EABTC. The donor would be asked to return after a period of time, e.g. 3 months, and maybe recommended to take iron tablets or visit their GP. The GP would be informed of the haemoglobin result.

120. The donor would then lie on a bed and a blood pressure cuff inflated to distend the veins in the arm. The skin would be cleaned, local anaesthetic injected, and the needle inserted. A donation of 450 mls

would be collected, usually within ten minutes, along with samples for testing for viruses and confirming the blood group. The donor would then rest for about ten minutes, then would have a drink or snack. The donor would be thanked, and a next appointment made. At each step, the donor would be asked to confirm their name and date of birth.

121. Over time, a number of changes were made, both in organisation and staffing and in the procedures at the session:

a) In 1991, it was agreed to establish a donor team in Thetford to serve Norfolk, with disbandment of one of the Cambridge teams, as discussed at a number of EABTC Management Team meetings, e.g. 4th March 1991 [NHBT0041285_004]. This would avoid staff having to stay away overnight so often and reduce expenditure on subsistence. This was led by Drs McDougall and Caffrey and had the support of the collection staff and the trade union. This turned out to be a huge success.

b) Over time in the 1990s, it became increasingly difficult to find good session doctors, and the need for a doctor at every session began to be questioned. Eventually, doctors were replaced by specialised and well-trained nurses, able to insert needles and deal with most donor questions. There was always a doctor on call on the telephone to support the nurses if tricky issues arose. Over time, the doctors on call for this work became only those whose day job was in donor care, with a separate on-call rota for doctors taking queries from hospitals. Later again, donor carers (as they were now called) were trained to insert needles, thus avoiding donors having to wait for a qualified nurse to be available for this step. Each donor session still has a qualified nurse as part of the team.

122. These changes have also been very successful and have been adopted in many other countries.

123. There have been many procedural improvements at donor sessions designed to improve the experience for the donor, minimise error, and enhance the quality of the donation. These include, but are not confined to:

i. An appointment system which now includes online booking, rather than sitting in a queue

ii. Full computerisation/barcoding of bags, samples and paperwork

iii. Trials of Haemacue and other machines to replace copper sulphate, including assessment of whether a finger prick sample, which many donors do not like, is necessary at every donation

iv. Following a clinical trial, donors are asked to drink a large cup of fluid before donation to minimise the fainting risk, and donors below a certain height/weight are no longer accepted for the same reason

v. At the request of donors, we ceased to use local anaesthetic routinely, although it remained available on request

vi. Improved skin cleansing with an abrasive sponge to minimise the chance of skin bacteria entering the donation

vii. Taking the samples from the donation pack rather than the donor's arm - this minimises mix-up of samples and by diverting the first portion of the donation, again minimises the bacterial risk

viii. Placing the donation on a mixer, with audible alarms should the flow rate drop, and when the required weight was reached

ix. Flat donation beds have been replaced by lightweight dental type chairs, a big improvement for donors and staff

x. Different post-donation arm dressings have been assessed and implemented to minimise bruising, another issue of concern to donors

xi. Donor wi-fi is available at fixed clinics

xii. The drinks and snacks have become more varied, with fruit as well as crisps and biscuits, although salty snacks may reduce fainting after donation.

17. What if any steps did the EABTC take to publicise itself to potential donor populations in order to increase donations? How successful were these steps? (NHBT0041285_004; NHBT0041230_001; NHBT0041234_002)

124. The documents referred to above are all minutes of the EABTC Management Team between January and March 1991, when all RTCs were asked to collect extra donations to be sent to the Army Blood Supply Depot to support the first Gulf War. East Anglia was also home to two air force bases, and it was anticipated that the region could receive as many as 500 casualties in the first wave. Cancellation of routine surgery was also a possibility.

125. I returned from maternity leave in January 1991 to find that the comprehensive Gulf War plan produced by the RHA had made no mention of blood requirements for the region. Plans were therefore developed rapidly to collect the extra blood required, with extra publicity. I think the BBC may have made a national appeal. In any event, we were able to meet the requirements for the extra blood. Thankfully, very little of it was needed, either in the Gulf or in the region.

18. The minutes of a meeting of the EABTC Management Group in February 1991 refer to changes in "special donor recruitment" for plasmapheresis donors (NHBT0041230_001). Please explain how the EABTC's special donor recruitment programme differed from that for regular donors during your tenure. What were the changes introduced following this meeting?

126. This minute refers to two groups of donors (1) bone marrow donors (2) plasmapheresis donors. Dr Rankin was proposing steps to increase recruitment, but apart from new information leaflets to be placed at routine blood donor sessions, I'm afraid I cannot recollect any other specific recruitment steps for these types of donors.

19. The Inquiry understands that the EABTC's policy was to not collect blood from prisons, borstals and similar institutions, although the EABTC reserved the right to collect blood from these sources in emergencies (NHBT0008628_001).

a. Are you able to provide any further information as to the extent to which the EABTC collected blood from prisons, borstals and similar institutions, either during your tenure or earlier?

127. From the time I arrived at EABTC in 1988 until we moved to zonal management in 1995, I regularly attended donor session planning meetings to be sure that the collection and manufacturing timetables dovetailed correctly. I do not ever recall us scheduling a donor session at any type of offenders' institution, nor even discussing it.

128. I note that the document referred to, a survey of practice at RTCs in England carried out by the Scottish RTDs [NHBT0008628_001], which reported that EABTC had collected blood at an open prison on a single occasion during a blood shortage in 1982. They had, however, discovered that the residents included many intravenous drug users, so they had never gone back. Given that event, I cannot imagine that the consultants running EABTC in the 1980s would have contemplated returning to such a practice.

b. As far as you can recall, did any emergency situations arise during your tenure which necessitated the use of blood from these sources ?

129. No, never. East Anglia was a good region in terms of blood donation and during my time as a local consultant (1991-95), we rarely ran into shortages. Even if we had, the Management Team would certainly not have contemplated collection from any offenders' institution.

20. Please describe the way in which donations were collected at the EABTC during your tenure. In particular:

a. What were the staffing arrangements during blood donation sessions?

130. I have covered staffing under Q16 above.

b. Where did these sessions take place?

131. There was a donor clinic within EABTC itself, mainly for apheresis donors, but it also collected whole blood. Otherwise, we hired venues across East Anglia, such as village, church or school halls, and we also carried out sessions at places of work. At some point, there was a Bloodmobile vehicle operating in East Anglia, but I think that was in the NBA era.

c. How frequently could a person donate blood?

132. From memory, I think men could donate three times/year and women twice/year.

d. How were blood donors recruited? (NHBT0002534)

133. In common with other RTCs, EABTC had an ongoing programme of publicity involving local newspapers, flyers delivered door-to-door by local volunteers and other specific publicity based on local knowledge, e.g. markets, football grounds etc. The use of volunteers was later discontinued on the grounds of data protection.

134. Once the NBA was created, there were zonal and national recruitment campaigns as well as local advertising.

e. Were there any age restrictions on blood donors? (NHBT0041235, NHBT0041284)

135. In the RTC era, EABTC operated a strict 'retire on 65th birthday' policy for blood donors. At the EABTC Management Team meeting on 10th October 1990 [NHBT0041235], Dr McDougall reported that he was receiving complaints from donors who wanted to continue past this age. It was agreed that, since Dr Blagden was still responsible for blood donors (he was about to retire), we would keep this rule for the moment but would plan to change it in the New Year to fit with what was permitted in the newly published 'Red Book', i.e. the Guidelines for the UK Transfusion Services. At the Management Team meeting on 11th March 1991 [NHBT0041284], Dr Rankin reported that she was putting in place new arrangements for regular donors to carry on donating until their 70th birthday.

136. The minutes of the MSBT meeting on 28th February 1998 [SBTS0000516_001] record that the age limits for donation would now be 17th to 70th birthdays.

137. At some point, again, in response to donor pressure, the UK Blood Services moved to have no upper age limit, and regular donors could continue for as long as they wished, provided they met the health criteria.

f. What questionnaires were used at donation centres, were there any improvements in these during your time at the EABTC? (NHBT0041396)

138. I cannot remember the details of the questionnaires in use at that time, but as a blood donor, I remember that they covered details of general health, travel to malarious areas and questions about injected drug use. Men were also asked about same-sex contacts.

139. From the document referred to above, which is a minute from the EABTC Management Team Meeting on 10th January 1994, it appears that a new national donor questionnaire had come into use, as our Head Nurse and one of the session doctors had been on a training course. I am sorry I cannot remember the details of this leaflet.

g. Did any of these matters alter during your tenure? If so, how?

140. I have covered changes under Q16 and Q20e above. The national donor questionnaire was updated from time to time, but I cannot remember details of when.

21. Did the EABTC have donation collection targets that it was required to meet? If so, who set these and how was this done?

141. The responsibility of EABTC was to meet the demand for blood for our hospitals in the region without running into shortages or outdating too much blood. In the RTC era, setting a collection target was largely a local matter, but I think when the National Directorate was created, data had to be returned on stock and outdated blood. Between 1990 and 1995, when I was a consultant and EABTC was operating regionally, we tried to gain intelligence about developments in regional hospitals which might have a big impact on demand for blood, e.g. development of the liver and bone marrow transplant programmes at Addenbrookes Hospital, Cambridge. This was not very systematic, however, and sometimes even the local haematologist would not be aware of new local developments.

142. Once the NBA was created, targets were set for each zone, with blood collection planning being done in the context of the wider geography. For example, some donor sessions in the east of Suffolk transferred to collection teams based at Brentwood.

22. Did the EABTC meet any donation collection targets in place during your tenure? If not, why not?

143. I do not recall particular blood shortages during my time when EABTC was accountable to the RHA. We actually had untapped donor potential, and in the discussions between Brentwood and Cambridge about rationalising services between the two centres (3rd November 1992, NHBT0002534], it was suggested that Cambridge should commit to a regular supply to Brentwood. This did not happen straight away, as Dr Gunson did not want any new cross-regional contracts to be set up in the run-up to creating the NBA (reported at the EABTC Management Team meeting on 22nd February 1993 [NHBT0035813]. By September 1994, as reported at the EABTC Management Team meeting on 19th September [NHBT0037680], Cambridge was accepted as a net exporter. I recall regular shipments to either NE Thames (Brentwood) or NW Thames (Colindale), amounting to 10-20,000 units/year.

144. Under zonal and national management, there were shortages from time to time, and the Blood Stocks Management scheme devised a red/amber/green system for monitoring and moving stock round to minimise the impact on hospitals.

23. What was done to improve blood collection? What more could or should have been done? What were the barriers?

145. As discussed above, I do not recall any particular difficulties with blood collection during my time at EABTC during the RTC era (1988-95). The zonal and national arrangements meant that national advertising could be organised and funded, which included celebrities on television, and an innovative 'missing ABO' campaign where companies agreed to have their logos used with the ABO letters missing.

Section 5: Plasma procurement and production of fresh frozen plasma at EABTC

Production of fresh frozen plasma

24. The Inquiry understands that EABTC procured plasma from blood donor sessions to produce fresh frozen plasma ("FFP") to provide to the Blood Products Laboratory ("BPL"). Please explain:

a. where the production of FFP took place (NHBT0006237);

146. Manufacturing of all blood components, including plasma for BPL, took place in the manufacturing laboratory at EABTC. This was in a new extension to the building, which opened in around 1990.

b. broadly, the process that was undertaken, the capacity of the EABTC to manufacture FFP and whether this changed during your tenure and why;

147. Whole blood donations were centrifuged so that the red cells sank to the bottom, and the clear plasma floated to the top. The bags were squeezed between two plates so that the plasma passed along a tube into a separate pack, and the tubing cut to free the plasma pack. This was an entirely closed system so that sterility was maintained. The plasma packs were rapidly frozen to minus 40 degrees Centigrade in a controlled rate blast freezer, then stored at minus 40 degrees C until transported to BPL in a minus 40 degrees C trailer. I think the trailer went two or three times/week.

148. Plasma collected by plasmapheresis was frozen and transported in a similar way.

149. I discuss capacity under the next question.

c. what proportion of blood collections were allocated to this process and how this decision was made, and whether this changed over time; and

150. As noted in the inspection of EABTC on 25th-27th July 1990 [NHBT0006237], EABTC produced 34,528 units of whole blood and 47,917 units of red cells, i.e. the plasma had been removed. Issuing 42% of donations as whole blood is not clinically indicated, as pointed out in Dr Willem Ouwehand's document 'East Anglia BTS towards the year 2000' [NHBT0006237]; he was suggesting we aim for less than 1% whole blood.

151. The inspection report of July 1990 noted provision to BPL of 41,610 plasma units/year, which, assuming 3 units = roughly 1 kg, equates to 13,870 kg, or 13.78 metric tonnes. We also provided to BPL 2,256 kg/year (2.2 metric tonnes) of apheresis plasma, making a total of 16,126kg (16.1 metric tonnes) of fresh frozen plasma. We also provided 1,300kg (1.3 metric tonnes) of 'time-expired plasma', i.e. plasma removed from blood donations which had reached the end of their shelf life without being issued to a hospital. This material did not contain enough factor VIII for the manufacture of clotting factor concentrate but could be used to make other plasma products, e.g. albumin.

152. My understanding is that in the 1980s, plasma targets for each RTC were reached by negotiation with BPL, up to BPL's limit of the amount it could fractionate. I am not sure what drove the amount of plasma being sent to BPL by EABTC up to1990. It could have been the maximum amount offered by EABTC, which in turn could have been limited by local production capacity before the manufacturing extension was built. Alternatively, EABTC plasma provision could have been limited by clinician demand for whole blood, though a figure of 42% seems unlikely on that basis (see below for a further discussion of this). Equally, it could have been due to the finite fractionation capacity at BPL. I cannot remember ever being told the exact reason, but since EABTC's population-based target for 1991-2 was 19 tonnes, it appears from the documents provided that EABTC's manufacturing capacity before the new wing was built may have been the rate-limiting step.

d. how quickly the EABTC could have increased its manufacture of FFP, had it wished to.

153. I cannot comment on what would have been possible during the 1980s, but from 1991 onwards, we embarked on a programme to reduce the amount of whole blood issued and concomitantly increase the amount of plasma sent to BPL. We had a new manufacturing suite, so space was not a limiting factor. I think we also introduced an evening processing shift.

154. Most clinicians in East Anglia were agreeable to this, as all medical patients, who probably used about half of all blood collected, would be served just as well with red cells as with whole blood. Indeed, the extra volume of whole blood may have been detrimental to them. We continued to provide whole blood to support cardiac surgery at Papworth Hospital and the liver transplant programme at Addenbrooke's Hospital, and I think we issued smaller amounts to other hospitals for trauma and major surgery. From the documents provided and my calculations, I think the figure we reached for whole blood in the first couple of years was in the region of 20%, making an extra 16,000 donations available for processing into plasma for BPL.

155. As recorded at the EABTC Management Team minutes of 7th January 1991 [NHBT0041234_002], we also increased the production of platelets by apheresis, thus making even more whole blood donations available for separation into red cells and FFP for BPL. EABTC Management Team minutes on 4th March 1991 [NHBT0041285_004] record that we had offered BPL 24 tonnes of fresh frozen plasma (a 50% increase) for 1991-2, but that they were willing to accept only 20.9 tonnes in total, consisting of 19.0 tonnes from whole blood and 1.9 tonnes from apheresis. Our plan to reach 24 tonnes included purchasing automated equipment for whole blood processing, changing to the 'bottom-and-top' method, which was standard in the Netherlands and proposed by Dr Ouwehand [NHBT0010585_002]. This method also

produces high quality platelet concentrates, a further benefit for patients. EABTC management team meeting minutes from 18th March 1991 [NHBT0041283_002] record that BPL's decision not to accept 24 tonnes of plasma meant that purchase of the automated equipment would have to be put on hold for financial reasons.

156. At the EABTC Management Team meeting on 10th August 1992 [NHBT0035847], I reported that BPL had agreed to take an extra 1.4 tonnes of plasma from whole blood, plus 500kg more of apheresis plasma. However, by 1994/5, BPL's demand for plasma was dropping, possibly in anticipation of the switch of haemophilia patients to recombinant products. At this point, the NBA took over, and negotiations were between BPL and zonal management teams.

25. As far as you are aware, how was plasma procurement at EABTC funded throughout the 1980s?

157. My first post in an RTC was in Sheffield in 1985. My understanding from that time is that it was accepted that provision of plasma to BPL was a core responsibility of RTCs, so the manufacturing costs were included in the budget which the RHA set for EABTC. Plasma products, as discussed further in Section 6, were provided without charge to regions on a pro-rata basis, i.e. in proportion to the amount of plasma provided to BPL. This was in acceptance that BPL would not be able to meet all hospital demand for fractionated plasma products.

158. On 1st April 1989, a system of cross-charging was introduced so that BPL paid each RTC for the amount of plasma provided, and then RTCs paid BPL for the products it needed to supply its hospitals, who I recall then reimbursed the RTCs. I learned later that not all RTCs acted as distributors for BPL products.

26. Please describe the arrangements for supplying FFP to hospitals and haemophilia centres within the region covered by the EABTC. Please

include any arrangements to supply FFP outside the NHS (i.e. to private hospitals). You may find NHBT0041234_002 item 5 of assistance

159. The vast majority of FFP units provided to hospitals are used to treat patients whose clotting system has become abnormal due to trauma, sepsis, major surgery or other rarer conditions. It is also used for plasma exchange to treat the rare condition TTP. It is used only to treat any inherited bleeding disorders for which a clotting factor concentrate is not available. I discuss cryoprecipitate under Section 7.

160. We were generally able to meet hospital requests for FFP. Occasionally stock of a particular blood group would run low, and there would be a discussion with the hospital regarding which other groups could safely be used.

161. There was minimal to no impact of supply to private hospitals on our ability to supply NHS hospitals across East Anglia.

Plasma targets

27. The Inquiry understands that the EABTC had targets for the amount of plasma that had to be collected by the centre, as you wrote in a letter to Dr Moore, the Deputy National Director of the North Western Regional Health Authority on 13 March 1991 (NHBT0003342). Who set these targets? What was the purpose of the targets?

162. The targets were set through a process of negotiation between BPL and the RTC to ensure that BPL's target for overall plasma procurement was met in an equitable way. My understanding was that the regional targets were set in proportion to the population of that region. This was one of the questions I put to Dr Moore, Deputy Director of NBTS, in my letter of 13th March 1991, since EABTC had the capacity to produce up to 24 tonnes of plasma for 1991-2, as opposed to our population-based target

of 19 tonnes. As explained under Q24d, BPL declined the extra plasma for that year.

28. The Inquiry understands that the EABTC's plasma target for 1991-1992 was 19,000kg (NHBT0003342). Can you recall whether the EABTC had a similar target throughout the duration of your tenure, or was the target subject to change?

163. I have covered this under Q24d above.

29. What impact did the setting of targets for the collection of plasma have on decision-making at the EABTC? You may find NHBT0041234_002, NHBT0041283_002, NHBT0041284, and NHBT0041285_004 of assistance.

164. From 1991 onwards, the EABTC management team was committed to providing BPL with as much plasma as possible, along with top-quality blood components for patients in the region. The introduction of cross-charging for plasma and fractionated plasma products from 1989 onwards meant that there was income which could be reinvested in both endeavours, e.g. purchase of automated processing equipment, which would have resulted in even more plasma being available.

165. However, if BPL did not wish to purchase extra plasma, or if its demand for plasma fell below the baseline population-based target, the RTC income would drop, and we would not be able to balance the books. One of the issues was that BPL plasma targets were set one year at a time, making planning difficult.

30. What were the consequences if the targets were not met? (NHBT0041234_002)

166. Before 1st April 1989, there was no cross-charging between BPL and RTCs, but regions received plasma products pro-rata to the amount of plasma received. Therefore, if a region did not meet its plasma target, the hospitals in that region ran the risk of shortfalls in the supply of BPL products, increasing their reliance on commercial concentrates.

167. After 1st April 1989, the supply of plasma products from BPL to RTCs was financially based and no longer directly coupled to the provision of plasma. However, RTCs had to purchase these plasma products from BPL and could only do so within their budgets, one aspect of which was income from BPL from plasma. So, the uncoupling of product supply from plasma provision was not absolute. If an RTC failed to meet its plasma targets, it ran the risk of going into the red financially, which until the NBA was created, would have been a matter for the RHA to deal with.

168. I discuss the tension between RTC's wish and need to provide plasma to BPL with their regional obligations and accountability in Section 18, under Issues.

31. Were there any benefits to the EABTC if the targets were exceeded?

169. Conversely to the above, provision of extra plasma to BPL (if they agreed to take it) before 1st April 1989 meant more BPL products for that region and less dependency on commercial concentrates.

170. After 1st April 1989, provision of extra plasma to BPL meant more income which could be reinvested in the manufacture of more plasma, e.g. by automated processing or plasmapheresis. Provision of factor VIII concentrates was based on the number of haemophilia patients in that region [NHBT0057426_002].

32. Were targets agreed following discussion between the EABTC and BPL? Was there ever uncertainty around the targets or the quantity of plasma

that could be processed by BPL? If so, how did this uncertainty impact upon the operation of the EABTC? (NHBT0041285_004; NHBT0035837; NHBT0041403)

171. Yes, annual targets were agreed between BPL and all RTCs. When the National Directorate was created, discussion on targets was done through Dr Moore, Deputy Director. The EABTC Management Team expressed concern on 30th November 1992 [NHBT0035837] and 16th August 1993 [NHBT0041403] that there was uncertainty regarding plasma targets for 1993-4 and 1994-5 respectively.

172. At the 16th August 1993 meeting of the EABTC Management Team [NHBT0041403], I tabled a draft letter to Mr Barry Savery, National Finance Director, expressing concern at the adverse effects on EABTC of the short-term planning decisions regarding BPL's plasma requirements.

33. In 1989, cross-charging was introduced in England and Wales to act as an incentive for RTCs to increase the amount of plasma being sent to BPL (see NHBT0057426_002). As far as you are aware, what effect (if any) did cross-charging have on the plasma supply in England and Wales?

173. I do not feel able to comment on the national picture. There were frustrations at EABTC during 1991 that the extra plasma we offered to produce was not accepted at BPL. I cannot recall if we were told whether this was due to limits on fractionation capacity or for financial reasons.

Plasmapheresis

34. As early as 1981, plasmapheresis was being considered as a means of increasing the plasma supply to help achieve self-sufficiency (CBLA0001287). Please explain, as far as you are able, what consideration EABTC gave to implementing plasmapheresis, including:

a. whether manual or machine plasmapheresis was preferred;

174. As confirmed in the inspection report [NHBT0006237], EABTC was running a plasmapheresis programme in the centre by 1991, using automated plasmapheresis equipment, with 100-120 donors/week. When I was training at the Sheffield RTC in the mid-1980s, there was also automated plasmapheresis running. New machines were being evaluated to increase plasma provision to BPL. I do not recall ever seeing manual plasmapheresis at either location.

b. the relative cost differences between each method;

175. I have no detailed price information, though I believe that automated plasmapheresis was more expensive. However, as a clinician, I would not have recommended manual plasmapheresis, as it would have been very suboptimal for the donor, requiring a whole blood donation to be taken, transferred to the laboratory, the plasma separated, and the red cells returned to the donor.

c. the infrastructure, expertise and capacity of EABTC to introduce plasmapheresis; and

176. I have covered this in Q24d above.

d. whether, in your view, plasmapheresis would increase the amount of available plasma.

177. There is no question that a huge expansion of plasmapheresis nationally would have increased plasma provision towards self-sufficiency, although the resources and costs would have been considerable. In his paper of 23rd February 1981 [CBLA0001287], Dr Gunson had calculated that to achieve self-sufficiency, 283 tonnes of plasma/year would need to be collected by plasmapheresis, equating to 28 plasma collection centres

and 55-60,000 donors. This would have been a huge task but probably achievable, provided (1) funding and staffing could have been obtained and (2) the number of donors could have been achieved.

35. Please set out the extent of the plasmapheresis programme at EABTC during your tenure. As far as you are aware, did this programme differ from other RTCs? If so, why? You may find NHBT0006237 and NHBT0041283_002 (page 2) of assistance.

178. I have set out the plasmapheresis programme at EABTC in Q24d above. I am not aware of fundamental differences in approach to other centres, nor whether the amount we collected/head of population differed from other centres.

Use of plasma reduced blood and red cell concentrates

36. What steps, if any, did EABTC take to persuade hospital clinicians to use less whole blood and more red cell concentrates and/or plasma reduced blood to release more plasma for fractionation?

179. I have covered our initial steps in 1991-2 in Q24d above. From memory, I think that the demand for whole blood continued to fall, as we worked with haematologists and other clinicians on the clinical benefits of using components (red cells, platelets, FFP and cryoprecipitate) as determined by clinical need, particularly the results of clotting tests, rather than simply replacing the whole blood which had been lost.

Section 6: Arrangements for obtaining and allocating blood products at EABTC

37. Please describe the arrangements in place in the East Anglian region for the purchase and holding of, and the allocation to haemophilia centres

within the region, of (a) NHS factor concentrates and/or other blood products ("NHS blood products")

180. EABTC acted as a purchaser and distributor for BPL plasma products, for which we had to obtain a Wholesale (Dealers) Licence from MCA. When BPL was able to fulfil all the orders, we simply distributed them. Sometimes there were shortages, particularly of albumin, which required discussion with the hospitals. I do not recall any system of batch allocation of products to individual hospitals operating during 1988-95, but as all clotting factor concentrates were virus inactivated by then, this may have been thought not necessary. Normal stock control practice would have operated.

and (b) imported factor concentrates and/or other blood products ("imported blood products").

181. EABTC did not handle commercial/imported clotting factor concentrates at any time during my tenure.

In particular:

a. Please identify which haemophilia centres were supplied with such products by the EABTC and over what period of time.

182. I think that between 1991 and 1995, we supplied BPL products to the haemophilia centres at Addenbrookes hospital, Cambridge and the Norfolk and Norwich Hospital, Norwich. Other hospitals may have received smaller quantities of concentrates to be collected by patients on home treatment.

b. Please outline the respective responsibilities of the EABTC, BPL, the East Anglian Regional Health Authority ("East Anglian RHA"), and haemophilia centre directors, and how these responsibilities changed over time.

183. The haemophilia centre directors were responsible for determining which products they wished their patients to receive and telling EABTC what volumes of clotting factor concentrates from BPL they needed each year. EABTC then ordered these from BPL, then stored and distributed them to meet hospital orders. BPL took the orders from EABTC and delivered the products to EABTC. The RHA may have handled some of the financial arrangements before the NBA took over.

38. Please explain whether any forums were established between the EABTC, BPL, the East Anglian RHA, and haemophilia centre directors to discuss and facilitate these arrangements. Were meetings held regularly? Were they minuted? If so, by whom? What was discussed at these meetings?

184. I recall meetings with Dr Ernie Gascoigne, BPL to discuss plasma product requirements, and also with Dr Trevor Baglin, Haemophilia Director, Addenbrookes Hospital, but I do not recall any formal meetings which were minuted.

39. As far as you are aware, were arrangements for the purchase, holding, and distribution of (a) NHS blood products and (b) imported blood products similar in other regions, or was there a degree of regional differentiation (and if so what)?

185. From memory, I think arrangements were patchy, with some regions distributing BPL products while others choose not to do so. I am not aware whether any RTCs distributed commercial products, either alone or alongside BPL products. I think Sheffield only handled BPL products, for instance, and I am sure EABTC did likewise.

40. The minutes of a meeting of the EABTC Executive Committee in January 1992 refer to discounts offered by BPL if RTCs would take complete responsibility for ordering and delivering BPL products to hospitals in

their region (NHBT0035861). Please explain whether the EABTC entered into any arrangements of this nature with BPL.

186. Yes, EABTC acted as a purchaser and distributor for BPL plasma products, for which we had to obtain a Wholesale (Dealers) Licence from MCA.

41. Did you, or anyone else at the EABTC, contract directly with any pharmaceutical company involved in the manufacture and/or importation and/or sale of imported blood products?

187. No, EABTC never handled commercial plasma products of any type, the exception being for the trials of SDFFP discussed in Section 13.

188. In 1991, budgets for blood components and plasma products were devolved to districts. Hospitals in our region were very loyal to BPL in their choice of supplier of plasma products (as far as BPL supplies allowed), but at the EABTC Management Team meeting on 19th October 1992 [NHBT0035842], I reported that haematologists were being put under pressure to buy cheaper commercial products. I cannot recall whether this included clotting factor concentrates as well as albumin and immunoglobulin. The management team affirmed that we would not undertake the distribution of commercial concentrates.

If so, please describe:

a. how and by whom the decision was made to contract with the particular pharmaceutical company;

b. the broad terms of the contractual agreements made; and

c. the factors taken into account when determining whether to contract with one pharmaceutical company over another.

189. EABTC never purchased or handled commercial clotting factor concentrates, so Q41a-c do not apply.

42. What was the **impact on the EABTC of shortfalls in NHS product coming from BPL? How frequently did this occur?**

190. Shortfalls, particularly of albumin, were not infrequent. These were very irritating to us at EABTC, as they undermined our attempts to keep East Anglian hospitals loyal to BPL products. For the hospitals, it inevitably pushed them towards commercial products. I was never made aware of any serious impacts on individual patients because the hospitals made sure they always had stock, be it commercial or from BPL.

43. Was the EABTC in any way responsible for decisions about the choice of product used to treat patients in haemophilia centres and/or hospitals, for example the choice between one imported factor concentrate over another?

191. In a general sense, I tried to encourage East Anglian hospitals to use BPL products, but none of us at EABTC could ultimately take the decision. We certainly didn't enter into discussions that I can remember over the choice of commercial products.

44. If haemophilia centre directors were responsible for these decisions, did the EABTC have any influence over their product choices?

192. No, as per Q43.

45. What, in your view, were the key factors influencing the choice between NHS blood products and imported blood products?

193. During my consultant tenure in the RTC era, all plasma products were considered virally safe. Therefore, choice of product would likely be based on other factors, such as the tendency of a given product to cause reactions in patients, reliability of supply, and of course, cost. The big concern regarding clotting factor concentrates was whether they

triggered production of factor VIII antibodies (otherwise known as inhibitors) in the patient.

46. Please explain, in your view, the impact of clinical freedom on the relative use of NHS blood products and imported blood products in the UK.

194. Haemophilia directors, and other clinicians were free to prescribe any plasma products they chose, provided their hospital was willing to pay for them. My contact with haemophilia centres in the 1990s suggests that practice was very mixed, with some preferring commercial products, and others using BPL products as far as possible.

47. As far as you are aware, what influence did pharmaceutical companies have in the way that the imported blood products they supplied to the East Anglian Region were used? For example, can you recall whether pharmaceutical companies provided advice on the use of the products?

195. Pharmaceutical companies would have talked directly to clinicians and hospital pharmacists about the use of their products. I expect they would have covered indications for their use. EABTC medical staff were not involved in these discussions.

Section 7: Production of cryoprecipitate at EABTC

48. The Inquiry understands that the EABTC produced cryoprecipitate (see point 5 of NHBT0006237). Please describe:

a. where the production of cryoprecipitate took place;

196. This was in the manufacturing suite at EABTC, from single unpooled units of FFP. This is in contrast to the manufacturing process at BPL, where production of cryoprecipitate from plasma pools was the first step

in factor VIII manufacture. No cryoprecipitate from BPL was ever reissued for hospital use.

b. broadly, the process that was undertaken, the capacity of the EABTC to manufacture cryoprecipitate and whether this changed during your tenure and why (NHBT0001565);

197. To make cryoprecipitate, single units of plasma from whole blood donations were rapidly frozen to minus 40 degrees C, then thawed in the fridge at 4 degrees C overnight. This caused certain 'cryoproteins' to precipitate out in clumps. These included the clotting factor VIII (eight), fibrinogen, and factor XIII (thirteen). The thawed packs were then centrifuged, causing the cryoprecipitated proteins to fall to the bottom. Most of the plasma was then squeezed over into another bag as 'cryo-poor plasma' or 'cryosupernatant', leaving the cryoprecipitate in about 30 mls of plasma. This meant that larger amounts of these clotting factors could be given to patients without the risk of fluid overload, which could have resulted from the equivalent amount of FFP.

198. The MCA inspection report of July 1990 [NHBT0006237] records that EABTC had manufactured 1,961 units of cryoprecipitate in the latest annual figures. This amount was to satisfy demand from regional hospitals. I commented in my letter of 5th November 1992 [NHBT0001565] to Dr Moore, NBTS Deputy Director, that nearly all the cryoprecipitate which we produced went to support the liver transplant programme at Addenbrookes Hospital.

199. My letter to Dr Moore was a reply to his enquiring as to whether we could provide BPL with any cryo-poor plasma (NOT cryoprecipitate) for the manufacture of a new product, fibrin glue, used to stem bleeding from raw surfaces. I replied that, unfortunately, we were not able to do so, as we were now offering cryo-poor plasma to regional hospitals for specific clinical situations (1) to reverse warfarin anticoagulant for

patients about to undergo heart surgery at Papworth Hospital (2) for plasma exchange procedures to treat the rare condition TTP.

c. what proportion of blood collections were allocated to this process and what sent to BPL and how this decision was made, and whether this changed over time; and

200. The 1,961 units of cryoprecipitate manufactured in 1990 was from a total of 82,000 donations collected, so about 2.4% of the total. This contrasts with the 41,610 units of plasma derived from whole blood sent to BPL (50% of the total). So, hospital demand for cryoprecipitate had minimal impact on provision of plasma to BPL. Hospital demand for FFP had a slightly bigger impact, with 6,878 FFP units issued, or 8.4% of the total donations collected.

201. Given that there was already a mixed commercial/BPL economy in plasma products, we took the view that we needed to supply regional hospitals with all the FFP and cryoprecipitate which were needed to treat patients, with the remainder going to BPL. I have discussed under Q24d the great extent to which EABTC increased its supply of plasma to BPL between 1991 and 1994 without detriment to patients in the region.

d. how much funding was provided by East Anglian RHA for the production of cryoprecipitate.

202. There was no specific funding for cryoprecipitate production. Given that cryoprecipitate amounted to about 1% of all components issued, its manufacture had a very limited impact on our budget.

49. Please explain what consideration EABTC gave to increasing the production and use of cryoprecipitate in response to the growing awareness of the risks associated with Factor VIII concentrate products in the 1980s.

203. I cannot comment on this, as I did not arrive at EABTC till 1988 and was not a consultant till 1991. By then all clotting factor concentrates were virally inactivated.

50. Please describe the steps taken by the EABTC to increase the production of cryoprecipitate during this time. If no steps were taken, please explain why.

204. As per my answer to Q49.

51. Did the EABTC ever collaborate with other RTCs in the production of cryoprecipitate? (NHBT0035837)

205. During the early 1990s, we entered into discussions with the NE Thames RTC at Brentwood with a view to rationalising some small-scale specialist activities between the two centres. Cryoprecipitate manufacture was on the list of possibilities. I cannot recall whether this happened, as, under zonal management arrangements, all manufacturing and donation testing activity moved from Cambridge to Brentwood anyway.

52. Please describe the arrangements for supplying cryoprecipitate to hospitals and haemophilia centres within the region covered by the EABTC.

206. There were no specific arrangements for cryoprecipitate, as we were able to supply as much as hospitals needed. It was included as a routine request in hospital orders for the daily deliveries of red cells, platelets and FFP, shipped under conditions to prevent thawing. We could also send one-off orders for urgent cases by 'blue-light' vehicle if necessary.

Section 8: Self-sufficiency

53. 'During your time at EABTC what did you understand the term 'self-sufficiency' to mean? Did this change over time?

207. I have always understood self-sufficiency in this context to mean that a country could meet its need for plasma products by plasma collected from donors within that country. It might mean fractionation within the country by a commercial or public sector fractionator or shipping the plasma to a fractionator in another country. The key point is that plasma products used in the country are manufactured from plasma collected in that country. My understanding of this has not changed.

54. In your experience at EABTC, to what extent was 'self-sufficiency' a concept that informed the following:

a. plasma procurement;

208. As I have explained above, EABTC did everything possible in the early 1990s to provide as much plasma as BPL could take, although there were times when BPL could not take it all. I do not know why in the 1980s EABTC did not send more plasma to BPL. The manufacture may have been limited by insufficient space at EABTC prior to the opening of the new manufacturing suite in 1990.

b. decisions with regard to cryoprecipitate production;

209. As explained in section 7, production of cryoprecipitate was entirely to meet the needs of regional hospitals. This had only a very small impact on the amount of plasma available to send to BPL. We used 1,961 units of plasma to manufacture into cryoprecipitate, compared to the 41,610 units of plasma which we sent to BPL. If we had ceased cryoprecipitate production altogether, availability of plasma to BPL would have increased only by 4.7%.

c. purchases of commercial blood products;

210. EABTC never purchased or handled commercial blood products. As far as the hospitals were concerned, they had to purchase commercial products because England & Wales were never self-sufficient in plasma products.

d. funding received from the East Anglian RHA.

211. The number of whole blood donations collected by EABTC was driven by the requirements of the regional hospitals for red cells/whole blood. Other components (FFP, cryoprecipitate, platelets and most plasma to BPL) were mostly by-products of whole blood collection. Therefore, the bulk of our EARHA funding was to meet the needs of the region. Separation of plasma for BPL, and particularly its freezing, storage and transport, incurred additional costs. From 1989, BPL reimbursed RTCs for the plasma on a unit cost basis. I am not sure whether this reimbursement exactly balanced the extra costs of plasma handling or whether there was a small cross-subsidy from/to the RHA. So, in day-to-day terms, I do not think RHA funding, at least post April 1989, impacted materially on our ability to supply BPL with plasma.

212. However, the situation regarding investment in facilities and equipment was not helped by having two funders. For example, we wished to purchase automated equipment for component processing (EABTC Management Team minutes of 18th March 1991, NHBT0041283_002), which would have provided better quality platelets and more plasma to BPL, but since BPL could not accept the extra plasma, we could not make the additional investment needed.

55. What was your view on the prospect of the UK achieving self-sufficiency?

213. I always thought it was a worthy aim, having started my career in Scotland, where the Protein Fractionation Centre (PFC) was able to fractionate enough plasma to make Scotland self-sufficient in plasma

products. With the passage of time, however, self-sufficiency in England seemed to become less and less likely, for reasons which were never clear to me. When plasma products became virally safe, I think I became used to the mixed economy, not helped by intermittent shortages from BPL. It is interesting that the Eastern Division of haematologists recorded, at their meeting on 24th May 1990 [NHBT0118144], their concern that we still did not have self-sufficiency. Although I was at that meeting, I cannot recall the discussion. It is a pity that their reasons are not minuted because by then, all clotting factor concentrates were virally inactivated.

214. However, the issue is still pertinent. Apart from the safety aspects, it seems to be undesirable to have such important medicines dependent on a fluctuating international plasma market and on multinational companies for whom supplying, the UK might not always be their top priority. The current shortage of immunoglobulin illustrates this.

215. I recall several discussions at the European Blood Alliance between 2007 and 2016 as to whether Europe should try to achieve self-sufficiency in plasma products to reduce dependence on fractionators elsewhere, particularly the USA.

56. As far as you are aware, did your views on self-sufficiency accord with the views of your peers and the Blood Transfusion Services?

216. I don't recall clinicians ever thinking self-sufficiency was a bad idea in concept, though there was inevitable scepticism that it would ever be achieved. Finance staff in hospitals, however, might have preferred a mixed economy to engender competition and drive down prices.

57. Did the EABTC provide blood or blood products to private hospitals during your tenure? If so, what if any impact did this have on self-sufficiency?

217. Yes, but there was not a big private hospital sector in East Anglia, and this had minimal impact on our ability to supply plasma to BPL. We also supplied air force bases at Mildenhall and Lakenheath, but mainly with red cells, so again this provision had minimal impact on plasma supply to BPL.

Section 9: Services for donors at EABTC

58. What counselling was offered to donors prior to (i) HIV testing (ii) HCV testing and (iii) HBV testing taking place? Please describe the process (see NHBT0042773, and point 2.3 of NHBT0010585_002).

218. Every donation was tested for HIV, HBV and HCV. This was explained in the standard donor information pack and on the consent form, which was given to every donor each time they attended to donate. However, there has never been a one-to-one discussion between every donor and a doctor or nurse at the donor session, unless the donor had questions or concerns, in which case a doctor or qualified nurse was on hand to answer them. Donors who had questions before they came to donate, or between donations, could ring the service to speak to a qualified nurse or, if the question was complex, a doctor specialising in donor care. Nowadays, all routine information is also on the blood donation website www.blood.co.uk.

59. What counselling and psychological services were available for donors who tested positive for hepatitis or HIV? Were such services delivered by EABTC or were referrals to other agencies made? Please describe the process.

219. Before answering this question, I would like to discuss the use of the term counselling as it applied in the Blood Services. This was traditionally used to cover the discussion a blood service clinician had with a donor who has tested confirmed positive for an infection. At some

stage, it was pointed out by Dr Patricia Hewitt that this could not truly be termed counselling, as our staff were not trained psychologists and were not, in the conversation with the donor, going to be dealing with the psychological consequences of having such an infection. The discussion mainly covered the nature of the infection and the need for the donor to be referred for a specialised medical opinion and follow-up. The Blood Service clinician would also be trying to elicit any risk factors the donor might have for acquiring the infection to ascertain whether the donor information material might have been unclear or misleading. Therefore, we began to use the term 'post-test discussion' to cover the meeting(s) between infected donors and blood service clinical staff, reserving 'counselling' for any meetings between donors or patients and qualified counsellors outwith the blood services.

220. I do not recall what arrangements were in place at EABTC during the 1980s since I arrived as a trainee only in 1988. When I became a consultant in 1991, we were preparing for the start of HCV screening, so I will discuss arrangements being put in place at that time. We appointed an additional consultant, Dr Elizabeth Caffrey, to be responsible for all donor matters, who then undertook the post-test discussions with donors who had tested HCV positive. The need for improved services for donors with positive screening tests had been identified in 1989 by Dr Willem Ouwehand when he arrived as a new lecturer/consultant [NHBT0010585_002]. I am not sure what training Dr Caffrey had initially, but when the zonal arrangements came into place, there were meetings of donor consultants at the different centres within the London and South -East Zone (LSE) and later at national level. I think there was work done to make sure that all doctors (and later nurses) undertaking this work were trained and working to an agreed protocol.

221. As I do not recall any HIV positive donors at EABTC in the RTC era, I will refer to referral arrangements for donors infected with hepatitis. As discussed above, the first clinical contact an infected donor would have

would be with a blood service clinician (Dr Caffrey), who would then refer the patient to a hepatologist in their local hospital. I do not recall EABTC having a link to a psychologist who would see donors directly. I am not sure whether the hepatology services had a psychologist as part of their team, but the hospital clinician would have been able to refer the donor, who by then was their patient, to a psychologist if necessary.

60. What counselling and psychological services were available for recipients of infected donations? Were such services delivered by EABTC or were referrals to other agencies made? Please describe the process.

222. There are two situations in which recipients of infected donations would be identified:

a) If they were found by a clinician caring for them to have HIV or hepatitis, which further investigation would reveal had come from a transfusion. In this case, blood service clinicians would not be involved in seeing the patient but would provide any information required to the hospital clinician.
b) As part of a lookback. When the HCV lookback was being established in 1994-5, SACTTI discussed at its meeting on 5th August 1994 [NHBT0057381_004] whether patient 'counselling' should be done by the Blood Services or by hospitals or GPs. As it turned out, I think there was mixed practice, with some GPs preferring to see the patient themselves, with others preferring to leave it to the Blood Service. I think the GP would always have the choice as to whether the patient should be informed that they had received an infected component and then who should deliver the information.

223. I do not recall that EABTC made any direct arrangements for recipients identified in the HCV lookback, and then seen by Dr Caffrey, to be referred directly to a psychologist. Our arrangements were with

hepatologists across the region, and I do not know whether, at that time, they had psychologists as part of their teams.

61. Were these arrangements sufficient in your view? If not, why not?

224. Our primary concern was referral of an infected donor or patient to a specialised clinician, which I think was the correct first step in providing care for that person. I can absolutely see that they may well then have needed to see a psychologist. It was always a bolt from the blue for a donor or patient to be told that (s)he had acquired HIV or hepatitis, and an even bigger shock, in the case of the patient, to be told it had probably come from a transfusion.

225. I do not recall there being any discussion at EABTC as to whether we should provide a direct psychological referral. If we had done this, I suspect we would have concluded that such a referral should come from the hepatologist as part of the overall care of the patient. We were always careful not to step over into the 'patient treatment' area unless we had a specific remit to do so. We did not have access to medical records, and we did not know the whole health and social situation of the donor. It seemed better for the donor's wellbeing to refer them to clinical services which could care for the donor in the round.

Section 10: Meetings of various committees

Eastern Division

62. Please explain:

a. What purpose(s) were the Eastern Division Meetings established for?

b. How frequently did this group meet?

c. Was this the only form of cooperation between RTCs in the Eastern Division?

d. What was the relationship between the divisional meetings of BTS consultants and the meetings of the National Directorate?

The Inquiry holds minutes of this group between 1990 and 1992 which are provided for your assistance: NHBT0016087, NHBT0097463_001, NHBT0097468_001, NHBT0097469_018, NHBT0097471_029, NHBT0097472_009, NHBT0097473_029, NHBT0118144

226. I shall address parts (a), (b), and (c) together, then address part (d). This meeting, which took place quarterly, involved the consultants from EABTC plus the RTCs at Colindale, Brentwood and Tooting. It was later expanded to include the non-medical Director of the South Thames RTC at Tooting. There were corresponding groups in the North and South-West. One of its main purposes was to connect with the National Directorate through the chair, to act as a route of dissemination of information, to be consulted on matters under discussion at a national level, e.g. a draft donor information leaflet about AIDS, and to be a conduit by which local concerns could be escalated to the National Directorate, e.g. the slowness of progress towards national plasma self-sufficiency (as discussed in section 8). The group also discussed regional matters such as trainee education and transport.

227. I cannot comment on co-operation across the three RTCs covering London, but, as discussed in section 7, EABTC began discussions with the NE Thames RTC at Brentwood, I think in 1992, to see whether we could rationalise small scale specialist activities between the two centres. From memory, this work was overtaken by the absence of Professor Allain and the creation of the NBA.

Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation

63. In 1993, the Department of Health Advisory Committee on the Virological Safety of Blood ("ACVSB") was replaced by the Advisory Committee on the Microbiological Safety of Blood and Tissue for Transplantation ("MSBT"). The Inquiry has provided minutes of the meetings of this group that you attended for your assistance: SBTS0000523, DHSC0006195_003, DHSC0014973_005, NHBT0002418_003, DHSC0038559_047. Please describe the function and remit of this committee and the nature of your involvement with the committee.

228. **Function and remit of MSBT and my involvement with it.** I was never a member of this committee. I was invited to 6 meetings between February 2000 and March 2004 to present updates on vCJD, and the NBS plans to minimise vCJD risk by changes to blood component provision. The specific topics on which I presented were leucocyte depletion, importation/virus inactivation/appropriate use of FFP/cryoprecipitate, reduction of plasma content of red cell and platelet components, and sourcing more platelets by apheresis. Detailed explanations are provided in Sections 13 and 17.

64. Please describe:

a. Who did the MSBT report to, how frequently and by what means?

229. MSBT was a DH committee, but I do not know precisely the reporting line of MSBT within the DH.

b. How frequently did the MSBT meet

230. I believe MSBT met several times/year and was chaired by one of the Deputy Chief Medical Officers.

c. Did the MSBT have any powers or was it purely advisory? Was the NBTS required to implement its decisions?

231. My understanding is that MSBT existed to give advice to health ministers on matters concerning the microbiological safety of blood and tissues (and later organs). Decisions taken by ministers would result in instructions from DH to the Blood Services. I recall, for example, the announcement in the press in July 1998 by the Secretary of State for Health, Frank Dobson, that leucocyte depletion of the blood supply should be undertaken as a vCJD risk reduction measure. This was followed by an instruction from DH to NBS to implement.

d. As far as you are aware, did the Health Ministers generally take the advice of the MSBT? Please set out any instances relevant to the Inquiry's Terms of References, where the MSBT's advice was not accepted.

232. As far as I am aware, Ministers generally accepted the recommendations of MSBT.

233. The MSBT minutes of 29th October 1998 [DHSC0004026_032], however, record that Ministers had rejected an MSBT recommendation for HTLV screening. Following a further review of available scientific data, this recommendation was accepted by Ministers, as recorded in the released MSBT summary of its meeting on 19th April 2001 [NHBT0008129].

Serious Hazards of Transfusion

65. The Inquiry understands that you were closely involved in the establishment of the ("SHOT") haemovigilance scheme. You chaired a number of groups relevant to this scheme in the 1990s, including the SHOT Working Group, Standing Working Group, and SHOT Executive Group, and also attended meetings of the SHOT Steering Group. Please describe the remit and composition of these committees and their role in the establishment of the SHOT haemovigilance scheme. The Inquiry holds some minutes of the meetings of these committees that you

attended which have been provided for your assistance: NHBT0007853_001, NHBT0007848_002, NHBT0019435_010, NHBT0007858_002, NHBT0017300, NHBT0017298_001, NHBT0118019, NHBT0085385, NHBT0085384, NHBT0085383, NHBT0085386

234. I will give a chronological account of SHOT's establishment, remit and how it operated, including the purpose of the different committees.

Establishment of SHOT

235. In 1994, the 4 UK Transfusion Services agreed that a UK-wide haemovigilance scheme was required to gather data about transfusion-related deaths and serious harm to patients arising from administration of blood components (red cells, platelets, FFP and cryoprecipitate). These are not licensed medicines and are therefore not covered by the MCA's 'Yellow Card' system for reporting the side effects of drugs. The scheme would not include plasma products, which, as licensed medicines, would be covered by the MCA's 'Yellow Card' scheme. I was asked by Dr Angela Robinson to convene a group (the SHOT Working Group) to establish such a scheme to collect data, publish reports and make recommendations to improve safety for blood component recipients.

236. The SHOT Working Group met several times during 1995 and agreed on the remit, case definitions and reporting arrangements, secured funding, appointed staff and purchased a database. We also liaised with Royal Colleges and professional societies, particularly the BSH, to ensure that hospital staff involved in transfusion were comfortable with the arrangements.

237. SHOT was launched in November 1996, with information going to all hospitals and publicised through professional channels, with an editorial in the British Medical Journal (Exhibit WITN0643051).

Scope of SHOT reporting

238. The SHOT Working Group agreed that there were 3 major types of transfusion incidents for which we needed data.

239. (1) Transfusion-transmitted infections. This would cover viruses, bacteria and other infections such as malaria. This would require close working with the Public Health Laboratory Services in each of the four home nations.

240. (2) Incorrect blood component transfused, whether harm to the patient occurred or not, and occurring due to error either in the blood services or in hospitals. We knew from data from the reporting system in the USA run by the Food and Drugs Administration (FDA) that every year, a small number of transfusions were given of the wrong ABO blood group and that ABO incompatible transfusions could be fatal. In the UK, a survey published by Dr Brian McClelland in 1994 concluded that 'wrong blood to patient' episodes might occur as often as 1 in 30,000 transfusions and that a proportion of those would result in harm to the patient (McClelland DBL and Phillips P. British Medical Journal 1994;308:1205-6) (NHBT0000037_022). Both the FDA and UK data showed that, since blood service laboratories operated under controlled conditions and operated to Good Manufacturing Practice (GMP) standards, such incidents nearly always occurred on the hospital ward or in the busy hospital transfusion laboratory. We defined 'Incorrect component' as '*either one intended for another patient or one which did not meet the specific requirements of the patient .e.g for irradiated blood'.*

241. (3) Major immunological reactions between the donated blood and the patient. These are generally unpredictable and include transfusion-related acute lung injury (TRALI), transfusion-associated graft-versus-host disease (TA-GvHD), post-transfusion purpura (PTP), delayed haemolytic transfusion reactions, and acute major reactions such as anaphylaxis. We considered that learning more about such incidents

might result in ways of preventing and treating them (see Evolution of SHOT below).

How reports were submitted

242. In considering the model of reporting to be used, we looked at the systems in the USA and France, which was the only European country to have established a haemovigilance system at that time. We also looked at the Confidential Enquiry schemes running in the UK for certain types of death, e.g. Maternal Death, Stillbirths and Deaths in Infancy, and Perioperative Deaths (NCEPOD). We concluded that the NCEPOD model best lent itself to our situation, with reports being sent to a small independent expert group for analysis, followed by production of an annual report containing the data, some anonymised case reports, and recommendations.

243. Because it was essential that the supplying blood centre was involved in investigation and component recall arising from any suspected transfusion-transmitted infections, a dual reporting route for incidents was established. Suspected infections were reported initially to the local Blood Centre and, from there, to the PHLS. In England, such reports were collated at the Communicable Disease Surveillance Centre (CDSC) of the PHLS by an infection surveillance officer jointly funded by the NBS and CDSC, while in Scotland, reports were collated by the National Microbiological Reference Unit.

244. Reports of errors and immune complications were made directly to the SHOT office, using a two-stage reporting system and medical review.

245. Inclusion of 'near miss' events were added in the second or third year, as was a 'nil return' card.

Organisation of SHOT and role of the different committees.

246. We established a small Standing Working Group of clinicians and SHOT staff to oversee the running of the scheme and consider future developments, chaired by myself till ~1999, and with Dr Elizabeth Love as Medical Advisor. We shared our analysis of cases by topic among group members and wrote the respective chapters for the annual report.

247. We considered it essential that hospital staff felt that SHOT belonged as much to them as to the Blood Services. We, therefore, established a much larger SHOT Steering Group, with representatives of all the professional groups involved in the handling and administration of blood. This was done by inviting the Royal Colleges and professional societies covering nursing, laboratory staff, and medical staff from the major blood-using specialities such as surgery, obstetrics, paediatrics and haematology. We were gratified that, with the exception of the Royal College of Midwives, all professional groups whom we invited agreed to join the Steering Group. There were twelve organisations represented: the Royal Colleges of Anaesthetists, General Practitioners, Nursing, Obstetrics and Gynaecology, Paediatrics and Child Health, Pathologists, Physicians, and Surgeons; the British Blood Transfusion Society, the British Society for Haematology, the Faculty of Public Health Medicine and the Institute of Biomedical Sciences. The Steering Group also included representatives from the UK Blood Services, the PHLS Communicable Disease Surveillance Centre, and the Republic of Ireland, and was chaired by Dr Hannah Cohen, the British Society for Haematology representative. The Terms of Reference of SHOT, the Steering Committee and the Standing Working Group are described in NHBT0077594_005.

66. SHOT has been the UK's independent, professionally-led haemovigilance scheme since 1996. Please explain how SHOT was established and for what purpose(s) (NHBT0007367).

248. See response to Q65 above.

67. Why was it considered important for SHOT to be independent of the NBA? How was this achieved? You may find NHBT0007853_001 of assistance.

249. We considered whether the Blood Services should run the scheme, as they would clearly have to be involved in the handling of any incidents of suspected transfusion-transmitted infection. However, the scheme was designed to include errors occurring in the Blood Services as well as in hospitals, so this would have led to conflicts of interest. We were also aware that there would be reluctance by some hospitals to report to their local blood centre and that they would be concerned about confidentiality and security of data.

68. Please explain why it was decided that the SHOT system would function on a voluntary basis. (NHBT0007853_001, page 2). In your view, were there limitations to a voluntary as opposed to mandatory reporting system?

250. We had no mandate to make reporting compulsory, there being no legal framework at that time under which this could be imposed (for later developments in this regard, see under Q73, relationships with other bodies). We wanted to proceed with the minimum of delay and bureaucracy, the freedom to make recommendations to decision-making bodies, and with the maximum flexibility for the scheme to evolve as required. We also wanted SHOT to lead a learning culture of continuous improvement in transfusion safety and as an educational platform to improve transfusion practice across the healthcare system. We, therefore, established SHOT as a professionally-led scheme, with reporting to be voluntary. The SHOT Working Group minutes of 13th February 1995 [NHBT0007848_002] record that Dr Robinson had agreed SHOT's voluntary nature with Dr Jeremy Metters, one of the Deputy Chief Medical Officers. Progress on the establishment of SHOT was also given to MSBT by Dr Robinson on 13th October 1995. The MSBT minutes [SBTS0000516_001] record that members welcomed

these developments, again with no suggestion that reporting to SHOT should be made compulsory.

251. We knew that the biggest drawback to a voluntary system would be incomplete reporting. However, by the end of 2 years, 65% of hospitals were taking part, and there was no adverse reaction to SHOT by the professions or the media. We had more than sufficient data for estimation of the relative risks of different transfusion complications, and the number of reports of ABO incompatible transfusions was not significantly different from those received by the mandatory French reporting system. The acceptance of SHOT by the healthcare system paved the way for a Department of Health recommendation that hospitals participate in SHOT (NHS Health Circular HSC 98/99, Better Blood Transfusion).

69. What is the remit and functions of the SHOT scheme? You may be assisted by the Terms of Reference from 2001 (NHBT0077594_005). The Inquiry has also provided copies of the SHOT scheme's annual reports from 1996 to 2002 for your reference: NHBT0057437_001, SHOT0000020; NHBT0040229_001, NHBT0057438_002, NHBT0057439_001, NHBT0057439_002; SHOT0000016.

252. I have covered the establishment, remit and organisation of SHOT above. I will now turn to the Annual Reports and impacts of SHOT.

Production of annual reports and recommendations

253. The first annual report, covering 1996-1997, was published in 1998, with a press conference and considerable media interest. In the second year, we introduced a 'Nil Return' card so that we could better gauge the completeness of reporting. After the second report, covering 1997-98 and published in 1999, the data from the two reports were summarised in a publication in the British Medical Journal (Exhibit WITN0643052). This analysis showed that we had reached 65% hospital participation, with

366 cases reported and, sadly, 22 deaths, 17 of which were due to immune complications, with 3 due to ABO incompatible transfusion and 2 due to infections (1 bacterial and 1 malaria). Taking all 366 reports together, 191 (52%) were incidents of Incorrect Component Transfused, 163 (45%) were immune complications, and 12 (3%) were transfusion-transmitted infections. Six of these were due to infections not tested for at the time (1 malaria, 1 hepatitis A and 4 bacterial), and five were caused by infections for which testing was in place (1 HIV, 1 hepatitis C and 3 hepatitis B). An additional hepatitis C case was newly identified from a transfusion which occurred before testing was introduced in 1991. Three of the bacterial cases were due to platelets.

254. The main recommendations from the first two reports included a number of suggestions for improving patient identification and minimising transfusion errors in hospitals. The BCSH (the guideline group within the BSH) then agreed to produce a national guideline covering these points (Murphy MF et al, Transfusion Medicine 1999:99; 227-238) [AHCH0000049]. We also recommended that joint hospital/blood service protocols be produced for the investigation of immune reactions and for suspected bacterial transmission. The final key observation / recommendation was that there were several organisations responsible for decision making in transfusion safety and that a unified approach to setting priorities for transfusion safety would ensure the best use of resources. I return to this in Section 18, Issues.

70. Please describe how SHOT operated during your tenure. In particular:

a. Who did SHOT report to, how frequently and by what means?

255. SHOT staff were accountable to the Medical Advisor, with the Standing Working Group accountable to the Steering Group, which met twice yearly for the content of the reporting questionnaires, conclusions, recommendations and productions of Annual Reports. As chair of the Standing Working Group, I also reported to the UK Blood Services

annually on the overall direction of the scheme and the use of the funding. The Royal College of Pathologists did not ask for any specific reports, but as one of the organisations represented on the Steering Group, they received copies of all annual reports.

b. Did SHOT have any powers or was it purely advisory?

256. SHOT had no power to insist on change to practice. From the outset, we intended that the data produced by SHOT be used to make recommendations to decision-making bodies. Some of the impacts of SHOT data are discussed more fully under Q72 and include steps to reduce bacterial sepsis and TRALI, as well as informing guidance for safer hospital practice.

c. How was it funded? (NHBT0017307_001; NHBT0007856)

257. To establish SHOT, we took a funding proposal of £36k/year to the UK Blood Services, who agreed to fund the scheme for 2 years and allow the appointment of a data manager and purchase of a database. Both the BSH and the BBTS contributed £5k/year each. The Republic of Ireland may also have contributed. As SHOT was not a legal entity, the NBA agreed to employ the staff, although their accountability remained through SHOT. The NBA also provided office space for the staff in the Manchester Blood Centre. To provide a professional 'home' for SHOT, the Royal College of Pathologists (which includes haematology and transfusion medicine) agreed that SHOT could become an affiliated organisation.

71. What was the relationship between the SHOT scheme and other bodies involved in reporting systems for infectious hazards, in particular the PHLS, CDSC, the MCA's Yellow Card System, and the National Institute for Health and Care Excellence ("NICE")? (NHBT0007848_002, NHBT0019435_010, NHBT0017300, NHBT0118019, NHBT0007856, NHBT0007857)

258. **PHLS/CDSC.** Close working with PHLS/CDSC was integral to the establishment of working of SHOT from the outset, as described in my response to question 69, and remains so.

259. **MHRA**. From November 2005, the countries of the UK were legally required to operate their blood services, as well as important aspects of hospital transfusion services, under the legal requirements of the Blood Safety (and Quality) Regulations (BSQR), 2005, which was the transposition into UK law of the EU Blood Directives. For the Blood Services, the Acting Competent Authority under the Regulations is the MHRA. Since the EU Directives mandated a reporting scheme for transfusion events, MHRA had to consider whether (1) SHOT's activities were adequate as the UK's recognised reporting scheme under the law (2) whether SHOT should be stood down and totally replaced by a new scheme run by the MHRA or (3) whether some sort of hybrid scheme would be the best solution.

260. In practice, option (3) was chosen for a variety of reasons, notably that the range of issues covered by SHOT and the BSQR requirements did not perfectly overlap, with some types of incidents covered by one system and not the other. In addition, the involvement of SHOT in education of staff and in making recommendations was much appreciated by the professions, particularly in hospitals. The MHRA, therefore, established a reporting system called SABRE (Serious Adverse Blood Reactions and Events) and worked with SHOT on a single reporting route through the systems to meet both organisations' requirements while avoiding duplication of reporting. This is set out in detail on the SHOT website www.shotuk.org.

261. **Yellow Card scheme**. SHOT had no formal relationship with the MCA's Yellow Card scheme. However, SHOT decided to include two licensed blood products in its remit as follows:

(1) anti-D immunoglobulin. This is given to RhD negative women during or after pregnancy to prevent Rhesus haemolytic disease of the fetus/newborn and has to be administered in a timely manner to be effective. Hospitals wanted to report incidents where there were errors resulting in late or absent administration of anti-D, putting the current or future pregnancy(ies) at risk, so SHOT agreed to receive and analyse such reports. Note: although an intravenous form of anti-D has transmitted hepatitis C in the Republic of Ireland, the product used in the UK is for intramuscular administration, making this a very safe product from the infection point of view. I am not aware of any reports of infections from anti-D in the UK.

(2) Solvent-detergent fresh frozen plasma (SDFFP). Because this is a pooled product, it is a licensed medicine. Since SHOT receives reports of incidents involving standard FFP and cryoprecipitate, it was decided that for completeness and comparison, SHOT would also receive reports relating to SDFFP.

262. **NICE.** There is no formal link between SHOT and NICE, although as part of its 2015 transfusion guideline, NICE recognised the importance of identification errors in blood administration and noted that automated systems using barcoded wristbands and automated tracking were available and probably useful (nice.org.uk Transfusion NG24, 18th November 2015). However, NICE stopped short of formally recommending their use because a health economic study of their cost-effectiveness had not been undertaken (such a study has now been approved and funded from charitable sources).

72. In your view, did the introduction of the SHOT scheme improve hazard reporting and recall procedures at the NBTS?

263. **Impact on hazard reporting and evolution of SHOT**. There was no national reporting system for transfusion risks before SHOT, clearly an unacceptable situation. The establishment of SHOT was, to some extent,

helped by the creation of the NBA, as it was easier to obtain approval and funding for what the SHOT Working Group was proposing. For the first time, SHOT provided a comprehensive national picture of transfusion risks across the UK, capturing data on hospital errors and immune complications as well as infections. Importantly, it provided a platform from which data-driven recommendations for safety improvements could be made across the whole transfusion chain from blood collection services to the patient's bedside, truly 'vein-to-vein'. Safety improvements which have been implemented, at least partly as a result of SHOT data, include:

(1) a programme of work to minimise the risk of bacterial contamination of platelets, comprising improved skin cleansing of blood donors' arms, diversion pouches, bacterial testing of every platelet donation, and education of hospital staff on how to visually identify possible contaminated platelet units;

(2) identification of donor HLA antibodies as a possible cause of TRALI and its prevention by use of fresh frozen plasma from male donors, implemented in 2003 (Exhibit WITN0643022)

(3) identification of the additional benefits of universal leucodepletion (implemented for vCJD risk reduction) in also preventing the immune complications PTP and TA-GvHD (Exhibit WITN0643021

(4) Guidelines produced by the BCSH to improve hospital transfusion laboratory practice and to minimise the risks of errors of identification have drawn on SHOT data in formulating their recommendations.

264. It is important to note that SHOT has evolved in both organisations and in types of hazards collected. SHOT's status has also evolved from being a totally voluntary organisation. Participation in SHOT was included in the DH's 2002 Health Service Circular HSC 2002/009 [NHBT0062177_001], hospitals being asked to *'ensure participation in*

the SHOT scheme and that timely reporting is in place' being professionally mandated for hospital laboratory accreditation by Clinical Pathology Accreditation then by UKAS, the national accreditation body. Creation of a joint scheme with the MHRA SABRE scheme completed the journey to a legally mandated scheme. Thus, hospital participation in SHOT is virtually 100%.

265. New areas covered by SHOT over the last 25 years have included autologous transfusion (both pre-deposit and cell salvage), near-miss events, transfusion-associated circulatory overload, and events due to computer system errors. SHOT has also provided education on human factors and systems design to minimise human errors.

266. Further important development has been the replacement in 2008 of MSBTO with the Advisory Committee for the Safety of Blood, Tissues and Organs (SaBTO), with a remit to examine and provide advice across all transfusion risks, including transfusion errors and immune complications. SHOT has called for such an overarching body since its early annual reports in the late 1990s.

267. The SHOT model has received recognition from both the European and International Haemovigilance Networks (IHN), and I was honoured to receive the IHN's annual award for contribution to haemovigilance in 2011. The SHOT model has also been the basis of haemovigilance in other countries, e.g. the Danish Registry of Transfusion Risks (DART).

73. Do you consider that arrangements for hazard reporting and recall procedures were adequate before the introduction of the SHOT scheme?

Impact on recall procedures

268. When a suspected transfusion-transmitted infection is reported by a hospital to its supplying blood centre, there may be other components

from the same or earlier donations still in the system. Procedures for recall of such components implicated have existed since at least the 1980s, long before the creation of SHOT, in the context of investigating cases of post-transfusion hepatitis and HIV. The launch of SHOT would not have had any direct impact on its effectiveness but may have heightened awareness of such procedures. Please note that since SHOT's remit did not cover fractionated plasma products, no change to recall procedures for batches of clotting factors or immunoglobulins resulted from SHOT activity.

Standing Advisory Committee on Transfusion Transmitted Infections

74. In 1989, the UK Advisory Committee on Transfusion Transmitted Diseases ("ACTTD") was set up by Dr Harold Gunson to consider the implications of transfusion-transmitted infections on the transfusion services in the UK and provide advice to the Department of Health. The Inquiry understands that ACTTD was replaced with the Standing Advisory Committee on Transfusion Transmitted Infections ("SACTTI") following the creation of the NBA in 1993 (DHSC0006906_013). Please explain the extent of your involvement in the SACTTI. The Inquiry has provided minutes of the meetings of this group that you attended from 1994 to 2000 for your assistance: NHBT0000088_006, NHBT0000088_008, NHBT0000088_009, NHBT0000088_010, NHBT0000088_013, NHBT0000088_016, NHBT0000088_022, NHBT0000088_023, NHBT0001972, NHBT0005590, NHBT0009458_002, NHBT0010921, NHBT0010970, NHBT0017284, NHBT0000236_024, NHBT0017405_001

269. **My involvement in SACTTI.** I was a member of SACTTI from 1993 till 1st January 1997, when I left to chair SACBC. I acted as Secretary from April 1996 till the end of my membership. I presented information from the studies on anti-HBc testing (described in detail in section 14). There were later joint meetings with SACBC, e.g. on virus inactivated plasma.

75. What was the function and remit of SACTTI? In particular:

270. SACTTI is one of the seven Standing Advisory Committees which sit under the Joint Professional Advisory Committee (JPAC) of the UK Blood Services. The remit of JPAC is discussed under Q76 below.

271. SACTTI's primary remit is to produce the chapters in the Guidelines for the UK Transfusion Services, which cover in detail the way in which microbiological testing of donors is carried out in blood centres. These include the standards which the assays must meet and specific details of their use, e.g. pool size, as well as how donors testing positive on screening are further investigated and, if appropriate, reinstated as donors.

272. Along with the other SACs and JPAC, SACTTI acts as an advisory committee to the UK Blood Services.

273. Other tasks undertaken by SACTTI also include maintaining a list of specific manufacturers' assays which have been approved through the UK Blood Services Kit Evaluation Groups. SACTTI also defines standards for environmental monitoring of processing facilities, and guidance on how to investigate a suspected transfusion-transmitted infection. Finally, SACTTI maintains a list of potential infectious threats to the UK blood supply, including infections in humans in other parts of the world or in animal species. These are reviewed against a standard framework at least annually, and if an infection risk is considered to be rising, this can be elevated through JPAC to SaBTO (see Q76 below).

274. Members of SACTTI are doctors or scientists from the UK Blood Services, PHLS or academia who have expert knowledge in transfusion-transmitted infections and their detection and prevention, epidemiology and public health.

a. Who did SACTTI report to, how frequently and by what means?

275. The chair of SACTTI is a member of JPAC, and accountability is provided by SACTTI providing reports at every JPAC meeting, which were held quarterly at least up until I retired in 2016.

b. Did SACTTI have any powers or was it purely advisory? In particular, please advise whether the Department of Health took advice from SACTTI.

276. SACTTI was not in a position to advise DH directly. However, certain MSBT minutes make reference to work done by SACTTI. For example, SACTTI held a special meeting on HTLV testing in 1996 [NHBT0005734], the outputs of which fed into subsequent MSBT discussions. As far as I know, there has never been a formal link between SACTTI and MSBT, although I believe this was explored at one time. Currently, the Chair of JPAC (but not SACTTI) is an observer at SaBTO. The respective responsibilities of JPAC and SaBTO are discussed under Q76 below.

c. How did SACTTI's remit differ from its predecessor ACTTD?

277. I cannot comment on the detailed workings of the Advisory Committee on Transfusion-Transmitted Diseases (ACTTD), as I never attended any of its meetings, nor have I seen any minutes. My understanding from general reading is that ACTTD was set up in 1989 to advise the Blood Services on the technical and operational implementation of virus screening. In that regard, its role sounds similar to that of SACTTI, as I assume it took responsibility for the microbiological section of the first edition of the UK Guidelines for the Transfusion Services ('Red Book'), published in 1990.

278. There was another committee, the Advisory Committee on Virological Safety of Blood (ACVSB), whose remit, I believe, was to advise DH on

transfusion-transmitted infections. I do not know whether there was any formal link between ACTTD and ACVSB.

279. SACTTI has never had a formal link to DH, either directly or through MSBT.

76. In a joint meeting of the SACBC and SACTTI in November 2000, you queried whether there was a "transparent pathway to support decision making" for the development of a test for vCJD. More generally, Dr John Barbara requested "clarity with regard to where responsibility lies for proposing, agreeing, approving and implementing precautionary measures" (NHBT0001972, point 2.3.4)

a. As far as you can recall, what was your understanding of the respective responsibilities of the DoH, UKBTS and professional Standing Advisory Committees/the Joint Executive Leadership Committee in regards to policy decisions relating to blood safety?

280. I will discuss my understanding of the roles and responsibilities of these different bodies individually. I do not recognise the term 'Joint Executive Leadership Committee'. I think it may have been an earlier name for what is now JPAC.

281. **DoH.** My understanding is that the final decisions on major issues of blood safety lay with Health Ministers. I cannot comment on the detailed workings within DH leading up to such decisions, but from 1993 until it was replaced by SaBTO in 2008, MSBT was the DH advisory committee on transfusion-transmitted infections. Following a Ministerial decision, DH's role was to issue instructions to the Blood Services to implement.

282. **UKTS** were responsible for the implementation of DH's instructions to an agreed timetable and for the running of the organisation to ensure a safe and secure blood supply. UKTS could also implement safety measures within its own budget and regularly did so, e.g. bacterial screening of

platelets, plus malaria and later West Nile virus testing of returning travellers. UKTS also had a responsibility to be up-to-date scientifically and to investigate and propose to DH additional safety measures for consideration. This developmental aspect of the UKTS's responsibility was one of the functions of JPAC and its SACs.

283. **JPAC and its SACs.** The remit, structure and accountability of JPAC and its underpinning SACs are set out on the JPAC website www.transfusionguidelines.org. As mentioned under Q74/75, JPAC has two distinct remits:

i) To prepare detailed service guidelines for the United Kingdom Blood Transfusion Services. These are contained in the 'Red Book', which was first published in 1990. The entire contents can be found at www.transfusionguidelines.org.

ii) To be an Advisory Committee to the United Kingdom Blood Transfusion Services, normally by reporting to the Medical Directors of the individual Services who are themselves individually accountable to the Chief Executives of the Services. Decisions on policy and implementation would be vested in the individual Chief Executives and their Service boards and, where appropriate, their respective Health Departments.

284. There are seven Standing Advisory Committees which feed into JPAC, covering the span of Blood Service activity, as well as the use of blood in hospitals. There are SACs on Blood Donation, Transfusion-transmitted Infection (SACTTI), Blood Components (SACBC), Immunohaematology, Tissues and Cells, Information Technology and Clinical Transfusion Medicine- this last one produces, in conjunction with the BSH, the Handbook of Transfusion Medicine provided to hospital staff.

285. The membership of JPAC consists of the chair of each SAC, the Medical Directors of the four UK Blood Services, and the Director of the National

Institute of Biological Standards and Controls (NIBSC), which since 2013 has been part of the MHRA.

b. Was there often confusion around these responsibilities?

286. As outlined above under Q63/64, my understanding is that DH was advised by MSBT. I was never a member of MSBT and attended only a few meetings, and then for specific items only. I recall discussions in the 1990s which tried to establish formal links between SACTTI and MSBT in order to improve clarity of decision making. This was not agreed at the time, and the chair of SACTTI had no role at MSBT meetings. SACTTI often did a great deal of work on an issue and prepared papers on particular issues, which were discussed at MSBT, e.g. on HTLV testing.

287. However, because MSBT minutes and discussions were confidential, there would be limited feedback from MSBT meetings. Dr Robinson was a member of MSBT and did communicate back as much as she could when there was a major decision taken. This degree of confidentiality caused some frustrations within SACTTI and NBS more widely, particularly if a recommendation was rejected without the logic being explained.

288. I do not recall an instance when I was unclear which organisation was taking the decision for a particular issue, but there were concerns about the Blood Service liabilities if a decision from MBST/DH was taking a long time or if safety step was rejected by them.

289. The question I asked, quoted in Q76, was in relation to vCJD. There were additional committees now involved in advising the government about BSE and vCJD, such as the Spongiform Encephalopathy Advisory Committee (SEAC) and its Risk Assessment sub-group. The UK Blood Services did not employ any prion experts. I was seeking clarity as to where the definitive advice to the government would come from and where decisions would be taken.

c. Did these responsibilities change in any way during your tenure with the NBTS?

290. The only major change was when MSBT was replaced by SaBTO in 2008. SaBTO's remit was broadened to include the overall safety of transfusion recipients, and the chair of JPAC became an observer at SaBTO. There were regular meetings between Blood Service representatives and DH officials to agree on the matters for which SaBTO would investigate and provide advice to health ministers. Although respective responsibilities did not change, I believe that governance became much clearer with the creation of SaBTO. I discuss this further in Section 18, under Issues.

Standing Advisory Committee on Blood Components

77. The Inquiry understands that you chaired the Standing Advisory Committee on Blood Components ("SACBC"), which was a subcommittee of the SACTTI between 1997 and 2002. What was the remit and composition of this committee? The minutes of the meetings you attended from 1997 to 2002 have been provided for your assistance: JPAC0000029_158, NHBT0001972, NHBT0059328, JPAC0000026_144, JPAC0000028_170, NHBT0002620, NHBT0002642, NHBT0010943, NHBT0010964, NHBT0016319_001, NHBT0041167_002, NHBT0041167_005, NHBT0041167_020, NHBT0041168, NHBT0041172, NHBT0041173_001, NHBT0041174_001, NHBT0043199, NHBT0098059_003

78. What was the relationship between SACBC and the SACTTI? As a sub-group, did the SACBC report to the SACTTI?

291. I will answer these two questions together. I have covered the remit of JPAC and its SACs above. SACBC is not a sub-committee of SACTTI

but advises JPAC directly on matters relating to blood components evaluation and manufacture.

292. The remit of SACBC covers three areas:

(1) General guidance for component manufacture, including tests for process monitoring, shelf life, labelling, storage, release and transportation, as well as recall and traceability.

(2) Detailed specifications for each component (red cells, platelets, granulocytes, fresh frozen plasma and cryoprecipitate), including specific requirements for newborn babies and pathogen inactivated or irradiated versions of each component as appropriate. This remit does not cover fractionated plasma products produced by BPL. I believe that when UK plasma was used for fractionation (this ceased in 1998), there was also a specification for the collection and processing of such plasma, e.g. how soon after collection it had to be frozen and the specification for the rate of freezing.

(3) Guidance on how to evaluate components produced by new methods for viral inactivation or leucocyte filtration, as well as apheresis equipment and blood packs.

293. Membership consisted of doctors, scientists and operational managers with particular expertise in blood components from the four UK Blood Services, as well as a representative from the National Institute for Biological Standards and Controls (NIBSC).

79. Did the SACBC have any powers or was it purely advisory?

294. SACBC had an advisory role to the UK Transfusion Services, through JPAC. It had no direct powers of implementation. I sometimes presented work done by SACBC at MSBT, e.g. on leucocyte depletion in the context of vCJD prevention.

80. What was the role of the SACBC in respect to viral inactivation, and in particular, the development of Virus Inactivated Plasma? (NHBT0002642 (page 5), NHBT0010943 (page 2-3), NHBT0043199 (page 2-3))

81. What was the role of the SACBC in component evaluation, in particular new fresh frozen plasma and cryoprecipitate components? You may find NHBT0040170 of assistance.

295. I will answer these two questions together and will first describe the general process for consideration of new technologies.

296. SACBC members are expected to undertake horizon scanning for new developments in the field and bring them to SACBC for possible evaluation. During my time as chair, there was increasing agreement across the four services regarding which service would evaluate which new technologies for component manufacture, with the results being shared at SACBC and accepted for UK-wide sign off. This avoidance of duplication sped up the evaluation process and increased cost-effectiveness. This process applied to all methods for leucocyte depletion, pathogen inactivation and irradiation which could be applied in Blood Centres. Specific UK-wide arrangements were established for prion filters for vCJD risk reduction (see section 17 for details).

297. Therefore, SACBC had oversight of the evaluations of methylene blue/UV light treatment of fresh frozen plasma and cryoprecipitate (published as [NHBT0042349], Exhibits WITN0643014 (pages 253-254) and WITN0643015 with WITN0643023 an invited editorial on the subject). These evaluations were conducted jointly by NBS/SNBTS. I discuss virally inactivated FFP and cryoprecipitate in detail in section 13.

298. SACBC also reviewed specific pathogen inactivation techniques for platelets and red cells, but these came along after I had stepped down as SABC chair in 2007, when I became Medical and Research Director.

299. Because SDFFP is a licensed medicine produced on an industrial scale from pooled plasma, its assessment was not part of SACBC's remit. The same applied to an industrial method for methylene blue treatment developed by Grifols, which would have involved sending UK plasma to their Spanish facility for MB treatment in large pools. Because of concerns regarding pooling, this method of MB treatment was not implemented, the UK Blood Services adopted the method provided initially by Baxter and then Macopharma for the treatment in Blood Centres of individual units of fresh frozen plasma, some of which would then be manufactured into cryoprecipitate.

Section 11: Information handling by and information sharing between RTCs

82. Please describe the record keeping system in place for blood donations and blood donors at the time of your directorship of, and during your employment at, the EABTC. In particular, please explain what records were kept, in what form and who had access to them and at what times. You may find NHBT0041286_003 and NHBT004103 of assistance.

300. When I first arrived at EABTC in 1988, record keeping was largely manual, e.g. with donor records on cards called '101's, which showed the donor's personal details, blood group, and records of all their donations. Records of issues to hospitals were kept in large ledgers. Between then and the MCA Inspection in 1990, a computer system was installed called TRACE. This was a system initially installed in Cardiff, then through a consortium arrangement, made available to other RTCs. I recall that Leeds and possibly Southampton were in the Consortium.

301. At its meeting on 18th February 1991, EABTC Management Team [NHBT0041286_003] recorded a serious gap in the functioning of TRACE. The internal workings of TRACE were set up in two sections, one handling donor information and donation test results, and the other handling manufacturing and product issues. This design was to protect

donor confidentiality and minimise access to sensitive information such as a positive HIV screening test.

302. The problem was that if a donor phoned in out of hours with health information affecting the possible safety of a recent donation, the on-call laboratory staff could not access the donor part of the computer system to link the donor information with components made from that donation, and their location. This was an unusual event, but I can recall at least one occasion when, as the on-call doctor, I went into the Centre either in an evening or weekend to access the necessary information to withdraw the components or recall them from a hospital. In practice, most of these post-donation calls did not provide information of importance to the safety of the components, e.g. the donor had developed a cold. However, I recall a phone call from a donor who had forgotten that a recent sexual partner was bisexual. That was certainly an occasion that I went into the Centre to withdraw the donation, even though the donor's virology results were all negative.

303. I cannot recall the technical details of how we resolved the issue.

304. It is interesting that even in 1990, there were concerns about Data Protection which appeared to override information sharing. This confusion has continued over the years, with Dame Fiona Caldicott updating her guidance in 2013 to include an overarching recommendation '*the duty to share information can be as important as the duty to protect patient confidentiality'* (Information: To Share or not to Share. The Information Governance Review (www.gov.uk/government/publications/the-information-governance-review).

83. Please set out how long these records were kept for.

305. I think when RTCs became subject to MCA licencing, we were required to keep all records relating to blood donors, donations and the resulting

components for a minimum period. Hence RTCs suddenly had to consider precisely which documents were to be kept and how they were to be stored. The duration of storage was, I think, eventually agreed to be 30 years, although this was not clear to start with.

84. Please set out what policy or practice was adopted by EABTC in relation to the destruction of these records.

306. The EABTC Management Team recorded at its meeting on 29th July 1991 [NHBT0041354] that we needed to consider local record storage in detail, so a group was set up with a representative from each department.

307. By its meeting on 11th May 1992 [NHBT0035853], we were clear that we needed to move long term storage off-site, but that we were still uncertain which documents had to be kept and for how long. We agreed to seek advice from the National Records Working Party, which had been set up. We discussed a draft report from them at our meeting on 16th August 1993 [NHBT0041403] and agreed to feed comments back to them. I suggested that much of the requirement could perhaps be met by electronic storage on TRACE, and Dr Ouwehand undertook to discuss this with Dr Robinson, as the Leeds representative on the TRACE Consortium. I cannot remember further details, but we certainly went on to use off-site storage, which continued till my retirement.

85. As far as you are aware, did all RTCs follow the same record keeping practices, or did each centre implement its own system?

308. I cannot answer that in any detail. I recall donor '101' cards in Sheffield in 1985-88, and I believe they were standard nationally. Requirements would have been broadly laid down under MCA requirements for Good Manufacturing Practice, but how each RTC complied with those requirements would have been decided locally. When centres began to become computerised, there was initially no requirement for everyone to

purchase the same system. I am not even sure there was an agreed national specification for computer systems.

86. Do you consider that the record keeping measures in place at EABTC were adequate to prevent donors who were suspected of carrying blood-borne infections from continuing to give blood donations at that centre?

309. I cannot speak for the pre-computer era, i.e up to 1989, but it is hard to imagine a paper-based system which could have definitively prevented a high-risk donor (based on what they told us) from attending more than once. If the donor's virology tests were all negative, I am not sure whether the system would have prevented the components being issued.

310. When EABTC became computerised, donors considered high risk, based on what they told us, were flagged as 'excluded' on the computer. However, there were no laptops which could have been taken out on mobile donor clinics. Therefore, I think a high-risk donor could still have donated more than once. The difference from the paper-based system, however, is that I think when the records from the blood collection session were entered into the computer back at EABTC, usually the next day, the donor would have flagged up as 'excluded' and the donation would have been discarded. No components could have been issued before entry of the donor records because there needed to be full reconciliation of donor test results such as blood group with previous records before components from the donor session could be issued.

87. For what purpose was the Records storage Task Force established? What impact did the Task Force's report have on record-keeping arrangements at the EABTC? (NHBT0041403)

311. I am not sure whether the question refers to local or national groups since there were both. I cannot recall much about the national Records

Working Party, but from the timescale and documents provided by the Inquiry, I think it would have been established to agree standardised ways of working across RTCs to ensure compliance with MCA requirements on record keeping, e.g. precisely which documents had to be saved and for how long, minimum requirements for an off-site storage facility, a standard filing system for archived documents, and standards for computer record creation and storage. I am not sure that all these aims were achieved, though, as I think EABTC devised a local filing system for archived documents.

312. The local group was set up to identify 'owners' (by role, not name) of all documents created and to agree which documents fell under MCA requirements and which didn't, before ensuring that those which did were stored according to guidance from either MCA or the national records Working Party.

88. What were the record keeping arrangements EABTC had with the hospital blood banks to whom EABTC provided blood and blood products? What information were the blood blanks expected to feedback to EABTC about the use of the products supplied to them, and in what form? Was this information routinely feedback, or were there problems with the hospital's compliance? If so, what if any steps were taken to remedy this.

313. I cannot recall details, but I think when I first arrived in Cambridge, hospitals had to send back any outdated components for disposal at EABTC. Later, hospitals were permitted to dispose of outdated themselves, but at that point, I think we asked them to give us the total number outdated, and perhaps individual donation numbers, for outdates of each component. There may have been some reluctance to share such information with us, but as we had no authority to require such returns, we could only try and persuade them.

314. In the NBA era, the Blood Stocks Management Scheme was set up and was a great success in creating the idea that blood in storage, whether in Blood Centres or hospitals, was a shared national resource and that sharing of information on stock holdings was a duty we owed to those who had donated it.

315. We did not require any information about the clinical uses of the blood components issued. Such information remains difficult to obtain on a routine basis, and usually, specific studies or audits have to be set up for the purpose. One example was the EASTR study (Epidemiology and Survival of Transfusion Recipients), which tried to obtain diagnoses and date of death for a representative cohort of adults and children transfused across England. The findings fed into vCJD risk assessments (see section 17) and were published (Exhibits WITN0643024, WITN0643025, WITN0643026, WITN0643027 and WITN0643028).

89. The Inquiry is aware that the Communicable Disease Surveillance Centre ("CDSC") maintained a database to keep track of reporting of blood donors who tested positive for HIV (NHBT0004742_001). The Inquiry understands that this database was in existence in 1989, although it is unclear for how long the CDSC operated it (NHBT0041996_001,). Please answer the following questions regarding this database, as far as you are able:

a. Were you aware of the database, if so, when did you become so aware?

b. Who proposed the creation of the database?

c. Did EABTC contribute data on HIV positive donors to the database? If not, why not? If so, what data?

316. I will answer these questions together.

317. I have no recollection of such a database, how it arose, nor of EABTC contributing to it, although EABTC may not have had any HIV positive donors by the time of Dr Mortimer's letter to Dr Gunson on 3rd November 1989 [NHBT0004742_001]. The letter reads as though the database of HIV positive people may not have been confined to blood donors, who are described in Dr Mortimer's letter as 'an important group'.

318. The second document referred to in Q89 [NHBT0041996_001] is a report issued by Alan Slopecki, National QA Manager and Kate Soldan, Joint NBS/PHLS-CDSC Infection Surveillance Officer, on 24th November 1995. It was the first of a series of monthly reports produced to give a national picture of virus testing in the NBS. It included numbers of donors testing positive for each virus by the Blood Centre, as well as data on the performance of different manufacturers' test kits. They also issued quarterly reports giving aggregated information on donor risk factors identified at post-test discussions with donors testing virus positive and the outcome of any post-transfusion infection investigations.

319. These reports from PHLS/CDSC reports gave an invaluable picture of infections in the NBS blood donor population. I cannot say whether this initiative superseded the database held by Dr Janet Mortimer or whether Dr Mortimer's database was still in operation in 1995.

d. Are you aware of whether other RTCs contributed data on HIV positive donors to the database?

320. I do not know whether other RTCs contributed to this database.

e. Did EABTC maintain a separate, or additional, database to track HIV positive blood donors?

321. I do not recall any database of HIV positive donors at EABTC.

90. A NBTS departmental memorandum dated 15 May 1989 notes that "it has been decided to re-introduce the original 'J' donor system" to identify donors involved in cases of post-transfusion hepatitis (NHBT0005388). Were you aware of the existence of this system? If so, please answer the following questions regarding this system, as far as you are able:

a. The use of the word "re-introduce" implies that the J donor system had been operational at an earlier time. When was the J donor system first introduced, and why did it stop operating?

b. Who proposed the re-introduction of the J donor system?

c. What was the intended scope of the J donor system? Were all RTCs expected to contribute to it?

d. Did the EABTC provide data to the J donor system? If so, what kind of data?

e. What was your view of the proposal for the re-introduction of the system?

f. What was the purpose of the system and what information was it intended to collect?

g. Was the J donor system re-introduced? If so, when and how did it work?

h. Was the J donor system widely used after the "re-introduction"? If no, why not? If yes, who was responsible for overseeing the system?

i. As far as you are aware, does the system still exist?

322. I cannot answer any of these questions as I have no recollection of such a system. Although the notepaper of this memo is headed National Blood Transfusion Service, I wonder whether, in fact, this is a memo internal to the Manchester RTC (the National Directorate was co-located with a Manchester RTC donor clinic). I suggest this because the memo mentions sending samples in the context of the 'MRI', which could be Manchester Royal Infirmary. Also, the memo is copied to, among others, 'Dr Love', who could be Dr Elizabeth Love, who was based at the Manchester RTC. I do not recognise the names of Mr Howell, Mrs Poole,

or any of the people to whom the memo was copied, other than Dr Love. I discuss below under Q91 how EABTC dealt with reports of post-transfusion jaundice.

91. In addition to the database(s) mentioned above, did the EABTC share information with other RTCs about excluded donors, donors that posed a risk to the safety of the blood supply, or infected blood donations? If yes, was this on a formal or informal basis? Please describe the mechanisms the EABTC used to share this information, if any.

323. I will discuss the three categories mentioned above separately and will refer to the period 1991-95 when I was a consultant at EABTC.

324. Donors are excluded because of either (1) information they have freely given us regarding high-risk behaviour/travel history OR (2) a positive virus test result from a previous donation. Either way, they would have been identified on our computer system TRACE, as described under Q82. If they had reattended to donate within East Anglia, the computer system would have blocked such donations from being released for clinical use. It is possible, although I cannot be sure, that information on such donors was shared among other TRACE members. At any rate, I do not recall any mechanism for sharing of this information with RTCs that did not use TRACE. Any mechanisms in use would have been formally incorporated into our quality management system, with a Standard Operating Procedure.

325. As explained in the previous paragraph, donors may be considered high risk (1) on account of information they freely give the blood service. If so, donations will not be taken from them, and they will be registered on the computer as 'excluded'. (2) if they test positive for virus infection, irrespective of whether they reveal any high-risk behaviour or not. Such donors are also listed on the computer as 'excluded'. The computer was programmed to prevent such donations from being issued for clinical use. These are essentially the same categories of donors are described

in the previous paragraph, so my comments about information sharing apply here also.

326. Infected blood donations, i.e. from donors with positive virus test results, were withdrawn before issuing from EABTC. The only situation where another RTC might have had to know about infected donations would be when a recall was initiated, e.g. if a recipient of a blood component developed HIV or hepatitis, or if a donor gave us post-donation information such that components still in the system might endanger any patients who received them. In either of those situations, the recall procedure would identify to where the other components from the implicated donation had been issued. If we had transferred any to another RTC, EABTC would have contacted the other RTC to initiate a recall. If such components had been issued from the other RTC to one of 'their' hospitals, it was the responsibility of the other RTC to recall and destroy them and to confirm this in writing to EABTC.

92. In his statement in *A and Others*, Dr Gunson expressed the view that "there was no central organisation to ensure that...all RTCs operated in a uniform manner" (NHBT0000026_009). Do you agree? In your opinion, were the information sharing measures in place between RTCs adequate to prevent donors who were suspected of carrying blood-borne infections from continuing to give blood donations?

327. I will discuss these two questions separately.

328. Yes, Dr Gunson is quite correct in stating that before the NBS was created, there was no management system to ensure that all RTC's operated to the same standards. The National Directorate, in place from 1988-1993, could coordinate but not demand or require RTCs to do anything. Standardisation was greatly helped by the requirements for RTCs to be licensed by the MCA and by the consequent publication of the First Edition of the Guidelines for the Transfusion Services ('Red Book') in 1990. This publication had the additional benefit of ensuring

standardisation across all four UK Transfusion Services. However, it was not until the NBS was created that there could be true standardisation and, even more importantly, accountability within a national structure. I return to this issue in Section 18, Q198.

329. I do not understand what is meant by 'donors suspected of carrying a blood-borne infection'. As explained under Q91, donors may be considered high risk based on information they freely give the blood service. If so, donations will not be taken from them, and they will be registered on the computer as 'excluded'. Alternatively, donors, irrespective of whether they reveal any high-risk behaviour or not, may test positive for virus infection, in which case they will also be listed on the computer as 'excluded'. I have covered under Q91 the limitations of information exchange between RTCs with regard to excluded donors. I cannot think of a further category of donors who would not be 'excluded' on the computer but who would be 'suspected' of carrying a blood-borne infection.

330. It is worth stating that, although a donor who tested positive for a virus could attend and donate in another region, the virus testing and GMP arrangements at the relevant RTC would again prevent such infected donations from being issued for clinical use.

331. It is worth stating that the vast majority of donors have always acted in good faith with regard to their personal risks. We were concerned when we began HIV testing in 1985 that men who had had sex with men (MSM) might donate blood in order to obtain an HIV test without going to a sexual health clinic. More recently, it is recognised that a small number of MSM who did not agree with the exclusion rules have donated despite them. Such donors, if they test negative in the virus testing, cannot be identified by any system, so safety continues to depend on the honesty of donors, coupled with the high sensitivity of the current virus tests.

Section 12: Knowledge of risk of infections while at EABTC

HIV/AIDS

332. As a general point, it should be noted that although EABTC was my place of work from 1998-2007, it ceased to exist as an RTC in 1994, when the centre became part of the NBS London and South-East zone, and later part of a national management and financial structure. Once zonal and national structures were in place, there was no managerial or financial mechanism for any blood centre to take unilateral decisions on the implementation of any safety step. All decisions and funding were zonal and then national, and the site of any activity became immaterial because blood components could be manufactured at any blood centre and provided, through national transport and storage mechanisms, to any hospital. Component manufacture and donation testing ceased at the Cambridge centre during the 1990s and transferred to Brentwood, providing greater efficiency and reduced costs of blood to the NHS.

333. In answering questions in the section, therefore, I will make the distinction where appropriate between the pre-1994 RTC era and the subsequent zonal/national arrangements.

93. During your time at EABTC, what was your knowledge and understanding of HIV (HTLV-III) and AIDS and, in particular, of the risks of transmission from blood and blood products? How did your knowledge and understanding develop over time?

334. Following my training in Sheffield in the mid-1980s, I arrived at EABTC with a very high awareness of both HIV/AIDS and hepatitis. I had seen haemophilia patients in Sheffield who were positive for HIV, and it was becoming increasingly clear that such patients had a high chance of progressing to clinical AIDS.

335. I was absolutely aware from the mid-1980s onwards that HIV, hepatitis B and non-A, non-B hepatitis could be transmitted through both plasma products and single blood components. This was knowledge which by then was expected of all trainee and consultant haematologists, whether transfusion specialists or not.

336. During the 1990s, much of my personal research and NHS work within the NBS coalesced around the study of techniques to improve the safety of blood components. i.e. pathogen inactivation, leucocyte depletion and later prion filtration. This work involved being fully aware of developments in the field through reading the literature, attending conferences and establishing research collaborations with academic, blood service and commercial partners.

94. How and when did you first become aware that there might be an association between HIV/AIDS and the use of blood and blood products?

337. Please see my response to question 93.

95. What, if any, enquiries and/or investigations were carried out at the EABTC in respect of the risks of transmission of HIV/AIDS? What was your involvement? What information was obtained as a result?

338. Between 1988 and 1990, I do not recall any specific studies or enquiries on HIV at EABTC, other than the medical staff, including myself, reading the scientific literature.

96. What was your knowledge and understanding of hepatitis (including hepatitis B and Non A Non B hepatitis ("NANB")/hepatitis C) and in particular of the risks of transmission from blood and blood products during your time at EABTC? How did your knowledge and understanding develop over time?

339. I had seen haemophilia patients in Sheffield who had tested positive for hepatitis B, and I was aware that this could develop into chronic hepatitis, cirrhosis and liver cancer. Due to the research in haemophilia patients in Sheffield, I was also aware of non-A, non-B hepatitis and the fact that this could be acquired from plasma products and blood components and could also progress to serious liver disease.

340. With the identification of the hepatitis C virus (HCV) as the cause of non-A, non-B hepatitis, and proposals to screen blood donations for HCV, my knowledge moved forward through reading scientific publications on the epidemiology of HCV, the different genotypes and their geography across the world, and the risks of transmission through transfusion.

341. When Professor Allain arrived in 1991, the centre began to prepare for HCV screening, with studies to select suitable screening tests and research on new tests to confirm apparently positive results in the screening tests. Confirmatory tests were required because all screening tests used on blood donations could give false positive results. As no suitable PCR tests were yet available, commercial RIBA (recombinant immunoblot assay) tests manufactured by Chiron were studied. Professor Allain also started a programme to develop PCR tests for HCV. I had no specific role in these studies.

342. Later, I collaborated with Professor Allain on 3 studies of donation screening, one on hepatitis C and two on hepatitis B anti-core testing. The HCV study, published in 1996, proposed an algorithm for identifying true positive HCV tests by sequentially screening donations with two different screening tests (Exhibit WITN0643029. Although the system as described in the paper was not nationally adopted, the principle was followed to reinstate donors with false positive HCV tests by selecting a different screening test for their subsequent donations.

343. The studies on anti-hepatitis B core aimed to establish the frequency of donors who, despite testing negative for the routine hepatitis B surface

antigen screening test, tested positive for another marker of hepatitis B, namely anti-hepatitis B core. Such donors may have been capable of transmitting hepatitis B. The first study, published in 1995, tested 10,000 donors in East Anglia and did not find any donors who were positive for anti-core who were carrying the hepatitis B virus, as determined by nucleic acid testing (NAT), (Exhibit WITN0643030. A larger study of 100,000 donors from East Anglia and S Thames was published in 1999 (NHBT0000112_034). This included lookback, with Ethics Committee permission, of recipients of certain categories of anti-core positive donors. Two symptomatic recipients were identified who had probably contracted HBV from transfusions. I discuss this study in detail in Section 14, Lookback.

97. How and when did you first become aware that there might be an association between hepatitis (including hepatitis B and NANB/hepatitis C) and the use of blood and blood products?

344. Please see my response to question 96.

98. What, if any, further enquiries and/or investigations were carried out at EABTC in respect of the risks of the transmission of hepatitis? What was your involvement? What information was obtained as a result?

345. Please see my response to question 96.

99. What was your understanding of the nature and severity of the different forms of blood borne viral hepatitis and how did that understanding develop over time?

346. Please see my response to question 96.

100. In a scientific paper dated October 1986, Dr Gunson stated that the best estimate of the incidence of transfusion-associated NANB hepatitis in the UK from published data at the time was 3% (SBTS0001120). He

further noted that 'if one assumes that the 2.3 million donations in the U.K are transfused to 750,000 recipients annually...then one would expect 22,5000 icteric or anicteric cases of NANB hepatitis each year.' Please answer the following questions

a. Were you aware of this paper and these findings at the time of publication? If yes, when and in what circumstances did you become aware of the findings of this paper? If no, when did you become aware of it and/or the conclusions set out within it

347. I do not recall seeing this paper before it was provided by the Inquiry. It is written in the form of a discussion paper about surrogate testing, and it states that he intended it for use by DHSS. It is not in the form of a scientific paper which would appear in the literature. It, therefore, may not have been widely shared.

b. Can you recall whether you discussed these figures regarding the prevalence of NANB post-transfusion hepatitis with your colleagues? If yes, please describe the general response to these figures.

348. I have not seen the paper before, so this question does not apply. There was general discussion about non-A, non-B hepatitis in haemophilia during my time as a trainee in Sheffield between 1985 and 1988, but I do not recall any discussion about possible numbers of donors affected.

101. Please provide details of any other information that informed your understanding of the severity and prevalence of HCV in the UK donor population.

349. Once blood donor screening for HCV started in 1991, this provided a great deal of new information about the prevalence of HCV carriage in a healthy population. Further information came from the HCV lookback, and the joint NBS/PHLS/CDSC reports covered under Q89.

General

102. How did your understanding of the seriousness of HCV and HIV/AIDS impact the donor selection policies and practice in place at EABTC?

350. In my time as a consultant at EABTC in the pre-NBA era (1991-95), national donor selection policies were followed. We did not collect blood in prisons or other offender institutions. We used national donor information leaflets and donor questionnaires. Our local processes aimed to ensure that no donations which tested virus positive could enter the blood supply. As discussed under Q82, we closed a technical loophole regarding the use of post-donation information to prevent possible high risk but virus negative components entering the blood supply. Prevention of infection was always at the forefront of our minds.

103. What advisory and decision-making structures were in place, or were put in place at EABTC to consider and assess the risks of infection associated with the use of blood and/or blood products?

351. The medical staff met to discuss cases and any problems which arose. Any local proposals would have been considered by the Management Team and referred to the RHA for funding. I do not recall any areas of concern which were not covered by national guidance or decisions. I discuss the introduction of HCV screening in section 13 and the anti-HBc studies in Section 14.

104. What if any role did EABTC have in advising those hospitals and haemophilia centres that it provided blood and blood products to, as to the risks associated with blood and blood products? Please give details of any steps taken in this regard.

352. We had responsibility for education on transfusion across our hospitals, and this included information about the risks of blood components. This

began with medical undergraduates at Cambridge University, to whom I gave an annual lecture. I included in this lecture a scenario where a transfused patient developed jaundice so that they learned about post-transfusion hepatitis at an early stage in their training. I also recall giving talks to trainee anaesthetists at Addenbrookes Hospital. For hospitals across the region, EABTC had a slot at the East Anglian 'Blood Club', described in section 3, and I was sometimes invited to give talks at individual hospitals.

353. The educational programme for hospitals was later expanded nationally under the CMOs Better Blood Transfusion initiatives, described in section 17.

Section 13: Reduction of risk of infections while at EABTC

Donor selection

105. What donor selection policies and processes were in place during your tenure at EABTC, and how did these change following the emergence of:

a. HIV/AIDS;

354. I arrived at EABTC as a trainee in 1988, so cannot comment on how donor selection policies at EABTC changed as a result of HIV/AIDS.

b. NANB/HCV; and

c. HBV?

355. I will answer these questions 105(b) and 105(c) together.

356. I do not precisely recall which document we were following in terms of donor guidelines when I arrived at EABTC in 1988, although it may have been the Council of Europe guidance. The First Edition of the Joint

professional Advisory Committee (JPAC) Guidelines for the Transfusion Services was published in 1990. Since then, this and subsequent editions of the guidance have been the basis of all procedures for donor selection, both in the RTC era and once the NBA was created.

106. What national guidelines (if any) informed the donor selection policies and processes at EABTC?

357. I have covered this under Q105.

In the event that the EABTC processes departed from any such guidelines, please explain how and why.

358. I am not aware of any donor selection policies at EABTC which differed from the national guidance.

107. How were decisions made at EABTC as to which donors were high risk and should be excluded from donating? What was your role in this process at EABTC? Were these decisions reviewed and, if so, how often?

359. In the RTC era, there was a doctor at every donor session who decided whether a donor should be accepted or not. Between 1988 and 1990, I acted as the doctor for a number of donor sessions around East Anglia, so I would have had to make such decisions. As I was still a trainee, I would have referred any difficult cases to the donor consultant the next morning so that any donations still in manufacture could be withdrawn. Such donations could not have been issued in the meantime, as placing components into issue stock could not happen until the donor records had been entered into the computer along with the blood grouping and virus testing results.

360. East Anglia was a low-risk area for blood-borne viruses, and I do not remember any contentious cases. I do not recall any regular review of such cases, as donors who were identified as high risk were rare.

108. The Inquiry understands that the donor questionnaires incorporating 'confidential unit exclusion' ("CUE") were trialled in the East Anglia region in 1997. Please explain how CUE operated and its intended purpose. Why did this need to be trialled in a region that had never detected a HIV positive donor? What was the outcome of this trial? (NHBT0010936)

361. The paper referred to in the question [NHBT0010936] is the minutes of the UKBTS/NIBSC Executive Committee on 19th June 1997 (this later became JPAC). I was not a member of that committee at that time, as I had not yet become chair of SACBC. I had no local involvement in this trial, as by then Blood Centres were under zonal management.

362. From memory, I think the CUE approach was to give donors an option to tick a box on the donor consent form to say that their donation should not be given to a patient. This was to cover the situation where a donor who knew (s)he was high risk attended a donor session with family or friends who were not aware of the donor's high-risk status. This was particularly true for MSM at that time. We had never used this at EABTC, but it was used in London.

363. From these minutes, it appears that what was to be trialled in East Anglia, as a low-risk region, was a new national donor questionnaire, which would include such an option. I imagine that including a low-risk area was to gauge donor reaction. It was also to be trialled in a high-risk region.

364. I cannot recall the outcome of this trial, as I was focused on component matters by that time. We definitely moved to a national donor

questionnaire at some point, but I cannot recall whether it contained a CUE option or not.

109. What information (either written or oral) was given to donors about the risk of them transmitting infections via their blood? When was such information provided? In particular, was there a nationally agreed leaflet or did each RTC produce its own leaflet? (NHBT0097469_018)

365. Document NHBT0097469_018 is the minutes of the Eastern Division Consultants meeting held on 9th January 1992, which I attended. There were two leaflets discussed: (1) a local leaflet concerned with donor recruitment and (2) the national AIDS leaflet for the public. It seems from the minutes that there was a proposal (perhaps by DH, I do not know) that this leaflet should be given to blood donors for information. I do not recall the meeting, but from the minutes, a number of members thought that the leaflet should be modified before being given to blood donors.

366. Throughout my career, information in blood donor leaflets explained which tests their blood was going to be screened for, but I do not think these explicitly spell out the risks that their blood would transmit infection to patients. The risks of infection are, however, included in information leaflets for patients, as discussed in Section 18, Issues.

110. How often were these leaflets updated, and how was their content decided?

367. I cannot recall how often such national donor leaflets were reviewed; it is likely to have been every 1-2 years. Such leaflets would be drafted by the SAC for the Care and Selection of Donors (SACCSD) and signed off by the UKBTS/NIBSC Executive Committee (which later became JPAC).

111. What, if any, additional information was given to donors about the risk of them transmitting infection via their blood besides that contained in donor leaflets? When and how was such information provided?

368. I am not aware of any specific information regarding the risk of infection to recipients being given to all donors. There would be general information as to why answering the donor questions carefully and in full was so important. Detailed information would have been included, however, in the post-test discussion with any donor who tested positive in the virus screening tests. This would have been done either face-to-face or over the telephone. I did not undertake such work myself.

112. How effective, in your view, leaflets and other communications at reducing the risk of donations from high-risk individuals?

369. The impact of any specific measure to deter high-risk people from attending donor sessions is very hard to assess, as there is no way of counting the number of such individuals who stay away from a donor session or don't return because of reading such a leaflet. Equally, some donors continue to attend even though they know they are high-risk because they do not agree with the policies and/or because they do not consider themselves high risk. I think multiple strategies are needed, with some form of mass communication through the media to supplement written material.

370. Towards the end of my time as Medical Director, Dr Su Brailsford from PHE/NBS was undertaking a study to assess whether donors had donated who should have been excluded because of failure to understand the donor questionnaire. The methodology of the study has been published (Exhibit WITN0643031), but I cannot find results in the medical literature.

113. Were there any difficulties in implementing the exclusion of high-risk donors at the EABTC? Please explain your answer.

371. High-risk donors in East Anglia were rare, and I do not recall any difficulties.

114. How did donor selection policies and processes change following the introduction of the Council of Europe Guidelines? You may be assisted by what is said at point 4 of NHBT0010936.

372. I do not recall which year the Council of Europe Guidelines were first produced. If it was before the first edition of the 'Red Book' in 1990, the UK would have been following those. The 'Red Book' would have been based on Council of Europe guidance as a minimum, though we may have applied stricter standards in some areas. I do not recall any specific issues. The UK Transfusion Services have always played an active role in contributing to the Council of Europe guidance.

Introduction of virally inactivated products

115. What role did you consider

a. NBTS/NBA had (or should have had) in pushing for factor concentrates to be virally inactivated during your tenure;

373. This does not apply, as all clotting factor concentrates were already virus inactivated by the time I arrived at EABTC in 1988.

b. EABTC had (or should have had) in pushing for factor concentrates to be virally inactivated in the late 1970s and early 1980s?

374. I cannot say what actions were taken by the EABTC consultants in the late 1970s/early 1980s, so I cannot say whether they should have done more.

116. At a meeting of the Executive Committee held on 27 January 1992 Professor Allain discussed providing virally inactivated FFP (see page 6).

a. What method was used to inactivate the FFP?

375. This discussion related to solvent detergent FFP (SDFFP), manufactured in Germany by Octapharma, who had approached Professor Allain to see whether EABTC/University of Cambridge could conduct a clinical trial of this product.

b. Was this taken any further? If not, why not?

376. Yes, it was, with a clinical trial (Exhibits WITN0643019 and WITN0643020 and a study on the manufacture of cryoprecipitate [NHBT0005103_009]. I discuss the clinical trial in more detail under Q199 below.

c. If so, was such product supplied by EABTC? If so, to whom?

377. As SDFFP was not licensed in the UK, EABTC (and later NHSBT) could not legally provide this product to any patients outside the clinical trial described above. I discuss national policy and progress with regard to SDFFP under Q121-126 below.

117. In the 1990s, new technologies were emerging to virally inactivate plasma, including solvent detergent treatment (Octapharma) and methylene blue photoinactivation (Baxter) (see NHBT0000236_024). What was your knowledge of these technologies during the 1990s?

378. I was first made aware of SDFFP in 1991 during the discussions with Octapharma regarding the clinical trial described above. I cannot recall precisely when I was first made aware of the Baxter methylene blue technology, but with Dr Chris Prowse SNBTS, I organised an evaluation of the product in 1997, as discussed below.

Please explain how these technologies worked to render the end product safer.

379. SDFFP: The method had previously been in use for virus inactivation of fractionated plasma products. A minimum of several hundred plasma donations have to be pooled together for SD treatment. The solvent (Tri (N-Butyl) phosphate and detergent (Triton X-100) are added to the plasma and dissolve the lipid (fatty) outer layer of viruses which have such a fatty coat. This includes HIV, HCV and HBV, against which it has proved very effective. However, the method has no effect on viruses lacking a lipid outer layer, such as hepatitis A, hepatitis E and parvovirus B19, so there has always been a required level of antibodies to hepatitis A and parvovirus B19 in the pools. The solvent and detergent are removed at the end of the treatment. The product now also includes a prion filter.

380. The methylene blue technology was the invention of Dr Harold Mohr at the German Red Cross blood centre in Springe. I do not know what prompted him to investigate methylene blue for this purpose, but it was a clever development.

381. Methylene blue, when activated by light of particular wavelengths, generates photoproducts which interfere with the proteins and DNA/RNA of viruses. Methylene blue at 1 micromolar concentration is added to single units of plasma which are then placed on a lightbox for a fixed period of time. I cannot recall the wavelength of light used by the first system developed by Baxter. The system developed by Macopharma used light of 590 nm wavelength. A further development incorporated by Macopharma was a filter manufactured by Pall, which removed >90% of residual methylene blue and other photoproducts, as there were concerns among paediatricians that methylene blue might be toxic to neonates. I discuss this further under Q124 below.

118. You note in your A & Others statement (NHBT0000032_001, paragraph 14) that methylene blue photoinactivation was developed in the 1980s by the German Red Cross. To your knowledge, was this method considered for development in the UK in the 1980s?

382. I am not aware of any work on methylene blue photoinactivation in the UK in the 1980s.

If not, why not?

383. I am not sure how the development of improved blood components (as opposed to fractionated plasma products) was organised in England during the 1980s. Individual RTCs could have embarked on research if they were able to obtain funding, but I am not aware of a national research programme or a process to obtain funding at that time. This changed for the better when the NBA was created, with a national research coordinator (Professor David Anstee, NBS Bristol), and a process for applying for research money.

119. The Inquiry understands that in 1991 Octapharma approached the University of Cambridge of Transfusion Medicine/EABTC about running a clinical trial of Octapharma's solvent detergent treatment process on UK plasma. There were contractual negotiations in 1992 between the Central Blood Laboratories Authority ("CBLA") and Octapharma regarding a clinical trial (see BPLL0002893).

a. What was the EABTC's role and your role in these negotiations and in the clinical trial? You may find BPLL0003377_002; NHBT0003749 and NHBT0003745_001 of assistance.

384. It was agreed that Professor Allain and I would develop a protocol for a clinical trial to assess the safety and efficacy of this product. This was developed with the collaboration of BPL, and RTCs and clinicians in Leeds and Birmingham, as well as Cambridge. Plasma for the trial was

collected by the Leeds and Birmingham RTCs and sent, I think via BPL, to Octapharma for SD treatment, then returned to be given to patients in the trial. The contract that was signed between the Central Blood Laboratories Authority (CBLA) and Octapharma [BPLL0002893] was to cover this treatment of the plasma.

385. In the absence of Professor Allain, Dr FA Ala (RTC Director, Birmingham) was designated the Principal Investigator for the trial, and I was the Medical Coordinator [reported in NHBT0000946]. The overall responsibility for the trial would lie with the National Medical Director, Dr H Gunson, who was to receive regular reports from the trial group.

386. Two clinical studies were performed (1) a randomised controlled trial of 49 patients with liver disease/liver transplant in which patients were randomised, with written consent and Ethics Committee approval, to receive either standard or SD treated FFP. They were monitored for side effects, correction of clotting, and for virus infections up to 18 months after transfusion. (2) a smaller study in Cambridge of patients receiving large volumes of plasma in plasma exchange procedures for the treatment of thrombotic thrombocytopenic purpura (TTP). The trials showed that SDFFP caused no side effects of concern, it corrected clotting as well as standard FFP and did not result in any viral transmissions. It was also effective for TTP, for which it later became the recommended product (see below). The results were entirely owned by the study investigators and made available to decision-makers in the NBS. The results were published in the medical literature (Exhibits WITN0643019 and WITN0643020).

b. To what extent were other RTCs, the SNBTS, BPL and PFC involved in the clinical trial? (BPLL0003518; BPLL0003548; BPLL0003359)

387. I have covered the role of RTCs and BPL in (a) above.

388. In a letter from Dr Chris Prowse, SNBTS to Dr Richard Lane, BPL in May 1992, it appears that SNBTS was going to be involved in providing plasma for the trial being developed by myself and others. However, he also mentioned that SNBTS was exploring a different type of SDFFP being developed, I think by the French Transfusion Service, EFS, in Lille [BPLL0003518], and they would conduct a parallel trial. I cannot remember the details, but in the end, SNBTS did not take part in the NBS Octaplas trial, and I am not aware that a separate trial of the Lille product took place either.

120. Please explain (in so far as you are able) why the licence exemption for the Octapharma clinical trial was rejected in 1993. You may find JPAC0000036_104, and NHBT0000946 of assistance.

389. As SDFFP is a licensed medicinal product, the trial required a CTX from the MCA. In his report on Virally Inactivated FFP in January 1994 [NHBT0000946], Dr H Gunson stated that there were two issues preventing the granting of the CTX: (1) concerns were raised by the MCA when they audited the Octapharma facility in Austria. (2) there were cases of hepatitis A in haemophilia patients in the USA who had received SD-treated clotting factors. Dr Gunson reported that the inspection concerns had been resolved and that he anticipated that the CTX would be granted. This is what happened, and the trial began in May 1995.

121. In anticipation of a licence being obtained from the MCA for Octaplas, SACTTI discussed the need for virally safer FFP (solvent detergent treated or methylene blue treated) on a number of occasions between 1996 and 1997 and considered the guidance that would be provided to clinicians on the use of standard FFP versus virally safer FFP (NHBT0000088_013, JPAC0000109_025, NHBT0010921, NHBT0000088_016, NHBT0000088_018, NHBT0000088_022). At a meeting in May 1997, it was noted that you would be chairing a Working Group to consider the operation implications of the introduction of virally safer FFP in the NBS (NHBT0000088_018).

390. SACTTI held a special meeting to discuss 'Virally Safer Plasma' on 3rd March 1995 [NHBT0017284]. The minutes of a previous MSBT meeting were provided to attendees as part of the meeting papers, but the date of the MSBT meeting is not given in the SACTTI minutes, so I do not know what MSBT had said about it. I have been unable to obtain the minutes of the 5th meeting of MSBT, held between December 1994 and October 1995.

391. The minutes of the SACTTI meeting on 3rd March 1995 [NHBT0017284] record that: "*It was recognised that against a background of public anxiety and expectations regarding blood safety, growing media scrutiny; an increasingly litigious patient population, and the availability of positive strategies now being adopted by European countries as well as the United States, it would be difficult for the U.K. to prevaricate. Statistically adequate data regarding the absolute safety of FFP may be difficult or impossible to obtain, and the political, perceptual dimension of this issue could not be deferred or ignored*".

392. It was concluded at this meeting 'that the essential task of the SACTTI was to consider how a "safe plasma" policy could be implemented when it could feasibly be introduced, and what operational and financial repercussions it might have for both UK Transfusion Services and hospitals. In other words, SACTTI would be operating within its remit discussed in Section 10, which was not to make the policy decision of 'safer FFP', which was an MSBT/DH role, but to advise the UK Blood Services as to how it should be achieved.

393. At the March 1995 SACTTI meeting, there was no great enthusiasm for SDFFP because of the pooling. The minutes [NHBT0017284] state:

394. *'It was recognised that plasma pools can be rendered essentially non-infectious for enveloped viruses. However, the need to pool meant that the potential for contamination with known non-enveloped viruses, e.g.*

parvovirus and hepatitis A, and with unknown agents was increased. Furthermore, since with a few notable exceptions, FFP usage is concurrent with exposure to blood and other products, the Committee felt, on balance, that pooled and SD-treated plasma would not necessarily increase overall the safety of patient treatment. For these reasons, the Committee elected to examine how changes within the current strategy of FFP procurement and usage would influence the safety of the product. After protracted debate, it was felt that the incremental steps, detailed below, aimed towards increasing safety of FFP should be introduced over a 2-year period, following consultation by both National Medical Directors with their operational units. The timescale was chosen in the light of the current organisational changes in the National Blood Service, the altering requirements for plasma and a recognition of the significant resourcing consequences of the recommendations by the Committee'.

395. The minutes laid out SACTTI's recommendations for these incremental steps to be explored by the UK Transfusion Services:

a) to exclude first-time donors, who had a higher virus risk, from FFP manufacture.
b) to source all FFP from apheresis, which was being done by some RTCs already.
c) to quarantine all FFP until the donor had tested negative on a further donation. However, this would not prevent transmissions from low-level HBV carriage and result in wastage of plasma from donors who did not give further donations.
d) Exploration of MB FFP when a commercial version became available.

396. SACTTI held a further meeting to discuss virally safer plasma on 19th September 1996 [NHBT0000236_024], to review what had happened regarding their 1995 recommendations and in anticipation of Octaplas being licensed in the UK. I have reviewed NHBT0000236_024, but this is only a partial record of the meeting papers and does not include the

minutes of the meeting. It would be helpful to have a full copy of the meeting papers and minutes if available.

397. The meeting papers for the 1996 meeting state:
'During 1995 the options were assessed particularly in relation to the feasibility and desirability of implementing quarantining of frozen components within the UK. It was estimated that the combined capital and revenue cost of this approach would be approximately £4.2 million and that this would result in an additional 30 tonnes of recovered plasma being made available for fractionation. Following this review a number of recommendations were formulated and endorsed by the Department of Health.

1) *More time was required for UK Transfusion Services to further consider the complex implications of introducing a virally safer clinical FFP and cryoprecipitate.*
2) *Whilst options were being assessed, Transfusion Services should actively promote the BCSH Guidelines for the use of Clinical FFP. This should include appropriate publicity and widespread clinical audit to encourage peer review and improvement in current FFP and Cryoprecipitate transfusion practice.*
3) *The clinical trial of Solvent Detergent treated FFP should continue, it was, however, recognised that the size of a clinical trial to show lack or infectivity by using options other than quarantining to improve the safety of FFP is prohibitively large and impossible to satisfactorily undertake.*
4) *Experience in other countries should be reviewed, and trials were undertaken in relation to Methylene Blue/light inactivation methods as soon as practically possible, together with a comparative cost-benefit analysis of the available options.*
5) *More data should be obtained on the seroconversion rate amongst regular donors in the UK and better data on the incidence of post-transfusion viral infections to determine a more accurate risk assessment."*

398. At the 1996 meeting [NHBT0000236_024], an important calculation of the risk of window period infections from repeat donors was provided by Kate Soldan as a baseline against which the effects of virus inactivation could be compared. Such a risk of HIV transmission due to window period infection was estimated to occur in the order of once every 5 years and for HCV once every 1.2 years. Since fewer than half of all whole blood donations are manufactured into FFP, the risk of transmissions from that product becomes in the order of 1 every 12 years for HIV and 1 every 2-3 years for HCV (the FFP calculations are mine). The data on HBV risk were not provided at the 1996 meeting, but it was acknowledged that 'tail-end' infections, when the donor is recovering, had to be considered as well as window period infections. This might make the risk of HBV higher than for either HIV or HCV.

399. It was noted at the 1996 meeting that MBFFP had been available within the German Red Cross (which invented the technique) since 1992 and that Baxter was developing a commercially available version, which, it was hoped, would be available for trials in 1997.

400. I reported on the ongoing Octaplas trial at the same meeting.

401. At the SACTTI meeting on 30th January 1997 [NHBT0000088_016], it was noted that MSBT was convening a group to decide whether Octaplas should be mandated. At the SACTTI meeting on 19th May 1998 [NHBT0000088_022], it was noted that there was a lack of clarity as to what MSBT had recommended. The minutes of the MSBT meeting from 25th March 1997 [NHBT0006016] record that MSBT supported a mixed economy of untreated and SDFFP to give a clinical choice. NBS was to be asked to pursue SD treatment of UK plasma.

a. Please provide further information in regards to the purpose(s) of the Working Group and your role within it (NHBT0007035, NHBT0000723_001, NHBT0000723_004).

402. By spring 1997, the last patient in the SDFFP trial had been treated, and it was clear that the product caused no significant side effects and corrected clotting as well as standard FFP. As explained in the above paragraph, and despite the concerns of SACTTI, MSBT had concluded that we should be offering SDFFP to clinicians, at least as an option. NBS, therefore, convened a Virally Inactivated FFP (VIFFP) group, of which I was a member.

403. The first meeting was held at BPL on 18th May 1997 [NHBT0000723_004], where we discussed with BPL the possibility of contract SD treatment of a proportion of our FFP. Plasma collected by RTCs would be shipped to BPL and from there to Octapharma, Germany, for pooling and SD treatment. It would then be redispensed into single units and shipped back to BPL for redistribution to RTCs. It was agreed that we needed to survey the hospitals to gauge demand, and I undertook to devise a questionnaire.

404. At the same meeting, it was noted that Baxter was proceeding with development of their methylene blue method, but it was still likely to be 9-12 months away from being licenced in the UK.

405. Some of the group met again on 16th July 1997 [NHBT0000723_001], while on an exploratory visit to the blood centre in Aarhus, Denmark, to look at what they were doing with the methylene blue technology. Regarding SDFFP, we hoped to have demand data by August and ship the first consignment of plasma to Octapharma by 1st November 1997. We also held meetings with representatives from Octapharma on 10th July 1997 [NHBT0002083] and 19th September 1997 [NHBT0001703], working on logistics and a contract. Octapharma was expecting the MCA to grant a UK product licence for SDFFP manufactured from German/Austrian plasma in the first instance, with a later amendment to include UK plasma. I explain subsequent events relating to the provision of SDFFP under Q124 below.

b. Please explain what the operational implications were of the introduction of virally safer FFP.

406. For SDFFP manufactured from UK plasma, I have covered much of this under Q121(a) above. An assessment of SD cryoprecipitate was also necessary, a preliminary study of which was performed at EABTC in 1997 [NHBT0005103_009]. There would also have been communication with hospitals and donors, and agreement with MCA/SHOT about reporting of adverse events.

407. For SDFFP manufactured from non-UK plasma, hospitals ordered this directly from the manufacturer, with no involvement of NBS in its distribution. The manufacturer had the primary responsibility for informing hospitals about the product, although I contributed information to the 2004 BCSH Guidelines on FFP and Cryoprecipitate.

408. For MBFFP, this was much more complex since MBFFP is not a licensed medicinal product. For example, the Macopharma system for MB treatment was licensed as a Class IIb Medical Device under the Medicines Devices Directive 93/42/EEC. Approval was by TUV Product Service, Munich on 2nd February 2000, through the EU-wide CE marking system, meaning that its approval in one EU member state allowed marketing in all of them. Licensing of medicinal devices, as opposed to medicines, does not require clinical trials and places much more responsibility for evaluation on the purchaser. I return to this general issue under Q126 and in Section 17, under prion filters.

409. Therefore NBS, working with SNBTS, had to conduct an extensive evaluation of the Macopharma system. Broadly, this evaluation was designed to cover compliance of the system with Good Manufacturing Practice (GMP) and to provide assurance on the safety and efficacy of the final component.

410. The Guidelines for the Transfusion Services (Red Book) lay down requirements for evaluation of systems for pathogen inactivation of components. These comprise (1) measurement of a wide range of parameters on 10-20 units, which are not issued for clinical use. For FFP, these parameters would be mainly clotting factors (2) Operational evaluation of (a) 100-150 units which are tested for the key parameter(s) to be used for routine quality control, which for FFP is clotting factor VIII (eight), since this is the most unstable clotting factor, and (b) production of several thousand units, which are issued for clinical use (3) clinical assessment, e.g. reporting of allergic reactions. Since the larger operational evaluation produces units for clinical use, this cannot be conducted until the product is licensed.

411. Implementing routine manufacture of MBFFP involved purchase/lease of lightboxes and purchase of methylene blue blood bags, reconfiguration of Blood Centre manufacturing space to accommodate the processing, agreement with MCA on process control (confirming that each bag had been illuminated), purchase of dedicated freezers for the MB product, a quality control programme, modification of IT to include MBFFP, information to hospitals and donors, and agreement with SHOT re-reporting of adverse events. An assessment of cryoprecipitate production from MBFFP also had to be done; this was performed by SNBTS and NBS in collaboration [NHBT0042349].

c. What guidance was provided to clinicians on the use of standard FFP versus virally safer FFP?

412. The organisation responsible for the production of clinical guidelines on FFP was the BCSH, part of BSH. They had produced guidelines in 1992, which at the SACTTI special meeting on FFP held in March 1995, NBS agreed to promote. However, there was no information on virally inactivated plasma in that guideline. Having agreed at the first meeting of the VIFFP group in May 1995 that we needed to assess demand for SDFFP, I produced an information sheet for hospitals [NHBT0009347].

Some concern was expressed about this, in case it was thought that this would constitute promotion of a product, which would not have been legal in the absence of a product licence; but we did not see how clinicians could otherwise decide whether or not to ask for the product.

413. On 21st July 1997, I also sent information about SDFFP to Dr Morris McClelland, Medical Director of the Northern Ireland Blood Transfusion Service, to see whether they wished NBS to provide them with SDFFP. [NHBT0041966_009] I do not have a copy of his reply.

414. On 15th September 1997, I wrote to Dr Christopher Ludlam, Chair of the UK Haemophilia Directors Organisation (UKHCDO), as FFP was being used for patients with certain clotting factor deficiencies where no clotting factor concentrate was available, e.g. deficiencies of factors V (five), VII (seven), X, (ten) and XI (eleven) [NHBT0001709]. My letter was to ask whether UKHCDO would wish to use SDFFP for such patients. In addition, I let him know that NBS could make this available to patients in Scotland. I do not have a copy of his reply.

415. The updated 2004 BCSH Guidelines on FFP and Cryoprecipitate included a table comparing different aspects of standard FFP, MBFFP and SDFFP, and suggested that patients who required large volumes of FFP, such as in plasma exchange procedures for TTP, might benefit from a virus inactivated product. However, caution was advised regarding the possible risks of hepatitis A and parvovirus B19 in SDFFP [BSHA0000045_001].

416. The 2003 BCSH Guidelines for the management of TTP and similar conditions stated that there was not yet enough information to recommend SDFFP. By the time this guideline was updated in 2012, and after further research, SDFFP was recommended as the optimal product for plasma exchange in TTP. This updated guidance makes reference to a DH publication from 2006, recommending SDFFP as the

optimal product for TTP to reduce infection risk and reactions (WITN0643032).

d. When was solvent detergent FFP licenced and made available in the UK

417. SDFFP was available for hospitals to purchase in 1998, but the licence prohibited the use of UK plasma for this because of the vCJD risk. Hospitals ordered this product directly from the manufacturer; the NBS was not involved in its distribution.

e. Was methylene blue treated FFP licenced and made available in the UK? If not, why not?

418. I believe the methylene blue system manufactured by Baxter was licensed in the UK in 1998, but I am not sure. The Macopharma system was licenced through the CE marking scheme as a Class IIb Medical Device on 2nd February 2000.

419. The dates of availability of MBFFP varied across the UK Blood Services, as a single implementation date was not mandated by DH. I discuss NBS implementation of MBFFP under Q124 below.

You may also find the following documents of assistance in answering the above questions regarding virally safer FFP: NHBT0009329, NHBT0006031_001, NHBT0002083, NHBT0000723_001, NHBT0001703, NHBT0000088_006, NHBT0001709, NHBT0009305, NHBT0009347, NHBT0010943, NHBT0041966_009, DHSC0017165.

420. I have also reviewed document DHSC0017165 but it is not immediately clear how it is relevant to the question.

122. In a letter to Dr Yardumian on 20 August 1997 [NHBT0002075], you suggested that:

a. "Alternative strategies for viral inactivation of single units of plasma without the need for pooling" would become available in the next year or two. Please confirm which strategies you were referring to.

421. This referred to methylene blue FFP, and, given the date, I assume I was referring to the system produced by Baxter rather than Macopharma.

b. Solvent detergent treated Factor VIII had transmitted hepatitis A on multiple occasions. What do you recall about the circumstances of these incidents?

422. I have no particular recall regarding specific incidents, which I think were all in the USA. I was made aware of them in the context of discussions with Octapharma in relation to the SDFFP trial. It was reassuring that SDFFP pools had to have a specified level of hepatitis A antibodies.

123. In a letter to Dr Ludlam on 15 September 1997, you wrote in regards to the introduction of virally inactivated plasma: "Each of the four Transfusion Services was at liberty to implement this as they saw fit, and I believe that SNBTS, and probably Northern Ireland, may be considering an alternative product, i.e. unpooled methylene blue/light treated plasma. This photoinactivation method involves provision of blood bags containing methylene blue (manufactured by Baxter and called PathInact) and exposure of individual plasma units to light of a suitable wavelength via a dedicated light box in Blood Centres. The NBS has looked at this method and feels that the current generation of light boxes does not provide the throughput we require" (NHBT0001709). Did Scotland and Northern Ireland adopt the unpooled methylene blue/light treated plasma? Do you know why the SNBTS' took a different approach on this issue?

423. From memory, I think SNBTS adopted MBFFP because of concerns about pooling with SDFFP and because they had the capacity to

manufacture enough MBFFP to meet demand, despite the slow throughput of the Baxter system.

424. I think N Ireland also adopted MBFFP. This may have been supplied by SNBTS.

124. In October 1997, in a document titled 'An assessment of strategies, including leucocyte depletion, to minimise the risk of transmission of new variant CJD by transfusion,' you raised concern over the use of pooled solvent/detergent treated plasma, given the recent data on the transmissibility of nvCJD. You proposed that the NBS review the decision to introduce this plasma. What was the reasoning behind your statement? What was the solution to this problem? (NHBT0004564, page 15)

425. During 1997, vCJD was a huge focus for the NBS. We were having meetings with DH and their external risk assessors DNV and following the scientific literature carefully.

426. The World Health Organisation (WHO) had stated in March 1997 that there was no evidence that classical CJD was transmitted through transfusion as referred to in [NHBT0004510].

427. However, as the WHO statement mentioned, it was becoming increasingly apparent that in BSE/vCJD, the risk might be different because, in experimental models, white blood cells and plasma were considered possible sources of infection.

428. Then, on 2nd October 1997, 2 papers appeared in the same issue of the scientific journal Nature, providing the clearest evidence to date that vCJD and BSE were caused by the same prion agent (Hill et al, Nature 1997; 389:448-450 [DHNI0000041_123] and Bruce et al, Nature 1997; 389: 498-501 [DHSC0004125_011]). This was a chilling event because it raised the spectre of thousands of cases of vCJD from eating BSE-

infected beef, plus possibly hundreds of secondary transmissions through other routes, of which transfusion was one.

429. In this scenario, I felt that proceeding with a pooled plasma product would be completely the wrong thing to do. On 8th October 1997, I wrote to Dr Robinson:

"Although the SD process removes cells and cellular debris from the final product, there is no information on the likely partitioning of prion protein during downstream processing. Thus, at the present time, the potential risk of prion transmission from pooled SD plasma cannot be assumed to be less than that of single unit untreated plasma. The balance of risks of Octaplas introduction should therefore be reviewed. It should also be noted that the methylene blue process includes an initial filtration step to remove leucocytes; this may be advantageous in the context of prion removal.

Early indications from user hospitals suggest that demand for a virally inactivated FFP may be between 30 and 40% of total use. Discussions with Operations staff suggest that this could perhaps be met by the current generation of methylene blue technology, provided a sufficient number of light boxes could be made available. The effect on demand of providing a single unit, as opposed to pooled, plasma is unknown at present.

The possible effects of raising undue concern over CJD and transfusion by any change of policy on FFP should also be considered.

Suggested actions.

a. *Review options at next Clinical Directors meeting.*
b. *Discuss with MSBT whether it is acceptable at this point to delay introduction of virally inactivated FFP till methylene blue technology can be introduced using current low throughput light boxes, with the caveat that it may not be possible to offer 100% VIP in the first*

instance. This option includes the likelihood that Octapharma will then proceed to market Octaplas manufactured from non-UK plasma (provided a product licence is granted).

c. *Urgently investigate resources, costs and possible timescale of providing 20%, 50% and 100% of total FFP issues as methylene blue plasma using current light boxes (Terry Male has already agreed to do this as part of the ongoing VIP project, but this review could be accelerated).*
d. *Investigate longer term options for introduction of 100% methylene blue treatment – these include the use of either low or high throughput light boxes from Baxter, direct in-licencing of the Springe technology, or contract large scale contract methylene blue treatment of plasma (Grifols).*
e. *Discuss at BCSH Transfusion Task Force the rapid production of a clinical guideline to help clinicians prioritise the use of methylene blue FFP [NHBT0004564, Appx 3, pp15-16]".*

430. Because of these concerns, at a meeting of the NBS VIFFP group on 7th November 1997 [NHBT0007035], we agreed to cancel the project with Octapharma (the contract had not been signed). We recognised that Octapharma would proceed to market anyway with the product made from German/Austrian plasma. We noted that from our survey, hospital demand was approximately 30% of total FFP.

431. At the same meeting, we decided to proceed with MBFFP, and some of the group had already met with Baxter to obtain lightboxes for assessment, and an implementation date of spring 1998 was discussed. It was also noted that

i. Grifols, Spain were offering contract MB treatment to external plasma providers, and it was agreed that some of the group would enquire about this when they visited Grifols for a planned audit regarding blood pack provision. This did not progress to implementation because Grifols did want UK plasma going through their plan in case of vCJD contamination.

ii. Macopharma was also developing a methylene blue technique, which we would keep under review.

432. During 1998, a number of issues with the Baxter MB technology gradually emerged (1) the throughput was slow (2) as minuted at SACBC on 12th June 1998 [NHBT0059328], Baxter had doubled the dose of methylene blue and were now stating that this was a 'risk reduction system', raising concerns about its efficacy (3) there was no method for ensuring that a pack put on the lightbox had actually been illuminated (4) paediatricians were becoming concerned about possible MB toxicity, so SNBTS were conducting a study in neonates. I recall meeting with the haematologist at Great Ormond Street Hospital, Dr Ri Liesner, to discuss her concerns.

433. At SACBC on 11th March 1999, it is minuted [NHBT0041174_001] that the regulator in Germany, the Paul Ehrlich Institute, was likely to require an MB removal step for licensing. I think around the same time, we were made aware that the technology being developed by Macopharma was possibly going to introduce a methylene blue removal step. At SACBC on 10th June 1999, it was minuted [NHBT0041173_001] that SNBTS was now evaluating the Macopharma MB system.

434. During 2000, NBS conducted a large scale evaluation of MBFFP produced by the Macopharma system [NHBT0016299_001], which included issue of MBFFP to hospitals. Although throughput was slower than expected, no specific problems were encountered.

435. Part of the evaluation was a survey of 24 large hospitals to gauge indicative demand. This indicated that 10 hospitals did not wish to purchase MBFFP, 13 wanted between 10% and 30% of their supply as MBFFP, with only 1 hospital indicating that it would like 100% MBFFP (in the event, no hospitals requested 100% MBFFP).

436. Regarding the use of MBFFP in neonates, 16 hospitals indicated that they would order MBFFP only if the methylene blue were removed, one indicated that it would like the product even without methylene blue removal, while 6 replied that they would not wish to order this component for neonates.

437. When asked about MB cryoprecipitate, 13 hospitals replied that they would not be ordering this component, with 7 indicating that they would order between 5 and 50% of cryoprecipitate as MB treated. There was interest in a fibrinogen concentrate as an alternative, but there were concerns about cost.

125. In a SACBC meeting on 9 October 1997, it was noted that the UK was the only country in Western Europe which did not produce virus inactivated plasma (NHBT0010943, page 2). In your view, why was this? Was the lack of additional government funding (see page 3) the main barrier?

438. On the date in question, neither MBFFP nor SDFFP were licensed in the UK, so we could not produce either of them. As described above, NBS was working with Octapharma towards contract treatment of SDFFP, a project which was cancelled in November 1997 due to the possible risk of vCJD from a pooled product.

439. In the minutes of this SACBC meeting on 9th October 1997 [NHBT0010943], it was noted that no extra government money would be made available in England for hospitals to purchase SDFFP. In 1998, SDFFP from non-UK plasma was licensed, so hospitals could purchase it as an alternative to standard FFP. In practice, very few replaced FFP entirely with SDFFP, but I cannot say whether that was due to lack of funding or for clinical reasons.

440. Equally, there was not a licensed technology for MBFFP production in 1997. So, at that point, lack of funding could not be said to be the main factor in holding up implementation.

126. Were the steps taken by the NBTS/NBA and/or EABTC to introduce virally inactivated products, sufficient in your view? If not, what more could or should have been done?

441. As described above, there were no VI techniques available for FFP in the RTC era. Neither SDFFP nor MBFFP could be implemented in the UK till the commercial processes were licensed by the manufacturers. SDFFP and the Baxter system for manufacture of MBFFP were licensed in 1998, and the Macopharma system for manufacture of MBFFP was licenced in 2000.

442. The NBS, to my knowledge, never had a specific instruction from DH to implement 100% virus-inactivated FFP. MSBT favoured a 'mixed economy' of standard and SDFFP in 1997, minuted at its meeting on 26th March 1997 [NHBT0006016]. Therefore, NBS followed the same strategy for MBFFP, producing it alongside standard FFP.

443. Between 1992 and 1997, until vCJD came into play, NBS was on a clear pathway for a clinical trial of SDFFP, followed by contract treatment of a proportion of UK plasma as an option for hospitals, in line with the MSBT mandate of a mixed economy. Because of the possibility of greater transmission of vCJD with a pooled product, we decided in November 1997 not to pursue this option.

444. NBS then changed its strategy for provision of virus-inactivated FFP to the MB technology, initially with the Baxter system, and then, due to the issues described above, with the Macopharma system. I have explained under Q121e above the extent of the evaluation Blood Services have to undertake of CE-marked systems for production of virus inactivated FFP. This can take up to a year to plan and carry out.

445. From 1997 onwards, decisions taken by NBS regarding VIFFP were overshadowed by the urgency and importance of vCJD risk reduction,

which was by far the most overriding concern. Whilst we knew that standard FFP was not entirely risk-free, the predicted rate of virus transmissions, as calculated by Kate Soldan, had to be balanced against the possibility of tens or hundreds of transmissions of vCJD. This had two implications which impacted on provision of MBFFP: limited operational capacity for its implementation alongside leucocyte depletion and consideration of importation of FFP as a vCJD risk reduction measure.

446. I will discuss each of those in turn.

447. Operational capacity in 1997-1999 had to be given over to the urgent implementation of universal leucocyte depletion. To put this into context, DH asked for a feasibility report on leucocyte reduction in November 1997, to be provided in 3 months; the Secretary of State for Health announced in July 1998 that universal leucocyte depletion would be implemented, and later an implementation date of 1st November 1999 was agreed. I discuss this in more detail in section 17, but it is worth noting here that this was the biggest project ever undertaken by the Blood Services. The same managers, scientists, doctors and quality staff were involved in both LD and FFP projects.

448. For example, at SACBC on 12th December 1997 [NHBT0010964], I reported that NBS was about to undertake an operational evaluation of 2000 units of MBFFP, but this was later postponed by the decision of the NBS Board. Since they had to prioritise LD implementation over FFP and everything else for all of 1998 and most of 1999, it is inevitable that the pace of implementation of MBFFP slowed down.

449. At the SACBC meeting on 11th March 1999 [NHBT0041174_001], it was reported that in SNBTS, MBFFP was in routine production for a proportion of their FFP. Concern was expressed about the asymmetric position across the UK, and I undertook to write to Dr Angela Robinson about this. I haven't been able to find such a letter written by myself or

any reply from Dr Robinson. It should be borne in mind, however, that hospitals were able to purchase SDFFP by this point, so a virus inactivated FFP manufactured from non-UK plasma was available to them.

450. A further factor limiting operational capacity during the second half of 1999 was preparation for the Millennium, covering both the possibility of a 'Millennium bug' in the IT systems and of a major incident during the celebrations. These were taken very seriously. For example, I was on duty on 31st December 1999 and was required to be present in the Blood Centre till well after midnight.

451. From 1999 onwards, and also discussed in section 17, Q185, provision of virus inactivated plasma became inextricably bound up with decisions of MSBT regarding the importation of FFP. Because the USA, which we first explored as a source of FFP, had a 4-9 times higher virus risk than the UK, it was agreed that any imported FFP had to be virus inactivated.

452. In practice, NBS implemented MBFFP made from UK plasma in, I think, 2000 for neonates and children initially. As discussed in detail in section 17, MB treated US plasma came on stream in 2004 for neonates and children born on or after 1st January 1996.

453. Given the issues which I have outlined above, I think that the NBS did its best to provide MBFFP in as timely a way as was appropriate, given the threat of vCJD at the time. MSBT were comfortable with a mixed economy, the results of the hospital survey suggested that clinicians were at best ambivalent about the component, and SDFFP was available as an alternative.

Provision of diagnostic screening kits

127. Please describe the arrangements in place at EABTC in regards to the provision of diagnostic testing kits for donation screening ("screening kits").

454. Before the NBA was created, each RTC could select their own manufacturer(s). From memory, the purchasing and contracting was through the RHA. In February and March 1991, the EABTC Management Group minutes record that Dr Angela Rankin, Associate Specialist, was looking at options for HIV and HBV screening, presumably because our contract was up for renewal [NHBT0041230_001, NHBT0041285_004, NHBT0041284, and NHBT0041283_002].

455. It appears from the minutes that we were using Wellcome kits up to that point, but Dr Rankin felt that Ortho or Abbott kits would be better (precise reasons not recorded). She was also looking at HCV test kits in preparation for the start of screening. At the meeting on 4th March 1991, Professor Allain asked whether a decision on those could be deferred until he took up the post on 29th March 1991 [NHBT0041285_004]. As it would be preferable to purchase kits for all 3 viruses from a single supplier, a short-term contract with Wellcome was agreed upon pending a final decision.

456. The final decision would have been taken by the Management Team, following a recommendation from Professor Allain, but I do not have minutes which record it. I recall it was either Ortho or Abbott, but I cannot remember which.

457. Once the NBA was created in 1994, purchasing and contracting became their responsibility. Decisions on which manufacturer to use moved to zonal management teams, possibly with national coordination. In 1999, when we moved to full functional management, decisions were made nationally as to how the contract was to be awarded.

128. Did you, or anyone else at EABTC contract directly with any pharmaceutical company involved in the manufacture and/or sale of screening kits, or were contracts negotiated on a national basis? You may find NHBT0000188_039 of assistance.

458. I have covered this in Q127 above. Document NHBT0000188_039 is a letter from Dr Gunson to Mr Follett at Ortho, dated 1st September 1989, simply confirming arrangements for demonstrations of the Ortho kits in three locations so that all RTCs could send someone.

129. The Inquiry understands that the EABTC was involved in the evaluation process of the Abbott Prism. (NHBT0007771_001, NHBT0007772_003). Please explain what the Abbott Prism is. What was the result of this evaluation and what was the impact on the EABTC?

459. The Abbott Prism was a machine for high throughput screening of blood donations for viral markers. It could test for anti-HIV, HBsAg, anti-HCV, anti-HBc, or any other markers for which Abbott manufactured reagents. An evaluation took place in 1995 at the Cambridge Blood Centre (as it was by then) on behalf of the National Blood Authority. Dr Robinson and Dr John Barbara (Consultant Virologist, NBS Colindale) attended a meeting with Cambridge staff and Abbott representatives at Cambridge on 22nd February 1995 [NHBT0007771_001].

460. A similar trial had been going on at SNBTS, and my letter to Dr Robinson dated 19th December 1994 [NHBT0007772_003] was to seek clarification as to how we should handle repeat reactive samples during the evaluation as it appeared that SNBTS and NBS policies differed in this regard. I do not recall the outcome.

461. The trial was successful, and NBS proceeded to use Abbott PRISM in a number of centres, including Cambridge, until virus testing was transferred to Brentwood.

130. What were the key factors influencing choice of screening kit and/or pharmaceutical provider? (NHBT0000015_106)

462. There are a number of key factors determining which virus test kits to purchase. Absolutely critical is the test sensitivity (ability to detect truly positive samples). Also of importance is the false positivity rate, i.e. the number of samples which test positive where the donor does not actually carry the infection. Other factors include throughput, degree of automation, integration with laboratory computer systems, provision of quality control samples, availability of confirmatory assays, customer support and cost of equipment, test kits and servicing.

131. What influence did pharmaceutical companies retain after supplying screening kits to the UK? For example, can you recall whether pharmaceutical companies provided advice on the implementation or use of the screening kits?

463. Involvement of companies at the time of setting up new test kits is essential to sort out teething problems. Manufacturers would send technical rather than sales staff to help with this. There would then be regular contact and visits by the company on an ongoing basis. Through SACTTI's Kit Evaluation Group, UK Transfusion Services devised a formal process for assessing different manufacturers' kits and maintained a list of approved ones.

Introduction of HIV testing

132. The Inquiry understands that HIV screening was to commence on 14 October 1985. As far as you can recall, did EABTC commence screening on this date? What steps were taken to ensure that EABTC could begin screening on this date?

464. I did not take up my post at EABTC until 1988 so am unable to answer this question.

133. Do you consider that anything could or should have been done by EABTC (or others) to introduce HIV screening any earlier?

465. I did not take up my post at EABTC until 1988 so am unable to answer this question.

134. Please describe the implementation of HIV screening at EABTC. In particular:

a. What was the process for screening donors and/or blood donations?

b. What impact did the introduction of HIV screening have on EABTC?

c. What happened to all the unscreened blood that had been collected prior to HIV screening being implemented?

d. What happened when a donation was found to be infected with HIV? Please set out the steps that had to be taken, both with respect to the donor, and in terms of passing on information to third parties and/or identifying recipients of previous donations from that donor.

e. What happened to donations that tested false positive? Were they discarded?

466. I did not take up my post at EABTC until 1988 so am unable to answer these questions.

135. In March 1985, some Regional Transfusion Directors published their opinion in the Lancet on the introduction of HTLV-III antibody testing. They supported HTLV-III antibody testing but advised that it be "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" (PRSE0004824). Were you aware of this opinion at the time? If so, did you agree with it? If not, why not? As far as you are aware, were the concerns expressed in this article resolved prior to the introduction of testing in October 1985?

467. The Lancet letter from a number of RTDs states strong support for the introduction of HIV testing of blood donors. They expressed two concerns, firstly that the high false positive rates of tests available might cause serious loss of donors to the blood supply. I will address these separately.

468. I did not take up my first transfusion post at the Sheffield RTC until August 1985. I do not recall particular concern over high false positivity rates among donors, nor do I recall huge donor loss when testing started.

469. I was certainly made aware of concerns about the 'magnet effect', i.e. if HIV screening was available at a blood donor session, it would attract people at high risk of carrying HIV infection, particularly MSM.

470. At that time, many MSM were not 'out' because of social stigma and would not necessarily have wanted to attend a sexual health clinic. It seemed to me reasonable to be concerned about the 'magnet effect', as no one knew what percentage of asymptomatic HIV carriers would be detected by the test kits. As I recall, there were moves by the wider NHS and public health organisations to offer and publicise HIV testing in other settings. I do not recall that the issue was totally resolved before we began screening.

471. The other issue raised in the Lancet letter [PRSE0004824] was the possibility of loss of many donations and possibly non-HIV infected donors if the kits had a high false positive rate. I do not recall this being a major problem.

Surrogate testing for NANB

136. A report prepared by Dr Gunson in August 1987 set out the conclusions of a Working Group established by the Council of Europe Committee of Experts on Blood Transfusion and Immunohematology to consider the

introduction of routine surrogate testing ('the Working Group report') (NHBT0008816_002). The Working Group concluded it could not provide a recommendation on the introduction of surrogate testing in light of the following considerations:

a. the use of surrogate tests to reduce the incidence of transfusion associated non-A non-B Hepatitis (NANB) and its possible value as a public health measure remained controversial;

b. there was no guarantee, in a given country, that there would be a significant reduction of NANB;

c. the introduction of surrogate testing in some countries could lead to a severe depletion of donors which could compromise the blood supply; and

d. if surrogate testing was introduced, provision would have to be made for interviewing, counselling, medical examination and treatment of anti-HBc positive donors and donors with raised ALT. Please advise whether you were aware of the Working Group's report. If you were, did you agree with the conclusions reached by the Working Group? If not, why not?

472. I was on maternity leave when this report was published, and when I returned to work in 1988, I do not recall seeing it or any discussion of it.

473. I do remember general discussions about ALT testing at Sheffield. It is a very non-specific test, and a very common cause of a raised ALT is excessive alcohol intake. I do recall the very great concern that many donors would be lost due to a high ALT of unknown cause and be worried about what it meant, or have hospital visits and investigations they did not really need. Another concern was that people would not come forward as donors knowing they would have this test.

474. I do not recall any specific discussions about ALT testing when I moved to Cambridge as a trainee. Compared to Sheffield, there was much less open communication and discussion of the issues of the day, the

Management Team preferring to keep such matters confidential. I comment on anti-HBc testing at EABTC under Q139 and 140 below.

137. The Working Group's report from 1987 commented: "If a stance is taken that blood should have maximum safety then the tests would be introduced" (NHBT0008816_002). Please explain your views on this statement. In your view, did the decision not to introduce routine surrogate testing indicate a decision not to provide "maximum safety"?

475. If the definition of 'maximum safety' means the introduction of any test which could detect even a single infected donation without consideration of the impact on donors or of cost, then ALT and anti-HBc would meet that definition and would have had to be introduced. However, the Working Party's comment about depletion of donors is a fair concern. Surgery for heart disease, organ transplants, and treatment for cancer all require a ready supply of blood components. Should there be shortages, there is also potential for patient harm. I do not know what steps were taken by the Working Group to check out their concerns, e.g. with a donor survey.

476. I note that decisions were taken by MSBT not to introduce either anti-HBc testing at its first meeting on 4th October 1993 [MHRA0020214]) or ALT at its third meeting on 29th September 1994 [PRSE0003670]. The minutes record discussion of these different aspects, but not any systematic analysis, supported by full data, of the risks and benefits. Such analysis may, of course, have been done behind the scenes. See also my answer to Q157d in a later paragraph.

477. In section 18 of this statement, under issues, I compare decision making on blood safety issues in the 1990s with my later experience in the SaBTO era. There is no doubt that from 2008-2016 when I retired, there was much greater transparency as to how safety decisions were reached.

138. In October 1989, Dr Gunson, the Chairman of the Advisory Committee on Transfusion Transmitted Diseases ('ACTTD'), recommended: "The routine introduction of non-specific tests should be deferred, unless this is necessary for the acquisition of product licences in the UK for fractionated plasma products" (NHBT0000188_072, paragraph 7.5). Then, in November 1989, the ACVSB concluded that there was no case for using surrogate testing for non-A non-B Hepatitis (NHBT0005043). Please advise whether you were aware of the decisions made by ACTTD and ACVSB. If you were, did you agree with the decisions made by ACTTD and ACVSB? If not, what were your objections?

478. I was not aware at the time of these specific decisions, nor do I know whether these committees used any kind of safety framework. I have discussed my views and the general issues about their use under Q137 above.

139. Please advise whether surrogate testing (namely ALT or anti-HBc testing) was introduced at EABTC during your tenure.

479. As far as I can recall, ALT testing was never used in NBS, either in the RTC era, under zonal management, or once NBS moved to national management.

480. Regarding anti-HBc testing, it appears from documents provided by the Inquiry that RTCs were preparing for anti-HBc testing during 1993. Minutes of the EABTC Executive Team on 5th July 1993 [NHBT0041409_002] record that the Regional Director of Public Health had supported the release of funds for anti-HBc testing and that a decision from Regional Finance was awaited. At the EABTC Executive meeting on 20th July 1993, I reported a discussion with Dr Gunson in which he told me that DH would be making a decision on anti-HBc testing, but not before the end of September [NHBT0041406_002]. At the EABTC Executive team on 20th September 1993 [NHBT0041398], it

was recorded that NBS national finance wanted us to make provision for anti-HBc testing in our 1994-5 budgets.

481. In practice, as recorded in its minutes of the meeting on 4th October 1993 [MHRA0020214], MSBT rejected anti-HBc screening, so EABTC could not introduce it.

140. If surrogate testing was introduced at EABTC, please explain what impact this had on EABTC.

In particular:

a. How was the surrogate testing performed?

b. What was the process for screening donors and/or blood donations?

c. What happened to the unscreened blood that had been collected prior to surrogate testing being implemented?

d. What happened when a donation tested positive? Please set out the steps that had to be taken, both with respect to the donor, and in terms of passing on information to third parties and/or identifying recipients of previous donations from that donor.

e. What were the circumstances in which EABTC stopped surrogate testing?

482. Since neither routine anti-HBc testing nor ALT testing was ever introduced at EABTC, none of these questions applies.

483. It should be noted that anti-HBc testing has, I think since the 1990s, been part of the national protocol for reinstatement of donors after routine deferral because of acupuncture, tattooing or body piercing, as detailed in the UK Guidelines for Transfusion Services ('Red Book'). I note that, following the observation that no anti-HBc positive donors had ever been detected in this context, SaBTO rescinded this requirement on 9th June 2017.

484. Although we did not implement anti-HBc testing routinely, EABTC was involved in two studies of anti-HBc screening in the mid-1990s. I have detailed the purpose and conduct of these studies in response to the amended Rule request dated 14 August 2020 – the 'lookback' request.

Introduction of anti-HCV screening

141. When did EABTC begin anti-HCV screening? You may find NHBT0041282_003 and NHBT0041278 of assistance.

485. I believe that EABTC started testing on the nationally agreed date of 1st September 1991 but the EABTC Management Meeting minutes I have available do not record this formally.

142. How was anti-HCV screening funded? What was the annual cost of introducing the anti-HCV screening at the EABTC? (NHBT0041283_002, NHBT0041284; NHBT0041230_001, NHBT0045585)

486. Funding came from the East Anglian Regional Health Authority. The annual cost was £350,000 [NHBT0041230_001].

487. Professor Allain also made a case to the RHA for an extra consultant to undertake counselling of anti-HCV confirmed positive donors (later called 'post-test discussion') and to contribute to research. This was also agreed by the RHA.

143. Dr Gunson wrote a letter to all RTC directors suggesting a delay in commencing anti-HCV screening from July to September 1991 so that "'second-round' comparative evaluation" of the testing kits could take place (NHBT0000073_065). It appears that this suggestion was discussed at a meeting you attended on 8 April 1991 [NHBT0041282_003] at which meeting Professor Allain indicated that he would prefer to introduce routine HCV testing at an earlier date which would be dependent on the research Dr Caffrey was undertaking. What

was this research and what relevance did it have to the start date for HCV testing?

488. Although I cannot be certain, I think this research would have been a pilot of HCV antibody screening to establish what would be the optimal confirmatory test(s) to distinguish true from false reactive results in the screening test. This was critical for the implementation of screening in order to know what to communicate to the donor.

489. It was noted at the EABTC Management Team minutes on 20th May 1991 [NHBT0041278] that the RHA had approved the funding with the proviso that if more than one donor tested positive in these studies, then testing would start straight away.

144. Did you agree with Professor Allain's view that testing should be started earlier than September 1991? If so, why? If not, why not?

490. I find it impossible to recollect clearly how I felt about this issue 35 years ago. It has been discussed so many times since then, and of course, we have had the HCV litigation. Any recollections are also inevitably coloured by the more precautionary approach, which has been adopted to more recent hazards such as vCJD,

491. The NBS strategy for adoption of new safety measures later recognised that some Blood Centres would be ready to 'go live' before others. This was encouraged, with a date set by which all Blood Centres must have adopted the new measure set. When I was Medical Director, I was comfortable with this approach.

492. Although I have not seen documents which confirm this, I am sure that testing actually began at EABTC on the nationally agreed date of 1st September 1991. It is certainly true that Professor Allain had been minded to introduce testing earlier. I cannot recall precisely why he seems to have changed his mind; it may have been that in Dr Caffrey's

studies, there were no positive donors, East Anglia being a llow-risk region at that time.

493. Ideally, there should have been a consensus on an implementation date around which Regional Transfusion Directors could coalesce, and it is deeply unfortunate that that was not fully achieved. I do not recall seeing any of the information on which rejection of the first-generation tests by the RTDs was based. My time in early 1991 was taken up with coordinating blood supplies for the Gulf War, and Professor Allain was the EABTC Director and an expert on transfusion-transmitted infections, so as a new consultant, I was happy to be guided by his views.

145. Despite Dr Gunson's suggestion to delay the introduction of screening, the Northern RTC led by Dr Lloyd introduced routine testing in April 1991, becoming the first centre to do so. Dr Lloyd's view, in contrast to that of Dr Gunson's, was that, the "Second Generation HCV tests were acceptable tests for donor screening" by June 1991 (NHBT0000076_009), and that deciding not to implement testing despite having the capability "would be indefensible under the current Product Liability Legislation" (NHBT0000074_014).

As to this:

a. Did you know about this decision? If yes, did you agree or disagree with Dr Lloyd? Please explain the view you had at the time.

494. I was made aware of Dr Lloyd's actions at the EABTC management team meeting during the summer of 1991. I remember feeling rather irked that he had jumped the gun, as this would put the other centres in a very awkward position.

b. Have your views changed since then? If so, why?

495. I now have more sympathy with Dr Lloyd's position that the NBS was in a good enough position to adopt the first generation tests. Implementation of later major projects in the NBS era, such as universal leucocyte depletion, accepted that some centres would be ready before others. Thus, projects had a 'date by which this must be implemented nationally' rather than an agreed start date or all locations at once. The creation of the NBS, with national accountability, made the introduction of new safety measures much easier to manage.

146. What impact did HCV testing have on EABTC?

496. I do not recall any particular negative impacts, as East Anglia had a relatively low rate of positives. We had enough laboratory staff and equipment, and we had an extra consultant to undertake post-test discussions. The main feeling was relief that testing had finally begun.

In particular:

a. What was the process for screening donors and/or blood donations?

497. The process was exactly the same as for the HIV and HBV screening in place at the time. A sample taken at the time of blood collection was returned to EABTC and tested with a batch of other samples using semi-automated equipment.

b. What happened to all the unscreened blood that had been collected prior to the HCV testing being implemented?

498. I cannot recall whether we adopted a 1st September 1991 start date for screening or whether we started 35 days earlier so that all red cells on the shelf were already screened. We may have swapped out plasma in

frozen storage for plasma that had been tested and found negative, but I regret I cannot recall.

c. What happened when a donation tested positive? Please include where a batch tested false positive. Please set out the steps that had to be taken, both with respect to the donor, and in terms of passing on information to third parties and/or identifying recipients of previous donations from that donor.

499. I will deal with a positive donation and various 'batch' scenarios separately. For screening tests, we use the term 'reactive' rather than positive, as a screening test does not provide a definitive diagnosis.

500. If a donor's sample was reactive in the screening test, it would be retested twice, and if confirmed reactive in either of the retests, the donation was discarded. The sample would then be tested by one or more confirmatory tests to establish whether the reactivity in the screening test represented true infection or was a false positive reaction. The results of confirmatory testing would inform what the donor was told.

501. If the confirmatory tests were positive, suggesting that the donor really had a virus infection, the donor would then be contacted by letter and invited for a discussion with a doctor. I think Dr Caffrey tried to do all of these discussions face-to-face to begin with. The donor would have a discussion about the implications of being HCV positive, and, with the donor's permission, the GP would be contacted, suggesting referral to a hepatologist. We had a list of hepatologists at the various hospitals throughout East Anglia who had agreed to see HCV positive donors. It may be that Dr Caffrey was able to refer donors directly rather than via the GP, but if so, the GP would certainly have been kept informed.

502. The EABTC computer system would then have been updated to show that the donor was permanently deferred from donation. This would block any future donations from being issued for clinical use.

503. Donors who showed repeat reactivity in the screening assay but negativity in the confirmatory tests usually did not have hepatitis C infection but were giving a false positive reaction. To begin with, such donors had to be excluded from future donations, as they would always test positive. Therefore, the computer was set to 'exclude' them, meaning that any future donations could not be issued for clinical use.

504. Donors who gave false positive reactions were informed that they did not have an infection but nevertheless could not donate again. Understandably, this sometimes caused worry, confusion and sometimes anger in donors.

505. To avoid alarming donors unnecessarily, an algorithm was later approved by JPAC to allow such donors to continue to donate by screening them with a different manufacturer's kit. This was called 'donor re-entry'. I cannot remember the date this was implemented. This approach had been proposed in a study led by Professor Allain (Exhibit WITN0643029).

506. I am not sure whether 'batch' here refers to a batch of virus test kits, a batch of samples or a batch of products. I will cover each possibility.

507. Each batch of virus test kits which arrived from the manufacturer was tested before use to ensure that it had the sensitivity and specificity required to avoid large scale false negative or positive results.

508. Each batch of samples would be run alongside positive and negative controls. If these did not give the correct readouts, the batch of samples would be run again.

509. The situation of a positive batch of components at EABTC did not arise, as donations were tested individually. I discuss actions taken if a BPL plasma pool tested positive under Q 150 below.

d. What impact did the introduction of testing have on the risk of transmission of HCV through blood donations?

510. Scientific studies have shown that, without a doubt, HCV antibody screening made a huge difference to the risk of HCV transmission from blood components. This was reduced even further by the introduction of HCV nucleic acid testing (NAT) in 1999.

e. What funding and operational support was EABTC provided with to assist with the implementation of testing? Did this have an effect on EABTC's ability or willingness to commence testing earlier? You may be assisted by pg.36 of NHBT0000026_009.

511. The document referred to is Dr Gunson's witness statement in the A & Others Litigation. On pg 36, he describes writing to all RTDs in January 1991 to ascertain the date by which they could commence screening. For Cambridge, the response, I assume from Professor Allain, was: '*Commence testing on 1st October 1991 if additional funding was made available and adequate progress with other matters, viz. development of a computer program, a degree of retraining of staff and recruitment to cope with an anticipated 10-15 cases per week, requirements for counselling and to decide which screening test to use.'*

512. It is worth reiterating that by May 1991, as covered under Q142 above, the RHA had agreed the funding, including an additional consultant. There was no indication in any of the EABTC management meetings from 1991 that a delay in funding or resources was an issue in agreeing a start date. Indeed, as discussed above, Professor Allain was for a time keen to start earlier than the implementation date, which was later asked for by Dr Gunson, i.e. 1st September 1991.

Recall practice and procedure at EABTC

147. Please give an overview of product recall practice at EABTC, and how this changed during your tenure.

148. What, if anything, do you remember about any formal recall or/notification procedure in place?

513. I will answer these 2 questions together.

514. There were three situations when a recall had to be initiated:

i. *Because the donor had contacted EABTC with some new information about their health, or because they had recently donated blood, then remembered a reason why they should not have donated on that occasion.* This required checking on the computer to find out what components we had manufactured from relevant donations and which hospitals had received them. We then contacted the hospitals by phone and fax, asking them to return the components for disposal. This was covered by a standing operating procedure (SOP). I think at some point, we changed the procedure so that hospitals could dispose of the components themselves and confirm in writing that they had done so. Some reasons for component recall did not apply to plasma for BPL, e.g. travel to a malarious area. However, if the new information was relevant, we would also contact BPL. It was noted in the EABTC Management Team meeting on 10th June 1991 [NHBT0041277_002] that BPL had issued a new recall procedure to cover this situation.

ii. *If we were contacted by BPL to say that a plasma pool to which EABTC had contributed had tested positive, as is mentioned in EABTC Management Team minutes on 18th February 1991* [NHBT0041286_003]. In this instance, as well as activating the recall, archive samples from every donation which had contributed to the pool had to be retested. If we found any of these samples to be

positive, we would invite the donor to come to EABTC for a discussion and repeat testing.

iii. *If BPL contacted us to initiate a recall of a batch of finished plasma products.* We were involved because we distributed BPL products to hospitals in East Anglia. If such a request was received, we would check in the computer which hospitals had received products in the relevant batch and ask them to return them to EABTC. I recall that the BPL procedure required the products to be sent to BPL and that local disposal was not an option.

149. In your opinion, were such practices and procedures effective? From your experience, did clinicians generally comply with recall requests, and if not, do you recall why not?

515. We did not have to use the recall procedure very often, but I do not remember any difficulties with recalls from hospitals. They were very often handled by the Blood Bank manager and staff. Once hospitals started to have quality systems in their laboratories, this would have been covered by an SOP.

150. Please outline the procedures in place at the EABTC to prevent infected donations from contaminating plasma pools at BPL, and the procedures in place to enable a contaminating donation to be traced. You may find NHBT0041286_003 and NHBT0041410 of assistance.

516. I have covered this in Q146 and 147 above.

Batch Dedication

151. What if any steps did the EABTC take in implementing a system of batch dedication for patients?

517. EABTC distributed BPL (not commercial) plasma products to hospitals. I cannot recall whether we adopted a process of matching batches to

specific hospitals. EABTC did not have any information on patients, which would have allowed us to dedicate batches to specific patients, a responsibility which correctly lay with the treating clinician. By the time I arrived at EABTC in 1988, all clotting factor concentrates were virally inactivated, so batch dedication was less of an issue.

General

152. Please describe all other steps or actions taken at EABTC during the time you worked there to ensure blood safety and to reduce the risk to recipients of blood or blood products of being infected with a transfusion transmitted infection.

518. I will focus here on the RTC era as I discuss national policies further under section 17, vCJD.

519. There are three elements to blood safety (i) policy decisions on donor selection, testing and manufacture (ii) systems to ensure that these are followed with a high degree of accuracy and consistency, with the chance of error minimised (iii) appropriate use of blood components, employing alternatives and avoiding unnecessary transfusion. I will consider each of these in turn.

i. *Policies.* As far as I can recall, EABTC always followed national policies. We were greatly aided by the publication in 1990 of the First Edition of the Guidelines for the UK Transfusion Services ('Red Book'). I do not recall any specific additional steps adopted at EABTC.

ii. *Systems.* From 1988 to 1995, there was a focus at EABTC on introducing a full quality system, maximising automation, computerising all processes and ensuring that the donor sessions and laboratories were fully staffed with motivated, well-trained people. We appointed a Quality Manager and an assistant. All procedures were turned into SOPs, against which people were trained. There were inspections by the MCA and we had to be

compliant with all requirements to obtain, and retain our Manufacturing (Specials) licence.

iii. *Appropriate blood use and alternatives*. It would be fair to say that this was not a huge focus of attention for all RTCs pre-1994, although the EABTC Management Team minutes of 28th June 1993 [NHBT0041410] record a discussion I had with Dr Trevor Baglin, Consultant Haematologist at Addenbrookes Hospitals, agreeing that EABTC would provide testing for a pre-deposit autologous transfusion programme which he was trying to establish. I also recall discussions with the Jehovah Witness group in East Anglia, as they were offering to provide machines to hospitals to undertake intraoperative cell salvage. I think that such a machine was installed at Queen Elizabeth Hospital, Kings Lynn.

153. Was blood safety ever subject to cost, time, staffing or any other constraints? If you felt a particular course of action needed to be taken to ensure blood safety, were you free to take it?

520. Any changes to policy would have been agreed at EABTC Management Team, rather than decided and implemented by myself alone. I do not recall any instances where any improvements to the safety of our blood components were rejected by the EABTC Management Team or the RHA. Of course, we were not free to implement steps which had been rejected by MSBT, such as anti-HBc testing.

154. How did the desire for consensus across the RTCs impact efforts to achieve blood safety at a local level?

521. I have discussed the issue of different RTC's wishing to implement HCV testing at different times above. I did not attend RTDs meetings, so it is difficult for me to say how much this impacted on other progress in the 1980s and early 1990s. I can imagine that trying to obtain a consensus among 13 RTDs could not have been easy. In that regard, the creation of the NBA was a huge step forward in the ability of the blood service in

England to act coherently and to provide consistent messages to DH, donors and hospitals.

155. To what extent was the EABTC reliant on the decisions of other bodies (advisory committees, directorates, NBTS, DoH) to achieve blood safety?

522. For major decisions, particularly on screening for infections, Transfusion Services have always been dependent on national decision making at the DH level. Before the NBA was created, it required DH to mandate the introduction of a new test before the RHAs would release additional funding. I think there was frustration at EABTC that MSBT had not recommended anti-HBc testing in 1993, but not to the extent that we tried to 'go it alone'. We were very conscious that we were part of a national service. So, if safety steps were turned down at MSBT/DH level, there was not really much one could do. As discussed in Section 10, this division of roles between DH and Transfusion Services continued after the RTCs amalgamated to form the NBS and is broadly unchanged today.

523. There was some leeway for local decision making on more operational matters, e.g. the NW Thames RTC at Colindale did not manufacture platelets from new donors because of increased virus risk. They also used a confidential donor exclusion tick box option as discussed under Q16 above.

524. In 1990, the first Guidelines for the Transfusion Services were published, with the creation of what is now JPAC and the Standing Advisory Committees, which underpin it. That provided a more operational layer of standardisation, aiming for optimal practice. However, JPAC had no budget, and it was up to each of the four transfusion services to agree to what JPAC was recommending. However, I do not recall much dissent about recommendations coming from JPAC. The membership of SACs consisted largely of blood service

doctors and scientists (plus PHLS for SACTTI), with at least two Transfusion Services represented on each one, so most factors influencing the decision had been considered. Over the years, the SACs had more operational people as members, which enhanced decision making further.

Who or what was responsible for defining what constituted safe blood?

525. Apart from 'DH' in a general sense, I do not think there was any individual or body with overall responsibility for 'vein-to-vein' blood safety. MSBT considered infectious hazards, and JPAC looked at those as well as immune complications. The BCSH had a Transfusion Task Force which produced both laboratory and clinical transfusion guidelines aimed at hospitals, and when the BBTS was formed in 1990, it also produced guidance and educational material. So, there were disparate groups dealing with different aspects of blood safety, but no decision-making body was considering how to enhance patient and donor safety in the round.

What happened if your own opinion conflicted with the decision or advice of that person or body?

526. As a consultant, one could talk to or write to the Medical Director with one's views. I think that such an opinion would be given a fair hearing in the organisation, in which I include JPAC and its SACs. I do not know whether such differing views would be passed on to other decision-making bodies, e.g. MSBT, but I suspect not if it were just one individual who was uneasy about a decision. If, however, there was a groundswell of opinion that a decision was unwise, then a paper could be written, e.g. by a group of consultants and/or scientists, explaining why the decision should be revisited by the decision-making body.

527. An example of that would be the Ministerial decision not to support HTLV testing in 1998, as recorded in the minutes of the MSBT meeting on 29th October 1998 [DHSC0004026_032]. Subsequent work by SACTTI led to the decision being reconsidered, with the summary of the MSBT meeting of 19th April 2001 [NHBT0008129] recording that HTLV screening had now been approved.

528. For an individual whose views were still at odds with a safety decision, they would have to decide whether they were going to escalate their unease, e.g. to the Chief Executive or Chair of the NBA. Alternatively, they could pursue a professional route through the GMC or go to the media. The ultimate action would be to tender one's resignation.

156. In January 1992, Dr Marcela Contreras wrote, ahead of an ACTTD meeting, that "the attitude towards transfusion safety has veered away from the concept of 'maximum benefit at minimal cost' towards the notion that if a procedure shown to prevent transfusion-transmitted infection and disease is available, it should be introduced" (NHBT0000044_095). Do you agree that this was a shift that the BTS made? Please explain the reasons for your answer, including any relevant references to discussions with colleagues and official policy within the BTS.

529. I have read the document referred to. It is a short paper from Professor Contreras to ACTTD dated 23rd January 1992, i.e. shortly after HCV screening was introduced, asking that ACTTD consider anti-HBc testing. I have considered the part quoted in Q156 in the context of what comes before and afterwards. The sentence before reads, '*The question of the likely benefit of anti-HBc screening of blood donations continues to reappear, especially so in the light of the introduction of anti-HCV screening'.* The quote is followed by the sentence: '*The latter approach is reinforced by loss of Crown Immunity, the introduction of Product Liability and the emphasis on Quality, Audit and Licensing by the MCA'.*

530. My interpretation is that the quote was a personal conclusion drawn by Professor Contreras in the light of the events she mentions in the same paragraph. In 1992, there were still 13 RTDs, with ACTTD being the advisory body on infections. Although I was not attending RTDs' meetings or any other decision-making body at that time, I do not recall, as a consultant on the EABTC Management Team, being told of any official policy coming from the National Directorate as to what constituted 'blood safety'. Major decisions on blood safety were, in any case, being made by MSBT, which had primacy on major decisions.

531. I have also addressed this issue under Q157d.

157. If you do agree:

a. When, in your view, was this shift made?

b. Who was responsible for the original policy and who for the change in policy?

c. What caused the change to occur?

532. I have nothing to add to my comments under Q156.

d. What is your opinion of the merits of a cost-benefit approach to blood safety as against the latter approach?

533. This is undoubtedly a very difficult issue. Blood transfusion is a life-saving treatment, and we accept that other life-saving drugs may have serious side effects. Of course, we want the risk of transfusion to be as low as we can sensibly make it, but we will never have 100% safe blood, just as we do not have 100% safe medicines. The same will apply to synthetic blood if it can ever be produced. On the question of cost, no one will expect the entire budget of the NHS to be spent preventing a single patient event, but I doubt whether any country in the world has a rigid figure of how much should be spent on blood safety. In

the UK, the National Institute for Clinical Excellence (NICE) applies a threshold of spend/quality-adjusted life year in considering whether a new drug should be available in the NHS, but this figure cannot rigidly be applied to blood safety.

534. To illustrate this, I would like to give 3 real examples from my career where possible patient impact and costs were considered and different conclusions reached.

i. *vCJD.* When we were considering this in 1997, the thinking moved very quickly from seeing this as a theoretical risk to a precautionary approach which dictated that we should take critical steps towards risk reduction. At that time, there had been no reported cases of vCJD through transfusion, so we did not know whether there was a risk to prevent or not. Universal leucocyte depletion alone cost £850M/year, but I do not recall any feeling in the NBS that this was unnecessary or a waste of money.

ii. *Hepatitis E virus (HEV) infection.* This disease appeared in the UK in 2012 and was mainly spread by infected pork products from The Netherlands and Denmark. It seemed possible that it could be spread by transfusion, but as with vCJD, the risk to recipients was uncertain. Again, there was a rapid reaction, with a study on incidence in blood donors and transmissibility to patients running from October 2012 till September 2013 (published as Hewitt PE et al, Lancet 2014:382; 1766-73). The study showed that 1 in 2848 donors was carrying HEV, a higher figure than expected. Forty-two per cent of transfusion recipients from these donors had a detectable infection, but fortunately, only one had any symptoms. However, immunosuppressed recipients took longer to clear the virus, with some showing persistent infection or infection, which cleared only after medication. There was, therefore, concern about the potential for long-term liver damage from HEV infection. In the light of the study results, SaBTO convened a working group in December 2013 to explore blood donor screening. During 2014, the work also included consideration of how to protect organ transplant recipients through diet as well as transfusion, and there

were discussions with the Food Standards Agency. In April 2015, SaBTO received the report from the working group and asked the Blood Services to prepare costed plans. An extraordinary meeting of SaBTO was held in July 2015 to make recommendations. The key recommendation was that HEV testing of blood components should begin in January 2016 to provide HEV-negative components for organ and stem cell transplant recipients, even though this was more expensive than the NICE threshold. A separate recommendation was made in September 2016 for the testing of live organ donors. This was later extended further to include blood for all immunosuppressed patients and neonates, then to ensure that everyone was protected, testing was extended to the entire blood supply in 2017, despite the additional costs.

iii. *SHOT* has consistently recommended the adoption of electronic methods for patient/blood identification to minimise errors in clinical areas of hospitals. NICE produced a transfusion guideline in 2015 covering safe administration (nice.org.uk Transfusion NG24, 18th November 2015). While the guideline was positive about the use of these systems, it stopped short of recommending them because a health economic study was yet to be done. Such a study is now in progress, using charitable funding,

535. I think, therefore, that it is unrealistic to leave costs out of the decision-making on measures to improve blood safety, but I believe that cost should be only one element in an agreed decision-making framework such as the one used by SaBTO. I discuss this in more detail in section 18, under Issues.

536. A particular advantage of such a framework is that it allows a decision to be made after a single piece of analytical work and appropriate consultation. This cuts down the time from problem to solution significantly, preventing the months or years of debate of the past.

e. Was the introduction of anti-HCV testing affected by this prior approach?

537. I cannot comment on this, as I was not party to discussions which led up to the decision to implement HCV screening.

What about other transfusion transmitted infections?

538. I have discussed this in relation to vCJD and hepatitis E under 157(d) above.

Section 14: Look back programmes at EABTC

HIV

158. Were you involved in setting up any national or local HIV look back programmes during your time at EABTC? If so, please describe this process and your role in it and how it was funded.

539. I was not at EABTC when HIV testing started in 1985, so this question does not apply.

159. Were you involved in implementing any HIV look back programmes during your time at EABTC? Please give details.

540. During my time at EABTC before the NBA was formed, I am not sure that we ever had an HIV positive donor. I was never involved in undertaking lookback on any donors.

HCV

160. Please describe the extent of your involvement in setting up and implementing the NBTS' HCV look back programme. Please describe

the process and your role in it and how it was funded. (NHBT0040583, NHBT0057381_004, PRSE0001236, NHBT0005879_017, NHBT0039758_022).

541. I was a member of SACTTI when we held an important meeting on 5th August 1994 [NHBT0057381_004] to consider whether we should recommend to MSBT that HCV lookback should be undertaken. A small preliminary study from Edinburgh was presented, showing that all 9 recipients of blood components from donors who had subsequently tested positive for anti-HCV had themselves tested positive. The group noted that HCV was now thought to be more aggressive than previously realised and that treatments were now available. The international picture on lookback was variable. It was recognised that the Blood Services had a full safety agenda, with studies into and consideration of: anti-HBc testing, HTLV testing, bacterial testing of platelets, and virus inactivation/quarantining of FFP. Importantly, however, it was concluded that we (the Blood Services) had a duty of care to the patients receiving our components and a moral obligation to identify them. It was estimated that there would be about 3000 recipients to be traced. It was therefore agreed that SACTTI would recommend to MSBT that an HCV lookback exercise be undertaken. It was also agreed that the preferred option would be for the Blood Services to undertake recipient counselling.

542. This recommendation went forward to MSBT, and it was reported at the SACTTI meeting on 19th October 1994 [NHBT0000088_008] that MSBT had had initial reservations but had established a small group, including Dr Robinson, to investigate further.

543. I am not clear precisely when MSBT/DH agreed that lookback should go ahead, but on 18th January 1995, Dr Robinson sent out a memo to all RTCs [NHBT0011115] informing us that the lookback would be going ahead, that NBS would be responsible for carrying it out, and setting out the frame of reference, i.e. it would cover all components and all

recipients, going back as far as possible. Recipients of BPL plasma products would not be traced in this exercise, but plasma to BPL from donors who later tested HCV positive was to be noted. Further information on the practicalities was received from Dr Pat Hewitt on 26th January 1995 [NHBT0019915], notably that each RTC was to identify a designated consultant responsible for the lookback and that Dr Jack Gillon (SNBTS) was producing an advisory paper on recipient counselling. Dr Elizabeth Caffrey became the designated consultant for EABTC.

544. I attended a meeting with Professor Allain and Dr Pat Hewitt on 29th March 1995 [NHBT0040583] to consider what research questions could be answered by the lookback programme. It was agreed that much could be learnt about the natural history of HCV and its potential to transmit through transfusion of different components and also to sexual partners. The study of recipients who had not become infected or who had recovered from infection would also shed light on what factors influence a person's susceptibility to HCV. There was a Cambridge HCV Study group which Professor Allain had set up in collaboration with a local virologist, Dr Tim Wreghitt, and a hepatologist, Dr Graeme Alexander. Since Dr Caffrey was the designated consultant for HCV lookback at Cambridge, I did not become involved in research coming out of the HCV lookback.

161. How was the HCV look back programme implemented at the EABTC? You may find NHBT0002752, NHBT0012321_001, NHBT0040594_001, NHBT0040542_001 and NHBT0095526_0006 of assistance.

545. I received the memos covered under Q160 in my capacity as Acting Director at EABTC. At the EABTC Management Team on 17th January 1995 [NHBT0040542_001], I undertook to produce a paper on the implications and costs of lookback.

546. EABTC had appointed a locum consultant, Dr Andrew Pollock, to support the permanent consultants in the absence of Professor Allain. At the EABTC Management Team on 8th August 1994 [NHBT0037682], possibly in anticipation of the lookback, it was agreed that he should be retained part-time to support the work needed.

547. RTCs were in transition to zonal management, and on 21st and 24th March 1995, I received memos [NHBT0040594_001 and NHBT0012321_001 respectively] from Dr Sue Knowles, London and South-East Zone's Medical Director, informing me that the lookback would be launched on 3rd April 1995 and that NBS had been funded for testing of recipients, even though this was to be done at local PHLS or hospital laboratories.

548. The practicalities of lookback were undertaken as outlined in Dr Robinson's memo of 18th January 1995. Donor records were interrogated to identify all donors who had tested anti-HCV positive since testing began on 1st September 1991. We had installed a computer system, TRACE, in the early 1990s, but it is possible that some relevant donor records were manual. We also interrogated manufacturing records to establish all the blood components (and plasma to BPL) which had been manufactured from previous donations. Finally, we had to look through issue records to establish which hospitals had received which components.

549. Since we were looking back into older records, most of these were on paper rather than on computer, so information could not be obtained instantly. We then had to send a list of components to each hospital, asking them to search their blood bank records to identify recipients of each component. Again, these would have been mainly paper records at that time. Then hospitals had to search medical records to establish whether the recipient was deceased or alive.

550. For deceased recipients, we asked for the cause of death to be reported to us, but on 9th May 1995 [NHBT0005879_017], I wrote to Dr Robinson seeking advice on how important this was because hospitals were telling us that they could often not find the cause of death in the case records. For recipients whose hospital records showed that they were not deceased, I think we contacted the GP first to establish whether the recipient was still alive (they may have died at home or in another hospital) and whether it was appropriate to contact them for HCV counselling and testing.

551. On 18th September 1995 [NHBT0002873_001], Dr Robinson wrote to Dr Pollock in answer to a query he had raised about the lookback. His question was whether, if a doctor is looking after a patient decided that (s)he should not be contacted as part of the lookback, the next of kin should be informed. Dr Robinson replied that she would seek legal advice and formulate a national policy, but I do not have any record of what was decided.

552. At the EABTC Management Team Meeting on 24th April 1995 [NHBT0040540_001]. I reported that Dr Pollock was spending all his contracted hours on lookback and that one of our scientists, Dr Charlotte Llewelyn, was helping in addition to her other work.

162. What was the role of the MSBT and the SACTTI in implementing the HCV look back programme? (PRSE0001236, NHBT0000088_010, NHBT0000088_013, NHBT0000088_008, NHBT0009383, NHBT0019915)

553. I have covered under Q160 above the involvement of SACTTI in recommending HCV lookback and of MSBT in making the decision, or perhaps making a submission to Ministers, that lookback should go ahead. I have not been able to locate the MSBT minutes which recorded their decision.

554. Once the lookback had started, both SACTTI and MSBT received progress reports. At its meeting on 12th June 1995 [NHBT0000088_010], SACTTI discussed several areas where there was potential for differences across the UK in the details of the way lookback was going to be performed, e.g. counselling and testing, and undertook to write to MSBT for clarification on these points.

555. At the MSBT meeting on 13th October 1995 [SBTS0000516_001], it was noted that '*substantial progress had been made*', and it was agreed that the lookback should be extended to include recipients of donors whose HCV results were indeterminate in particular ways (no details were minuted) and that any transfused person requesting a test should be given one. The same minutes also state that *'it did not seem likely to be cost-effective to test everyone who had ever been transfused'*. I have no further information on this point.

556. It should be noted that the Penrose Inquiry in Scotland in 2014 recommended that anyone who had received a blood transfusion should come forward for a hepatitis C test. This recommendation was picked up by Public Health Scotland as the appropriate organisation to lead such a campaign. I attach (Exhibit WITN0643033) a Public Health Protection Unit Newsletter from November 2016, which refers to a letter from the CMO regarding the detection of undiagnosed HCV in Scotland. The CMO letter from Dr Catherine Calderwood provides a reminder of the importance of considering the possibility of hepatitis C infection when assessing any patients who may conceivably have been exposed to the virus, including those who may have been infected via blood or blood products prior to September 1991.

557. By its meeting on 8th January 1996, however, MSBT was becoming concerned that progress was now too slow [DHSC0020692_118], a concern also voiced at the SACTTI meeting on 16th April 1996 [NHBT0000088_013]. A major source of delay was turning out to be the medical records departments, and SACTTI

suggested that, via Dr Robinson, MSBT be asked whether hospital Trust Chief Executives should be contacted about this.

558. At the same SACTTI meeting, it was noted that about 50% of recipients had been found to be deceased, and that of recipients tested, only 25-30% were negative, mainly from donors who on investigation were PCR negative. At later MSBT meetings on 2nd May 1996 [SBTS0000518] and 2nd July 1996 [SBTS0000519], it was reported that progress was better and that the lookback should be completed by the end of 1996.

HBV

163. In 1995, you submitted a research proposal to the Cambridge Health Authority for a look back study to be undertaken by the EABTC to identify markers of previous Hepatitis B infection (NHBT0040396_001). A similar application was submitted to the Norwich District Ethics Committee for Ethical approval (NHBT0042788).

a. Please indicate your reasons for initiating this study.

559. I have covered the background, contact and conclusion of this study in detail in paras 37-45 of my previous Witness Statement in response to the amended Rule 9 request dated 14 August 2020- the 'lookback' request, but I will summarise it here to set my answers to the questions below in context [WITN0643001].

560. This lookback exercise was part of a study of 100,000 blood donors performed by EABTC and the South Thames RTC to establish the prevalence of potentially infectious 'anti-HBc only' donors in those regions. These are donors who test positive for anti-HBc as a marker of ongoing or previous infection but who lack antibodies to the surface of the virus (anti-HBs), which protect against transmission.

561. To establish the infectious risk these donors posed, it was necessary to conduct a lookback exercise on their recipients and recipients of control donors, which was done with Ethics Committee approval. A total of 278 recipients from potentially infectious donors were identified, of whom there were 4 with a probable association with transfusion and 2 with a possible association. Six other recipients with markers of hepatitis B infection had other risk factors, such as country of origin. The conclusions from the study, which was published [NHBT0000112_034] were that screening blood donations for anti-HBc could identify additional donors infectious for hepatitis B.

a. What discussions were had around this time about HBc testing, both within your centre and within blood services more generally?

562. There were monthly meetings of the study group, which I attended. Towards the end of the study, there was a discussion about how to promulgate the results, and it was agreed that they should be presented internationally and published in the medical literature. We were aware that SACTTI were planning a meeting on anti-HBc testing and would naturally have made these results available for such a meeting, although I do not recall such a meeting taking place. I discuss the role of SACTTI in relation to anti-HBc testing under Q165 below.

b. Was this look back study implemented nationally? If not, why not?

563. A lookback study can be performed only in certain situations (1) when a new test is introduced as part of routine blood donor screening, e.g. HCV lookback (2) as part of some other surveillance, e.g. for vCJD (3) as part of a research study, as in this case.

564. Because anti-HBc screening was not mandated for routine screening, (1) did not apply, and neither did (2). We could not

continue to test donors at EABTC or South Thames, as that would have been outside the terms of the study and the Ethics approval.

c. How was the look back study set up and implemented? What were the results of this look back study?

565. I have covered these questions in summary form under Q163a above and in my previous statement [WITN0643001].

d. What effect, if any, did this have on the discussion around HBc screening within blood services?

566. I recall that I kept SACTTI updated on this study but cannot find any further discussion of anti-HBc testing in the SACTTI minutes which I have been sent, nor in any MSBT minutes. During 1997 and 1998, there was one overriding safety concern, that of vCJD. There were extra meetings with the external risk assessment organisation (DNV) and preparation for leucocyte depletion, the extent of which is discussed in detail in Section 17. The other safety issues also being reviewed at the time were HTLV testing, with a SACTTI special meeting on 14th May 1997 [NHBT0000088_018] and virus inactivated FFP. SHOT received only 1 report/year of HBV transmission. It seems that anti-HBc testing was, whether actively or by default, deprioritised against other more pressing issues.

You may find the following documents, including minutes of the Anti-HBc Screening Project Study Group meetings, of assistance in answering these questions: NHBT0042751, NHBT0114811, NHBT0040735, NHBT0116043, NHBT0042422_001, NHBT0042424, NHBT0042691_001, NHBT0042707, NHBT0040649_001, NHBT0040646, NHBT0040447_001, NHBT0114798, NHBT0114800, NHBT0042779_001, NHBT0040453_001, NHBT0040451_001

164. Were you involved in setting up any other national or local HBV look-back programmes during your time at EABTC? If so, please describe the process and your role in it and how it was funded.

567. There were no other HBV lookback programmes run from EABTC during my time there. I was not involved with any other HBV lookback studies nationally.

568. Although there had been other studies of anti-HBc donor testing, e.g. in Liverpool, I cannot recall whether these involved lookback.

165. From the early 1990s to the 2000s, SACTTI and MSBT recurrently discussed the possibility of introducing routine anti-HBc screening (MHRA0020214, NHBT0000088_011, NHBT0001954_001). Drawing on your experience as a member of both committees, please discuss:

a. What you recall about any arguments raised for and against the introduction of routine anti-HBc screening;

569. Firstly, I would like to clarify my position regarding these two committees. I was a member of SACTTI from 1993 till January 1997, when I left to chair SACBC. I was never a member of MSBT, although I was sometimes invited to present information, mainly in connection with vCJD and leucocyte depletion.

570. This was never a clear-cut issue. Arguments in favour were: adding this test would identify additional donors who might transmit hepatitis B, the Blood Services had a duty of care to prevent such transmissions, and some other countries were already doing it. Arguments against this included: only a few extra transmissions would be prevented, making this test not cost-effective, most hepatitis B infections were short-lived and rarely fatal, and the anti-HBc test kits available had high false positive rates, causing complexity in donor handling and possibly loss of donors.

b. Your personal view on the issue, and how this altered over time, if at all;

571. I do not think that I have ever felt that anti-HBc testing was top of the safety agenda. My views on this were based on SHOT data and other events. Between 1996 and 2005, reports to SHOT of HBV transmissions ran at 1/year, with none at all in 2001 and 2004. The exception was 1999 when 3 recipients were infected by 2 donors. Between 2006 and 2012, a total of 3 recipients were infected by 2 donors. There were no reports of HBV transmission between 2013 and 2019, possibly because HBV NAT had been introduced in 2009. None of these transmissions caused a death.

572. I give these figures not to belittle in any way the impact of these transmissions on the recipients and their families. I simply wish to put these 14 transmissions in 25 years in the context of priority setting.

573. In contrast, in the 12 years between 1997 and 2009, 37 recipients were infected by bacteria contaminating platelet transfusions, with 11 deaths. This was clearly a higher priority issue to be dealt with once suitable tests were available.

574. In the mid-1990s, screening for the retrovirus HTLV I was also being considered. This infection can cause serious and potentially fatal consequences, such as spinal paralysis and a rare form of leukaemia.

575. Looking at non-infectious complications reported to SHOT, there was increasing recognition that transfusion-related acute lung injury (TRALI), which is sometimes fatal, was caused by post-pregnancy HLA antibodies in donor plasma, and there was consideration as to whether FFP should be made only from male donors.

576. Then there were new diseases, notably vCJD, which, as I have mentioned in section 13 and will discuss further in section 17, was a threat of completely unknown magnitude, but one which was always 100% fatal. The capacity for implementing safety changes in the Blood Services from 1997 into the 2000s was dominated by steps taken to minimise the vCJD risk.

577. The appearance of hepatitis E in 2012 was another new challenge, as we did not know whether this would turn out to be a self-limiting infection or have the potential to cause chronic liver disease. Therefore, action was needed on donor screening.

578. However, hepatitis B did not, at any time, fall completely off the safety agenda. HBV nucleic acid testing (NAT), which tests for the DNA of the virus, was implemented in 2009, which may explain the further fall in infections after that date.

c. Why, in your view, the issue was discussed repeatedly by these committees but without final decision;

d. Whether you feel that this continued reassessment was appropriate in the circumstances.

579. I will consider these two questions together as they are related. I have discussed above some of the arguments for and against anti-HBc screening. I am sure these pros and cons contributed to it being repeatedly discussed, sometimes when new information became available. I have also tried to compare it to other safety steps. No matter which year it was discussed, the patient harm prevented by adding anti-HBc testing to the standard HBsAg testing always seems to have been less than from other infectious and non-infectious transfusion risks under consideration at the same time. Recommendations produced by neither SACTTI nor MSBT were subject to detailed health benefit and cost-benefit analysis using an agreed safety framework, as is used by

SaBTO today. This might have helped clarify where the safety priorities lay at any given time. I discuss this further under 'Issues' in section 18.

General

166. Please confirm whether you were involved in a look back process relating to any other infection during your time at EABTC. If so, please provide an overview of the relevant programmes and detail your involvement.

580. There were no other look back programmes running at EABTC during my time there.

167. Did you consider there was an ethical obligation to inform patients who may have received transfusions from infected donations? If not, why not?

581. In my view, there has always been an absolute ethical responsibility to inform patients of clear-cut harm which has come to them through clinical error or as a side effect of treatment, even if unavoidable. This is now codified in General Medical Council requirements under Duty of Candour.

582. In particular, ever since my experience working in the haemophilia clinic in Sheffield in the mid-1980s, I have considered it essential that patients are fully informed about any infections they have acquired and which have likely come from blood products or blood components.

583. I am therefore pleased that undertaking lookback, if medically relevant, on commencement of screening for a new infection is now the standard of practice in the Blood Services.

584. The situation becomes more difficult when the probability of transmission is uncertain and likely to be very low. The CJD Incidents

Panel has had to consider over the years whether recipients of different plasma products manufactured from pools containing plasma from a donor who later developed vCJD should be informed about their possible vCJD risk. The balance is between causing unnecessary worry versus concealing information which the patient may wish to know.

585. I think that over the years, I have increasingly moved towards telling the patient in these grey areas.

168. To what extent could an RTC implement its own local look back programme? Did EABTC do this? If so, please give details. If not, why not?

586. As I have covered under Q163c above, lookback applies only if a new test is implemented or as part of a research study. Since EABTC did not have a mandate to choose its own screening tests, it could not have performed any lookback studies. The only lookback we performed was as part of the anti-HBc study discussed above and in my previous witness statement ([NHBT0000112_034 , WITN0643001].

Section 15: My relationship with commercial organisations

169. Have you ever:

a. Provided advice or consultancy services to any pharmaceutical company involved in the manufacture and/or importation and/or sale of blood products?

587. Yes, to Cerus. This company manufactures photochemical technology (Intercept) for pathogen inactivation of blood components. I wrote a one-off report for them in the 1990s, I think, concerning platelet manufacture in the UK. I asked them to pay my fee directly to a charity of my choice,

but as their financial systems could not do this, they paid me, and I made a donation to the full value of the payment.

b. Received any pecuniary gain in return for performing an advisory/consultancy role for a pharmaceutical company involved in the manufacture, sale and/or importation of blood products?

If so, please provide details.

588. See my answer to a. above.

170. What regulations or requirements or guidelines were in place (at any time relevant to your answers above) concerning declaratory procedures for involvement with a pharmaceutical company? If you were so involved, did you follow these regulations, requirements and guidelines and what steps did you take?

589. I do not recall whether there were any regulations in the mid-1990s relating to work for companies. The General Medical Council later provided guidance regarding this and other types of conflict of interest. It became standard practice for members of committees to declare conflicts of interest, either at the start of each meeting or by an annual written return.

171. Have you ever undertaken medical research for or on behalf of a pharmaceutical company involved in the manufacture, importation or sale of blood products? If so, please provide details.

590. Octapharma, a commercial company, manufactures SDFFP (Octaplas). In the early 1990s, they approached EABTC to see whether we were interested in carrying out a clinical trial. As this fitted with my interests in clinical research and blood safety, we agreed to a trial involving colleagues and patients in Cambridge and Birmingham. Octapharma

funded the plasma and a trial coordinator through the University of Cambridge.

591. The trial required a Clinical Trials Exemption Certificate from the Medicines Control Agency as well as ethics approval and patient consent. We studied patients with liver disease/liver transplant (Exhibit WITN0643020 and a separate group who were having plasma exchange for thrombotic thrombocytopenic purpura (Exhibit WITN0643019 . We also studied the manufacture of cryoprecipitate from Octaplas [NHBT0005103_009]. The results were analysed by the study team, and we retained ownership of the data.

592. I received no personal benefits, financial or otherwise, as a result of this work. The funding was declared in the publications and at any meetings regarding FFP.

172. Have you ever provided a pharmaceutical company with results from research studies that you have undertaken? If so, please provide details.

593. No, in all studies of commercial products which I have undertaken, the sponsoring organisation, which was either the University of Cambridge, NBS or another NHS organisation, retained possession of the data.

173. If you did receive funding from pharmaceutical companies for research, did you declare the fact that you were receiving funding and the source of the funding to your employing organisation?

594. My substantive employer, the University of Cambridge, handled any research income, so there was complete transparency regarding funding. Regarding the NBS, I always declared research funding according to the requirements of the time. My academic and organisational research into methods for improving blood safety inevitably required collaboration with commercial manufacturers of blood filters, technologies for the pathogen

inactivation of blood components and, in the case of solvent-detergent FFP (SDFFP), a commercial manufacturer (Octapharma) of a blood product (Octaplas), as detailed under (b) above. Additional commercial relationships were as follows:

595. **Pall Biomedical.** This company manufactures white cell removal filters. In the early 1990s, an agreement with EABTC was reached for collaborative research to improve their filters. This involved EABTC providing units of donor blood (with donor consent) to Pall, while Pall seconded a laboratory scientist to EABTC to undertake specific projects on white cell filtration, e.g. filtration of whole blood as opposed to components, combining white cell filtration with gamma irradiation (Exhibit WITN0643034).

596. At some point in the 1990s, the seconded scientist was replaced by funding for a scientist employed through the University of Cambridge. This led to further work on Pall filters in relation to removal of different types of white cells (Exhibit WITN0643043) and of the viruses Human T Cell Lymphotrophic Virus I (Exhibit WITN0643017) and cytomegalovirus (Exhibit WITN0643018).

597. In parallel, and with colleagues in Cambridge, Leeds, Manchester and Plymouth, I co-led a clinical trial to see whether Pall white cell filters used at the patient's bedside would reduce alloimmunisation to HLA antigens on platelets. Pall provided the filters for this trial and also funding for an independent statistician and laboratory analysis. The study group undertook the analysis of the study, retained ownership of the data and published the results (Exhibit WITN0643016 and WITN0643035) without involvement of Pall.

598. I received no financial benefits from this research relationship and, as was the standard of medical practice at the time, declared the funding source when relevant, including in the publications. The study group

submitted an abstract of the study to a conference in the USA; I think Pall paid for my travel. I also had a visit to the Pall site in Portsmouth.

599. **Abbott.** This company manufactured the PRISM high throughput diagnostic technology for screening blood donations for viruses. EABTC conducted an evaluation of PRISM under Professor Allain's leadership. We later adopted this technology, and I attended an Abbott user group meeting in Scotland. The PRISM evaluation is discussed further in Section 13, Q129.

600. **Baxter.** They manufactured a system for MB treatment of FFP. They awarded a grant to Dr Chris Prowse and myself in ~1997 for evaluation of cryoprecipitate manufactured from MBFFP prepared on their system. I received no personal payments, and we were free to publish the results [NHBT0042349].

601. **Macopharma.** This company manufactures a photoinactivation system involving methylene blue and ultraviolet light for the inactivation of pathogens in fresh frozen plasma. In the late 1990s/early 2000s, they provided equipment for evaluation to the NBS Component Development Laboratory (CDL) at Brentwood. These studies were led by Dr Rebecca Cardigan, NBS Head of Component Development, who at the time was accountable to myself (NHBT0042349, Exhibit WITN0643014 (pages 253-254) and WITN0643015). Later, CDL evaluated a different Macopharma system which used ultraviolet light without chemicals to inactivate pathogens in platelets. This work was published in 2013 (Exhibit WITN0643036). I received no benefits, financial or otherwise, from this work other than a visit to the Macopharma site in Frankfurt. NBS retained ownership of the data throughout and published the results without involvement of Macopharma.

602. **Grifols.** This company offered industrial-scale methylene blue treatment of pooled fresh frozen plasma at their plant in Spain. I attended a meeting with them during a transfusion conference in Barcelona. We did

not take forward any collaboration with them as they did not wish to receive UK plasma because of the vCJD risk.

603. **BEST group. (Biomedical Excellence for Safer Transfusion).** Founded 30 years ago, the BEST collaborative is a unique international research group consisting of researchers (roughly 40 at any one time), commercial companies (currently 10) and blood services (currently 20). The objective is to perform the types of research studies which could not be carried out without this type of collaboration. Topics of relevance have included standardisation of white cell counting after leucodepletion, assessment of platelets after pathogen inactivation, and steps at the bedside to minimise errors of blood administration. BEST has published more than 140 peer-reviewed papers.

604. I was invited to join BEST in approximately 2001, initially chairing its components group. I then served as overall chair from 2004-2008, then as past chair/treasurer from 2008-2012. I then stepped back from active involvement, becoming an honorary member in 2012. When I first joined BEST, the funding came solely from the commercial members, who also contributed actively to the scientific discussions. When I was chair, the Executive group approved the creation of a membership category for blood services, who then also paid an annual fee and sent representatives to the scientific meetings.

605. When I was a member, scientific members were paid a travel fee for each of the twice-yearly scientific meetings, which generally alternated between Europe and North America. This was a fixed sum, depending on whether the member was crossing the Atlantic. Additional funding could be agreed for specific studies on presentation of a budget for the study. Apart from the travel fees, I received no personal financial gain from being a member of BEST. None of my BEST studies involved specific commercial products, so declarations of interest did not arise.

c. Sat on any advisory panel, board, committee or similar body, of any pharmaceutical company involved in the manufacture, importation or sale of blood products?

606. I have never sat on any advisory panel or board of any pharmaceutical company involved in the manufacture, importation or sale of blood products.

d. Received any financial incentives from pharmaceutical companies to use certain blood products?

e. Received any non-financial incentives from pharmaceutical companies to use certain blood products?

607. I have never received any financial or non-financial incentives from pharmaceutical companies to use certain blood products.

f. Received any funding to prescribe, supply, administer, recommend, buy or sell any blood product from a pharmaceutical company?

608. I have never received any funding to prescribe, supply, administer, recommend, buy or sell any blood product from a pharmaceutical company.

Section 16: Relationship between SNBTS and NBTS

609. These questions do not mention SNBTS but focus on the National Directorate/National Blood Authority.

174. In his witness statement for the *A v Others* litigation, Dr Gunson discussed the creation of the National Directorate to oversee the work of RTCs, although he noted that the Directorate "did not have executive authority and its successes came about by persuasion"

(NHBT0000026_009). What are your views on the success or otherwise of the National Directorate?

610. In 1988, the National Directorate was created with a national Medical Director, but RTCs remained largely autonomous, in that they continued to report to their RHAs. The National Directorate undoubtedly improved the sharing of blood stocks and data sharing, but inevitably there were conflicts between the wishes of the National Directorate and the RTCs. This is best illustrated in Section 13, Q143-145, describing the situation in 1991 when there was a wish for all RTCs to start anti-HCV testing on the same date. However, some RTC Directors wished to start earlier, and one actually did so.

611. An additional issue was that BPL was still managed separately within the Central Blood Laboratories Authority (CBLA). Therefore, this 'half-way house' arrangement was never going to be enough to create a single Transfusion Service which was truly national. This interim step, however, may have helped to bring RTC Directors on board gradually with the idea that their local autonomy would eventually disappear.

175. In the same statement, Dr Gunson commented that the work of the National Directorate became marginalised as a result of the devolution of health budgets to District level and eventually replaced by the creation of the National Blood Authority (NBA), which had responsibility for "both the central laboratories and the RTCs." What are your views on the need for centralised responsibility for RTCs?

612. There is no doubt in my mind that both donors and patients in England have been better served overall by the creation of a single National Blood Authority with clear central direction and functional, rather than geographical, lines of accountability. I discuss the advantages further under Q176.

176. What in your view were the strengths and weaknesses of the NBA?

613. The journey from 13 semi-autonomous RTCs plus BPL and BGRL to a single cohesive organisation was never going to be easy or quick. When the NBA took over the running of RTCs in 1995, they were merged into 3 geographical zones, each with a zonal management team, including a zonal Medical Director. This arrangement facilitated better management of blood stocks and greater consistency between Blood Centres (they were no longer RTCs) in the same zone. However, there was not necessarily consistency between zones. In addition, each zonal management team was pretty powerful and managed a large budget, so although the Chief Executive of each zone was accountable to the Chief Executive of the NBA, these zonal arrangements created tensions between the centre and periphery. Thus, I think that the period from 1995-1999 was a difficult time for the NBS. I would not necessarily call it a weakness of the NBA, however, as the creation of zones was probably a necessary interim step towards a truly national service. Moving 13 RTCs to national functional management in one step was not practical.

614. RTCs had a number of quite legitimate concerns about becoming part of a large national organisation: that they would lose local connections with donors and with hospitals, and that staff in the RTC would lose cohesion by reporting to different zonal directors thus resulting in conflicting instructions. These were gradually dealt with, e.g. by creation of local Heads of Centre who had a co-ordinating role. Gradually, too, the idea of centralised decision making became more accepted.

615. The real strengths of the NBA began to emerge fully only after the merger of the zones into a fully national organisation, with functional line management, national donor recruitment, a single IT system and national management of blood stocks. Gradually activities taking place in every Blood Centre were rationalised, e.g. to reduce the number of centres undertaking component processing and donation testing. This made the service much more efficient and meant that the cost of blood

to the NHS could be controlled. National strategies were produced, e.g. for tissue banking, research and development, reagent production, stem cell provision, and IT. The NBA could speak with a single voice in its interactions with donors, hospitals, DH, the media and other Blood Services. A final major benefit from my point of view was that the organisation became more clinically focussed, with a national strategy for joint working with hospitals on the appropriate use of blood components and their safe administration. I have expanded on this in Section 17 (vCJD) and in Section 18, Q198.

177. Please explain your understanding of the relationship between PFC and BPL (NB: Reference to BPL also includes the associated Plasma Fractionation Laboratory in Oxford). In particular:

a. What was the extent of collaboration and coordination between BPL and PFC? What impact did this have, if any, on the operation of RTCs in England and Wales?

616. I am not aware of how the relationship between PFC and BPL worked or whether there were any formal links or meetings between them. The role of RTCs in relation to BPL was for each RTC to provide an agreed volume of plasma to BPL for fractionation. Some RTCs also distributed BPL products. I do not recall any impact on the operation of EABTC of any joint plans between BPL and PFC.

b. Do you consider there would have been merit in a joint UK approach to Factor VIII production and research, in view of the fact that PFC and BPL were both engaged in the development of similar severe heat treated products (8Y and Z8) in the 1980s?

617. I do not know whether there were ever any discussions about creating a joint plan for fractionation. On the face of it, it seems like a good idea, but with many issues to consider: e.g. intellectual property, and the different

accountability and funding of the two organisations, but nothing unsurmountable.

618. In principle, a joint plan for research into fractionated plasma products, particularly heat treatment, should certainly have been in place. In the absence of a national blood service in England in the 1970s and 1980s, an instruction to produce a joint plan would have had to come from the DH if the two fractionators did not generate such a plan themselves. This does not mean that they had to be working on the same method as each other. On the contrary, there could have been merit in each fractionator taking a different approach, provided each had some merit. Of course, new discoveries in this area may have been patentable, so any collaboration would have had to be under a Confidentiality Agreement.

178. Please outline any statistics or studies of which you are aware that demonstrate the difference in morbidities and fatalities between Scotland and England/Wales.

619. I do not recall any collated data on comparative morbidities/fatalities between different parts of the UK in relation to transmissions of HIV/hepatitis C in the 1970s and 1980s.

620. While SHOT receives data from across the UK, we have chosen not to analyse comparative morbidities by home nation. We did not think that such an analysis would readily result in recommendations to improve blood safety and might compromise anonymity.

Section 17: Variant Creutzfeldt-Jakob disease (vCJD)

Following the BSE outbreak in 1985, and the first human death from vCJD in 1995, the risk of vCJD transmission by blood was confirmed in 2003. The Inquiry is interested to gain an understanding of your knowledge of risk, your

involvement in discussions within the blood services, and any actions taken with regard to vCJD since 1985.

Knowledge of risk of vCJD in blood and blood products

179. When and in what circumstances did you first become aware of the risks of transmission of vCJD through blood and blood products?

621. The paper describing the first 10 human cases of vCJD was published in The Lancet on 6th April 1996. I was certainly made aware of this paper at a SACTTI meeting on 16th April 1996 [NHBT0000088_013], where a report was presented on an ad hoc meeting held in Edinburgh on 9th April 1996 to discuss the implications of these cases for the Blood Services. I may have read the paper before 16th April 1996, but I cannot be sure. It was agreed at the SACTTI meeting to adopt a position of 'presumption of risk' of vCJD from blood products and components, and all actions thereafter flowed from that.

180. Please provide a summary of any discussions relating to the development of scientific understanding of the risks of both vCJD infection and of secondary transmission via blood and blood products. (NHBT0003473)

622. It would be fair to say that concern about vCJD in the blood supply and actions to reduce the risk dominated the thinking of NBS for the next decade. No one knew how big the primary epidemic would be; some estimates by modellers commissioned by DH, Det Norske Veritas (DNV), suggested there could be upwards of 10,000 cases from eating BSE-infected beef. The spectre of tens or even hundreds of transmissions through blood and blood products was a terrifying prospect. Although as transfusion specialists, we were following the BSE epidemic in the media and mainstream medical journals, our knowledge of prion infections was limited, so at the SACTTI meeting on 16th April 1996, it was agreed that two strands of work were needed (1) research by expert prion research laboratories to understand the distribution of abnormal prions in different

elements of blood (red cells, white cells or leucocytes, platelets and plasma), and therefore the potential of different blood components as issued by the blood services to transmit infection to patients. It was therefore agreed to develop a formal link with the cross-government Spongiform Encephalopathy Advisory Committee (SEAC), so that we could be kept briefed on scientific developments and, just as importantly, have them interpreted for us by experts in the field. It would also be a conduit to propose any research which we felt was needed regarding transfusion risk. (2) to assess the scale of the vCJD outbreak through epidemiological surveillance and to establish any link between human cases of vCJD and previous blood transfusion by undertaking an ongoing lookback exercise.

623. I will now summarise progress over the subsequent two years (1997-8) in the state of knowledge of these two aspects, research and epidemiology, from my point of view. I focus on this time period as it led to the major decision on leucocyte depletion of the blood supply. This cannot be a complete review of the scientific literature, but I will try to summarise key developments as I and colleagues in the Blood Services became aware of them.

624. I have focussed on blood components, as these fell within my area of responsibility. I will not cover the work undertaken at BPL and PFC to establish prion distribution across different fractionated plasma products, although I heard about this at various presentations.

625. Please also note that because of the presumption of risk of vCJD in the blood supply, ways of minimising the use of transfused blood, as outlined at Q183, were being developed in parallel.

626. **1. Research into risk from different blood components and possible benefits of leucocyte depletion.** In November 1996, with Dr Phil Minor (NIBSC), I submitted a framework document to SEAC via MSBT, outlining what research we thought was needed (LMW) and suggestions

for how it could be done (PM). This included trying to understand the possible benefits of leucocyte depletion. We did not receive a formal reply, but I note from the MSBT minutes of 25th March 1997 [NHBT0006016] that '*the joint MRC/DH research group thought there was a very low risk of transmission of TSE infection through blood and blood products, although this might need to be revisited in the light of nvCJD. This group had not been particularly impressed by the Minor/Williamson proposals. However, the joint DH/MAFF funding group would prioritise research proposals then advertise for bids to carry them out'*. I was never clear as to whether the group were unimpressed with what we thought needed to be done or by our suggestions for doing them. Interestingly, the research questions we suggested were included in later sheep transfusion experiments at the Roslin Institute in Edinburgh (see below).

627. In May 1997, SACTTI noted that DH was planning a workshop on vCJD research. I do recall attending a large workshop on this subject, I think chaired by Professor George Griffin, a Professor of Virology.

628. Two publications in Nature in October 1997, one from the Institute of Animal Health in Edinburgh (Bruce ME et al, Nature 389, 498-501 [DHSC0004125_011]) and one from the Prion Research Group in London (Hill et al Nature 389, 448-450 [DHNI0000041_123), provided the first scientific proof that the prion strain causing vCJD was identical to that causing BSE. These two papers, to me, were quite chilling, as they gave scientific underpinning to the theory that the BSE epidemic could, in time, potentially cause thousands of cases of BSE.

629. Other researchers in the USA (Paul Brown NIH) and in mainland Europe, e.g. Prof Aguzzi, in Zurich (Nature 1997), were also examining prion transmission from blood and its component parts in animal experiments. It became apparent that plasma and leucocytes were the key elements of blood containing prions and that 'pure' red cells and platelets, washed free of plasma and white cells, were probably low risk. Although the

manufacture of red cells and platelets totally devoid of white cells and plasma is not practical, manufacturing strategies then focussed on reducing the white cell and plasma content of blood components. These are discussed in more detail under Q185 (risk reduction).

630. Throughout this whole period, both SACBC and SACTTI had vCJD as a standing item, and new scientific developments were discussed as they became available. Key issues were reported to JPAC and, through the Medical Directors, to the Board of each Transfusion Service. See below (Q189/190/191/192) for further discussion regarding the roles and responsibilities of various committees regarding vCJD.

631. During 1997, the risk from different blood components was also examined as part of the independent risk assessment by DNV. I recall attending at least one meeting at DH with Dr Peter Flanagan (chair of SACTTI), DH officials, and DNV so that NBS could provide input to the risk assessment. DNV expressed the view that this issue had a higher degree of uncertainty than anything they had previously tackled. This report was presented to SEAC in June 1998.

632. It should be noted that, also in 1998, the Committee on the Safety of Medicines deemed that fractionated plasma products should no longer be manufactured from UK plasma. This also applied to the pooled but unfractionated SDFFP, as discussed in Section 13.

2. Epidemiology of any transfusion-transmitted vCJD in the UK population, and evidence of transmission through transfusion

633. I discuss this in detail at Q185 below.

181. What was your understanding of the relative risks of vCJD infection from the use of commercial or imported blood and blood products, as compared with the use of domestically produced blood and blood products?

634. Although there were no scientific data to confirm this in 1996-8, it was assumed that the risk of blood components and plasma products from any country would be proportional to the number of vCJD cases in that country, which in turn would relate to the number of cattle affected by BSE, along with the timing and extent of measures taken in each country to minimise the BSE risk from the food chain. It was the country of origin of the donors which mattered, not whether the components/products were commercial or provided by a public supplier.

635. The UK was obviously the BSE hub globally, with Ireland, France and Switzerland all also having significant numbers of cases. At that time, I think that Australia, New Zealand, the USA and Canada had either low numbers or no BSE reported. When importation of blood components began to be considered, I recall that DH kept a list of countries considered suitable.

636. The UK was generally agreed to be much the highest-risk country. By 2000, countries, including the USA and Canada, were banning current or former UK residents from becoming blood donors in those countries.

182. Please provide an outline of any steps you are aware of which were taken to ensure that the UK Government, blood services, NHS bodies, medical profession and patients were informed and educated about the risks of vCJD transmission via blood and blood products.

637. I cover education of blood service staff, NHS bodies, the medical profession and patients under Q185 Risk Reduction measures.

638. We were fortunate in having an agreed link to the government through SEAC, as well as MSBT. I recall that Professor Marc Turner, SNBTS, attended SEAC meetings, I think as an observer. In addition, I attended meetings with DH officials and DNV regarding the risk assessment. I

cannot comment on how the outcomes of these discussions were fed upwards to Ministers.

183. What do you recall about the use of blood sparing strategies, such as autologous transfusion, as a method to reduce the risk of vCJD transmission? What consideration was given to such strategies within UK blood services?

639. I cover this in Q185 (risk reduction) so that the Inquiry can see blood-sparing in the context of the overall Blood Service risk reduction strategy.

Role of Regional Transfusion Centres

184. The Inquiry seeks to understand what actions the UK Government, blood services and other organisations took in response to the risk of vCJD transmission via blood and blood products. We are particularly interested in the role of RTCs in responding to the risk. As to this:

640. By 1996, when the first human case of vCJD was described, RTCs had ceased to exist as such. NBS had moved to zonal management, and each 'RTC', now increasingly referred to as 'Blood Centres', was now managed by one of the 3 zonal management teams. I cover the NBS's overall response under Q185, Risk Reduction.

a. How did the blood services communicate the emerging risk of vCJD to the RTCs?

641. The communication routes at that time were from the National Executive team to zonal management teams to local teams. Such communications were increasingly along functional lines, e.g, from the National Medical Director, via the Zonal Medical Directors to all doctors in Blood Centres within each zone. There were parallel communication lines for operational and scientific staff.

e. We note from JPAC0000007_095 that a workshop was proposed by Elizabeth Love to discuss the issue of vCJD and the division of responsibility between various bodies and committees. Please can you comment on the outcome of these discussions, whether a framework document was prepared, and what role, if any, the RTCs were to play in this regard.

642. The question relates to activities in 1997, by which time RTCs had ceased to exist. I will refer to actions taken by the NBS and its advisory machinery JPAC and its SACs.

643. SACTTI/SACBC held a joint meeting on 22nd November 2000 [NHBT0001972] to discuss what further actions were needed regarding vCJD risk reduction. Recent data from sheep experiments conducted at the Institute of Animal Health in Edinburgh confirmed the transmissibility of BSE prions by transfusion (Exhibit WITN0643037).

644. At that meeting, Dr Brian McClelland, SNBTS, set out a framework of how he thought the decision-making on vCJD should be structured. The key features of this framework are set out in the minutes [NHBT0001972]:

'The characteristics of a decision-making process are: to make good decisions; ensure the decisions are defensible in the future, even if history proves them incorrect; contribute to improving public health, and provide a defence for actions taken.

They should also clarify the boundaries. UKBTS - it is our responsibility to: consider all the evidence, carefully consider all options, maintain scrupulous records, use explicit criteria to validate decisions, learn from history, eg Human Growth Hormone CJD transmission enquiry report, do things that make our products safer.

The UKBTS is not responsible for the standards of clinical practice but is in a position to influence practice to reduce risks, eg to promote increased use of autologous blood.

Illustrative Criteria: Changes that bring maximum benefit; feasibility; consequential risk of the change; effect of action taken on public's attitude; acceptability to clinicians; economic aspects; effect of the action taken on our relationship with the "healthcare industry"; selection of more highly specified donors; use non-UK donors; use alternative production approaches, identify groups of patients at greatest risk. (There is an MSBT precedent for this re the provision of more highly specified components for neonatal use). Genetic screening may help identify codon 129 MET homozygotes etc'.

645. Reference was also made at the meeting to the Phillips report of 27th October 2000 on the BSE outbreak, which reminded us that we needed to take all reasonably practical precautions and act with openness and respect for the public.

646. I reported at the meeting on the NBS Safer Plasma in Components Project, which combined MBFFP implementation with steps to reduce the plasma content of red cells and platelets. I also reported that MSBT was considering the importation of FFP.

647. Following the email referred to in the question from Dr Elizabeth Love dated 4th December 2000, a workshop was held by NBS on 18th December 2000, although I have no minutes of this. The NBS Chief Executive Martin Gorham then created and chaired a vCJD Steering Group which first met in February 2001. The specific purpose of this group was to ensure engagement of the whole NBS Executive Committee in the issue of vCJD prevention, with various sub-groups under a named Director to take further actions on vCJD risk mitigation (for details, see my answer to Q192/3 below).

648. Dr McClelland then took a paper to MSBT on 22nd January 2001, outlining further possible steps for action and also seeking clarity on where the responsibility for each measure lay. This is discussed in detail under Q185 (risk reduction measures).

Risk reduction measures

185. Please provide details of your involvement in, or knowledge of, any discussions or proposals, whether accepted or not, that were made in an effort to protect the blood supply from the risk of vCJD. To assist you we have referenced below documents which indicate your presence at meetings where particular risk reduction measures were discussed. The risk reduction measures include but are not limited to:

649. In my role as Chair of SACBC, Lead Consultant for Components for LSE and from 1999, National Clinical Director for Components, my main focus was on ensuring that we were providing components that were as safe as possible from the vCJD point of view. However, I will describe what I knew about steps along the whole supply chain, including the appropriate use of blood.

a. donor selection and exclusion policies;

650. **Vegetarians.** Unlike most other infectious risks, vCJD potentially affected the whole UK population, making donor selection very difficult. There was some early discussion about the feasibility of sourcing the entire blood supply from vegetarians. However, and quite apart from the question of whether there were enough vegetarians willing to donate, it was soon realised that bovine material was ubiquitous, e.g. in cosmetics, and in some medicines and vaccines. Therefore this option was not further investigated.

651. **Genotyping for codon 196 of the gene encoding prion protein**. It had been observed that all cases of vCJD so far observed had all had the

same genetic type at a particular point on the gene encoding the normal prion protein. This genotype (MM169) was found in about 30% of the Caucasian population. It was therefore considered whether we should genetically test blood donors to identify the 70% of the other genetic types (MV169 or VV169) on the basis that they might be 'resistant' to infection with BSE prions. Clearly, we could not exclude 30% of blood donors, but it was considered whether MV or VV donors could be directed towards specific components, e.g. for neonates and children.

652. It was eventually concluded that there was not sufficient evidence that MV or VV donors would be 'safe' from the vCJD point of view.

653. **Exclusion of donors at particular risk of vCJD.** One specific step that was taken by the UK Blood Services by late 1997 [NHBT0004564], via JPAC, and on the advice of SACTTI, was to exclude as a donor anyone who had been treated with any material derived from tissues near the brain, i.e. a corneal transplant, a transplant of dura mater, (one of the coverings of the brain), or hormones (human growth hormone and gonadotrophins) extracted from the human pituitary gland, sited at the base of the brain. We also excluded anyone with a relative who had had CJD.

654. **Exclusion of previously transfused donors.** The biggest donor exclusion step which was taken was to exclude from donation anyone who themselves had been transfused. This was discussed at several MSBT meetings, including 26th February 1998 [SBTS0000523], 29th October 1998 [DHSC0004026_032], 19th April 2001 [NHBT0008129], and, following a risk assessment by the DH's Economic, Statistical and Operational Research Group, 22nd October 2002 [NHBT0034821]. There were real concerns that if this were implemented, the Blood Services would be unable to maintain supplies to the NHS, with donor loss estimated to be 5-10%. The decision to defer anyone who stated they had had a transfusion in the UK since 1st January 1980 was recorded by

MSBT at its meeting on 11th March 2004 as in the document [DHSC0038559_047].

655. **'Club 96' donors.** A further possibility investigated by NBS was to use donors born on or after 1st January 1996 selectively for neonates and children. These donors began to reach their 17th birthdays in 2002 and were therefore eligible as donors. This was predicated on them being a 'safe' cohort unexposed to BSE through diet. A study of tonsil and appendix samples was being performed by the Health Protection Agency to see whether BSE might have been in the population after that date (or before 1980).

656. By the early 2010s, there were enough 'Club 96' donors registered for this option to be risk assessed. SaBTO were supportive of the concept and asked for detailed plans and a risk assessment. One concern was that, to minimise viral transmission, UK Blood Services did not, at that time, use first-time donors for neonatal components. A study was therefore performed to make sure that by allowing first donations from 'Club 96' donors to be used for transfusion, we were not inadvertently increasing the virus risk. The risk of HIV, HCV and HBV proved not to be increased in this group, but there were increased rates of other viruses of concern for neonates, e.g. Epstein-Barr virus.

657. There was also evidence that donors aged between 17 and 25 do not necessarily donate regularly and have high rates of deferral for low haemoglobin, foreign travel and piercing/tattooing. Therefore, there was uncertainty as to how reliable a source of components this group would be. For example, it was considered that it would take 10 years to accrue enough Club 96 donors to reliably support young patients with transfusion-dependent anaemias such as sickle cell disease and thalassaemia.

658. While the practicalities were being assessed, the assumption that these 'Club 96' donors would be prion-free began to be challenged when

preliminary results became available, I think in 2013, from the study of tonsil and appendix samples taken at surgery from people born after the BSE epidemic. It emerged that prions were present in the samples taken from some individuals born after 1st January 1996. The 'Club 96' option was therefore not pursued further.

b. development of screening diagnostic tests;

659. This was a huge scientific challenge because none of the approaches taken for virus screening could be used; there was no DNA or RNA for a NAT test, there was no antibody response in infected individuals, and the abnormal prions were present in the blood in very small numbers, against a background of large amounts of very similar normal prion protein.

660. There was clearly a need for such tests, but none were being developed when the first human vCJD cases were described in 1996. I was not directly involved in test development, but Dr Roger Eglin, NBS Colindale, Professor David Anstee, NBS Bristol, and colleagues in SNBTS began work to develop such a test. They were made aware that a group in France was working on this too, and there was a collaboration with them. They were also aware of the work of Dr Claudio Soto in Switzerland, who was developing a method to amplify infectious prions to generate enough material to be detectable in a screening test.

661. Because of the need for test evaluation to be conducted under a high degree of biological containment, I recall discussions between NBS and Dr John Stephenson, DH, about the creation of a Test Assessment Facility (TAF) to be run by NBS. This was eventually established at NBS Colindale.

662. One very real concern was whether donors would stay away in large numbers for fear of being told that they had a positive test. A survey indicated a potential loss of up to 50% of donors.

663. SACTTI kept a watching brief on the field, and when tests began to appear, the UK Forum established the Prion Assay Working Group (PAWG, chaired by Professor Marc Turner, SNBTS), I think in the mid-2000s, to liaise with manufacturers and oversee evaluations. I was not a member of PAWG, but I learnt through JPAC/UK Forum (UKTS Chief Executives and Medical Directors) meetings that PAWG was also working to ensure that vCJD assays were included in the Common Technical Specification requirements under the EU In Vitro Diagnostics Devices Directive. Unfortunately, and despite many efforts and investments, no satisfactory screening test has yet emerged from all this work.

c. importation of blood components from the USA or elsewhere;

664. Importation of the entire blood supply was not considered practical because of the scale of the requirement and the short shelf life of some components (5 days for platelets and whole blood for neonates). However, serious consideration was given to the importation of FFP. I will discuss this in some detail.

665. **Importation of FFP.** The component which was considered the most realistic possibility for importation was FFP, some of which could be further manufactured into cryoprecipitate. MSBTO discussed this in June 1999 [NHBT0004351] and asked NBS to investigate the possibilities. NBS investigated the options of voluntary and paid donors from the USA, and I reported back to MSBT in February 2000 [DHSC0006163_060]. By that point, all UK plasma was leucocyte depleted, and other factors also had to be considered, e.g. the possible need to use paid plasma donors in the USA, the need for virus inactivation and by which method, and prevention of TRALI.

666. Further investigative work on finding a safe source of plasma was undertaken by NBS throughout 2000, and I reported back to the MSBT

meeting on 22nd January 2001 [DHSC0014973_005]. At that meeting, a risk assessment on FFP was presented by Dr Peter Bennett of the DH Economics, Statistics and Operational research team (ESOR), who had taken over the risk assessment work from DNV. This suggested that, for a primary outbreak of 10,000 cases and under infectivity assumptions accepted by SEAC at that time, there could be as many as 85 infections/year from UK FFP. The minutes state:

'Members agreed that:

(i) there were sufficient grounds on precautionary basis to look at the feasibility of a switch to US plasma;

(ii) if there was to be a switch to US sourced FFP:

(a) Members had a clear preference for using single unit voluntary donated, MB treated plasma. If supplies were limited, this should be used for neonates and children;

(b) Members would need to have confidence in the processes for viral inactivation;

(c) Members would not favour using pooled solvent detergent treated FFP unless a 2nd viral inactivation step could be incorporated to deal with non lipid viruses;

(iii) there was a need for a wider scoping exercise addressing safety, supply (need for sustained alternative provision) and logistics;

(iv) the issue should be brought back to MSBT for a special meeting in April'.

667. At the MSBT meeting on 19th April 2001 [NHBT0008129], following NBS exploration of possible sources of non-UK FFP, I presented a paper containing some options. I also reported that worldwide demand for plasma had increased. Rather than attempting to paraphrase, I quote from the minutes:

'At the meeting on 22 January members agreed that there were sufficient grounds to consider the feasibility of switching to US FFP because of the risk of vCJD on the precautionary public health principle. The NBS examined issues of supply and sustainability of options for replacing all

UK FFP with a) single unit US sourced volunteer plasma or b) pooled solvent detergent plasma from American Red Cross. The paper focused on the provision of a combined option -single unit MB FFP from volunteers for neonates and cryoprecipitate production and, pooled SD FFP for the rest.

22.Dr Williamson said that obtaining plasma from the US was becoming increasingly difficult as world-wide demand had increased and costs had escalated.

The total NBS requirement was 120 tonnes. Of this, 2 tonnes would be needed as MB FFP for neonates and 28 tonnes for the production of cryoprecipitate.

23. The work so far had indicated that the option of providing the full requirement as MB FFP would be challenging given current markets. The plasma broker Seraplex indicated that contracts for could be established with 8 to 10 America Blood Centres but advice from BPL was that this would involve a protracted timeframe. In addition what was on offer was Frozen Recovered Plasma currently used for fractionation an frozen at up to 24 hours compared with FFP which was frozen within 8 hrs of collection. This would have a lower the coagulation factor content, especially following MB treatment. MB light treatment would need to be carried out under contract to Grifols in either Spain or UK as a separate operation. This was a very complex process presenting significant operational difficulties. The estimated costs were £27.5 million and implementation would take 16 to 29 months, depending largely on the capacity to treat the FFP with MB.

24. Provision of the full UK requirement as US donor pooled SD FFP would cost between £28 and 37 million per annum. In the case of Vitex, produced under contract to the American Red Cross, the timeframe for implementation would depend on licensing by the MCA, which is currently under consideration, and scaling up production in the US. Octaplas is already licensed in the UK but the product is made from European donors largely from Austria and Germany. Octapharma the producers of Octaplas plan to set up and

commission a new plant to produce SD FFP from US plasma. This is likely to take at least at least 12 months. While there was a risk of B19 transmission with SD FFP the risk of Transfusion Related Acute Lung Injury (TRALI) was avoided and this was a significant benefit.

25. *The American Red Cross and Octapharma have also made a joint proposal to provide the NBS with SD FFP. This again is in the same cost range. Implementation would again depend on time to granting a licence to Vitex and varying that of Octaplas as well as any scaling up of production, likely to be needed.*
26. *In the light of the difficulties of providing MB FFP in the quantity (120 tonnes) needed to treat all patients, the paper set out a further option, based on the provision of a combined MB and SD FPP supply. This option involved providing 90 tonnes as pooled SD FFP for adults and 30 tonnes as MB single unit FFP for neonates and cryoprecipitate production. The package could be justified in that pooled SD FFP is better than single unit UK FFP and the benefit of providing MB FFP for neonates is significantly greater than for adults. Importantly Seraplex has indicated that supply would be relatively easier to achieve. In addition there would be no need for a separate contract for MB light treatment, which the NBS could do in house at this level. In any case plasma frozen within 8 hours would be essential for the production of MB FPP and cryoprecipitate. This option would cost between £22.8 and 28.8 million.*
27. *Members agreed that the combined option should be advised and pursued. However there were concerns about the risk of a monopoly supplier though this would need to be balanced against the difficulties for handling several contracts. Dr Gorst asked if the two tonnes of single unit FFP required for neonates could come from other countries. Dr Williamson said that this had not been specifically explored, though preliminary work indicated that neither Canada nor Australia would be able to supply the entire demand. She gave a health warning about the estimated costs, which she said were subject to fluctuation of international plasma markets, and would*

need to be firmed up through more detailed exploration with potential providers.

28. *Dr Williamson, in response to questions from members at the January meeting, had investigated the possibility of laying down stocks of UK FFP in the event of the US market drying up, said that this would not be feasible or practical. The NBS could respond very quickly to this kind of supply difficulty and recommence producing UK FFP.*
29. *Professor Zuckerman and Dr Wyatt said that Octapharma had lobbied them very strongly about MSBT's views on Octaplas. (Octapharma had sent emails to MSBT members the evening before MSBT). Officials said they would investigate and respond as appropriate.*
30. *The Chair summarised discussion of the papers from EOR and the NBS. She said that an alternative source of FFP to reduce the unknown risk of vCJD from UK FFP could be found in line with advice from MSBT. She also noted the discussion and concerns about the costs of up to and possibly greater than £30m per year to reduce the risk and that the advice and position on feasibility would need to be considered by Ministers, when more detailed information was available. SEAC should also consider the EOR work and advise.*
31. *Dr Keel indicated that the combined SD and MB FFP importation option might not the preferred way forward in Scotland as the MB technology was already available. She suggested that scaling up current single unit MB FFP production was therefore a possibility. Dr McGovern said that DoH would work with the other UK countries on a submission providing advice to ministers. In the meantime DoH would write to NBS requesting that they prepare a full feasibility and procurement package focusing on the combined option advised by MSBT.*

    Action: DoH to write to NBS confirming MSBT advice and requesting a full

exploration of the options in particular the option advised by MSBT. DoH to work with colleagues in the devolved administrations on a full submission to Ministers on the advice and the implications".

668. At the MSBT meeting on 11th June 2001 [NHBT0002411_003], it was noted that DH would be writing to NBS requesting full exploration of the options, but that NBS was exploring the options in any case.

669. The minutes of MSBT on 22nd October 2002 [NHBT0034821] record a recommendation that neonates and children born on or after 1st January 1996 should receive US, single unit, MB treated FFP, ideally from untransfused males. I understand that this was announced on 16th August 2003 and implemented by the end of June 2004, as is discussed below.

d. surveillance;

670. Permission was obtained from MSBT, I think in 1996, to undertake a lookback exercise from any donor who went on to develop vCJD. This became a joint exercise with the CJD Surveillance Unit in Edinburgh, known as the Transfusion Medicine Epidemiology Review (TMER), which was developed throughout 1996 and commenced in 1997. This was led for the UK Blood Services by Dr Patricia Hewitt, with the database held in Cambridge and run by a scientist, Dr Charlotte Llewelyn, who was accountable to Dr Hewitt. I did not have direct responsibility for TMER, although I was well aware of it and its important findings.

671. It was this exercise which led to the first publication in The Lancet in February 2004, documenting the first case of transmission of vCJD from red cells transfused in 1996, i.e. in the pre-leucocyte depletion era. A follow-up publication in 2006 reported, sadly, a further 2 transmissions, again from red cells transfused before the introduction of leucocyte depletion (Hewitt et al, Vox Sanguinis 21st August 2006 [NCRU0000197_005]). Of the three reported cases to that point, 2 had

developed clinical vCJD, while in the third case, abnormal prions were found at post mortem, although the patient had no symptoms of vCJD in life. A third clinical infection was reported in 2007, 8 years after transfusion of non-leucocyte depleted red cells, and in 2009, a patient with haemophilia, who died of other causes with no symptoms of neurological disease, was found to have abnormal prions in the spleen (Peden et al, Haemophilia 2010: 16:296-304 [HCDO0000799]). A further publication in 2015 reported no further cases, so to my knowledge, the total number of patients known to be infected with vCJD through blood components in the UK remains at four, with the fifth transmission probably arising from clotting factors.

e. product recall;

672. Systems were put in place to recall any blood components in the system from any donor or the donors of any patients who developed vCJD. I think this was established during 1996.

f. quarantine of batches;

673. BPL also developed their own recall and quarantining procedures, which Blood Centres who distributed BPL products had to follow. I was not involved in developing or running the BPL process.

g. filtration policy; and

674. I discuss leucodepletion under Q190 (leucodepletion) below, and, to give a logical chronological account, I also discuss prion filtration under that question.

h. recombinant blood products.

675. **Recombinant and other synthetic blood products.** I was not involved in developing recombinant clotting factors nor in any decision-making

process about their use. I remember feeling great relief when it was announced in 1998 that boys with haemophilia would start to receive recombinant products. This was extended to all haemophilia patients in 2005.

676. With regard to 'artificial blood', there were two lines of research with which I was peripherally involved. The first was synthetic platelets. I attended a meeting at BPL around 2000 with Professor Alison Goodall, University of Leicester, to see whether BPL would like to take further Professor Goodall's research aimed at producing synthetic platelets using albumin microspheres coated with platelet proteins. The role of BPL would be to produce the microspheres from their albumin product. This was not taken further by BPL.

677. In around 2012, when I was Medical and Research Director, NHSBT, through the National Institute for Health Research (NIHR), funded a programme of research to develop red cells and platelets from stem cells. SNBTS had a parallel programme of work on red cells (now discontinued). The red cell work, led by Professor David Anstee at NHSBT Bristol and Dr Rebecca Cardigan's team at NHSBT Cambridge, has now reached the stage of 'first-in-man' studies. The platelet work, led by Professor Cedric Ghevaert, University of Cambridge/NHSBT, is at an earlier stage of development.

186. In providing this outline, please state where possible:

a. when and by whom any proposals were made;

b. the factors considered when deciding whether to implement these proposals;

c. decisions made on such proposals, including the date on which they were made or rejected;

d. how any such measures were implemented in practice, including efforts made to monitor their effectiveness; and

e. Whether, in your opinion, the risk of secondary transmission via blood and blood products was adequately mitigated in the UK in line with what was known about the potential risks of vCJD at that time.

You may find the following documents of assistance in answering these questions: NHBT0008646; NHBT0004564; NHBT0001804; NHBT0001920; DHSC0006195_003; NHBT0001900; NHBT0005599; JPAC0000061_022.

678. I will now discuss other strategies taken by NBS to minimise the risk of vCJD.

679. **A) Manufacturing steps.**

As discussed above, research had indicated that the elements of blood most hazardous for vCJD were plasma and leucocytes. Therefore, a number of measures were adopted to minimise patient exposure to these, either by reducing donor exposure overall or by producing components with less plasma, the NBS 'Safer Plasma in Components' (SPIC) project. I regret I do not have precise dates of implementation of each of these.

680. The SPIC project included:

(a) reducing the number of donors to whom a patient was exposed, e.g. sourcing more platelets from apheresis (1 donor/dose) rather than manufacturing them from pooled buffy coats from whole blood collections (4 donors/dose). MSBTO had mandated 50% platelets by apheresis. This requirement of 50% platelets by apheresis was rescinded by SaBTO in September 2013.

(b) reducing the amount of plasma in red cells donations by a change of manufacturing process to 'bottom and top' production

(c) replacing two-thirds of the plasma in platelet components with an additive solution. I am sorry I cannot give precise dates for each of these.

681. B) **Paedipacks.** These had been suggested by Dr Brian McCelland, SNBTS, as a general safety step and supported by MSBT even before there was concern about vCJD, according to the minutes of the MSBT meeting on 8th January 1996 [SBTS0000517]. Because premature neonates are highly transfused and have a long life ahead of them, Dr McClelland proposed to reduce their donor exposure by allocating an adult-sized donation to a single neonate. By splitting the donation into four or six smaller packs, the transfusion needs of a premature neonate over several weeks could be met by one or two donors, as opposed to a different donor for every transfusion. This was implemented by all the UK Transfusion Services and continues to the present time. This also allowed setting a higher specification for all neonatal components, e.g. exclusion of first-time donors.

682. **C) Fibrinogen concentrate**. It was reported to MSBT on 22nd February 2001 that PFC was developing a fibrinogen concentrate as a possible alternative to cryoprecipitate and that agreement with MCA on the design of clinical trials was awaited. (Note: I do not think this product was ever made available on a large scale).

683. **D) Development of infrastructure to drive appropriate blood use.** NBS recognised early on in the vCJD era that major efforts would have to be made to work with hospitals on a shared approach to blood use, both to drive down over-prescribing and to develop and trial alternatives. This major shift in policy and thinking, developed by Drs Tim Wallington and Angela Robinson and enacted from the mid-1990s onwards, meant that NBS became far more involved in what happened to the blood once it reached hospitals. It was necessary to create a whole new infrastructure to deliver this, which I will describe in detail to illustrate the scope. It included (I may have forgotten some elements):

- Recruitment of Professor Mike Murphy to a joint hospital/NBS post in Oxford, and to develop a national team of joint hospital/NBS consultants in each health region to lead education and best practice

- Creation of a parallel team of nurses to provide education and develop safer practice in the administration of blood
- Creation of a team of hospital liaison staff to run a new blood stocks management scheme and provide better intelligence on component usage
- Under the aegis of the Chief Medical Officer, development of hospital-based, regional and national transfusion committees to agree best practice and promulgate guidance. This had begun by February 1998.
- To assess the appropriateness of the use of blood components, a programme of audits was developed, to be conducted by the National Comparative Audit scheme of the Royal College of Physicians.
- Development of Health Service Circulars 'Better Blood Transfusion', the first of which was issued in 1999, and which set out actions to be taken by hospitals to improve transfusion safety. This was audited in 2001/2. The second was issued on 4th July 2002 as 'Better Blood Transfusion, Appropriate Use of Blood'
- To improve the evidence base for the appropriate use of blood components, Professor Murphy and I obtained funding from NBS R&D to establish a Systematic Reviews Initiative in Oxford, and a Clinical Studies Unit, to be led from Cambridge, in conjunction with the MRC Clinical Trials Unit in London.

684. **E) Specific blood-sparing initiatives.**

From the mid-1990s onwards, research has been carried out on a whole raft of blood sparing initiatives. Many did not become routine, and I will try to summarise the major options:

(i) *Autologous transfusion*. Both pre-deposit transfusion (banking the patient's own blood prior to surgery) and intra- and post-operative cell salvage were being practised on a small scale in the mid-1990s, and there was an Autologous Transfusion group in place by 1998, led by interested practitioners. In November 1997, it was noted at the NBS Leucocyte Depletion Steering Group that autologous transfusion and other blood sparing activities would be investigated by the NBS

clinical directors. The NBS teams described in the paragraphs above became more involved with these strategies and helped hospitals set up pre-deposit programmes. Pre-deposit never took off on a large scale because it was cumbersome for the patient, with several hospital visits in the weeks before surgery, and led to many patients going to the theatre more anaemic than they otherwise would have been. Also, postponement of surgery was not uncommon, leading to the blood outdating and being discarded. Intraoperative cell salvage was more promising but required purchase of capital equipment and funding for staff to run it and could not be used in cancer surgery. A more simple method was the use of a special type of surgical drain to affect postoperative cell salvage in joint replacement surgery, and this became widely adopted.

(ii) *Correction of anaemias with iron or vitamin B12* - this was easily done and promulgated through education programmes. Since many patients could not tolerate iron tablets, newer intravenous iron preparations were developed and used.

(iii) *Lowering the threshold of anaemia at which red cells are prescribed.* There was research in Canada (Exhibit WITN0643038) and studies in Jehovah's witnesses which showed that after surgery, patients on intensive care had better outcomes if their haemoglobin level was lower than was conventionally accepted. This led to further studies and acceptance that many patients did not need to be transfused as they had been in the past. A similar research-supported approach now also applies to platelet transfusion.

(iv) Erythropoietin (EPO). This blood-producing hormone is standard care for patients with kidney failure, saving many patients from regular transfusions.

(v) Education of NHS staff, donors and patients. I provided information for NBS blood collection staff from 1997 onwards [NHBT0001257], and JPAC developed a vCJD position statement to go on their website, reviewed regularly in the light of new evidence, e.g. Version 2 in 2002 [NHBT0007412] and version 3 in 2003 as documented in SACTTI minutes of 20th May 2003 [JPAC0000114_012]. By 2001, a

patient leaflet was in place explaining transfusion risks in the round, including vCJD.

685. F **) Epidemiology of transfused recipients**

i. An additional activity as part of the vCJD risk assessment work was to gain more knowledge about the numbers of different types of patients who were transfused, their ages and how long they survived after transfusion. There was a general assumption that most blood was used for surgery and trauma and that 50% of transfusion recipients had died of their underlying disease by 1 year after transfusion, but it was likely that these assumptions were out of date.

ii. With Drs Angus Wells and Charlotte Llewelyn, I, therefore, set up a collaboration with the MRC Biostatistics Unit in Cambridge to develop a methodology to establish the major uses of blood in adults and children and the survival of transfused recipients. This became the Epidemiology and Survival of Transfusion Recipients (EASTR) study, which published its novel methodology (Exhibit WITN0643025) and its main results (Exhibit WITN0643026).

iii. The EASTR study estimated that in the 12 month study period (2001-2), 443,000 people in England were transfused with red cells, with a median age of 69 years (Exhibit WITN0643026). There were also peaks of transfusion in the under 5s, accounted for by intensive transfusion use in premature babies, and in women between the ages of 20 and 40, because of transfusion associated with childbirth.

686. In contrast to the belief that most blood was used for surgery and trauma, recipients of red cells were split roughly 50:50 between medical and surgical diagnoses. Only 4% of red cell recipients had trauma. The commonest diagnoses associated with red cell transfusion were gastro-intestinal disorders (19% of all red cell recipients), with bleeding from the stomach or bowel being the single biggest group. This was followed by total hip or knee replacements (15%), haematological disorders such as

anaemias and leukaemias (13%) and women in childbirth or with gynaecological disorders (10%).

687. For recipients of FFP, whose median age was 64, gastro-intestinal disorders again accounted for most recipients (21%), with a further 15% having liver disorders. A slightly different picture emerged for cryoprecipitate, with vascular surgery (17%), liver disease (14%), trauma (12%) and neonates (12%) being the diagnoses in the biggest groups of recipients.

688. The picture was quite different for recipients of platelets (median age 59), where people with blood disorders accounted for 27% of recipients, followed by heart surgery (17%), use in babies and children (13%) and liver disease (10%).

689. This study was performed at a time when many initiatives to reduce blood usage were gaining momentum. Interestingly, a follow-up study at one hospital only two years later showed a 14% reduction in red cell use, but an absolute increase of 12% in medical patients (Exhibit WITN0643039). This illustrates the dynamic nature of blood usage and the need to have established methods of collecting this kind of data on an ongoing basis.

690. Survival of transfused recipients was much longer than had previously been thought. Of red cell recipients, 66% were alive at 1 year, with 47% alive at 5 years and 36% at 10 years (Exhibit WITN0643027). Survival was strikingly age-related, with 93% of people transfused aged 16-24 years still alive at 1 year, 90% alive at 5 years and 88% at 10 years.

691. The survival of transfused children paralleled that for young adults. Although neonates had a 15-20% early death rate due to prematurity, the long term survival of children receiving red cells was over 80% and over 70% for recipients of FFP and platelets (Exhibit WITN0643028).

692. This data fed into the ongoing DH risk assessment and risk reduction work on vCJD.

187. What was the role of the vCJD Clinical Incident Panel? (NHBT0001804)

693. I was never a member of this group, nor did I attend any meetings. Dr Patricia Hewitt was the NBS link to CJDIP and may have been a member. My understanding is that it was set up in 2000 by the Chief Medical Officer and is a subgroup of the ACDP TSE Working Group. The CJD Incidents Panel advised hospitals, trusts and public health teams throughout the UK on how to manage incidents involving possible transmission of CJD between people. This included possible exposure by surgical instruments, endoscopes, dialysis equipment, blood components, or human-derived hormones. It was dissolved in 2013. It considered, for example, what information should be given to patients who had had a possible exposure to vCJD, e.g. if they had received components from a donor who subsequently developed vCJD.

188. Please provide your view as to whether any decisions or actions could and/or should have been made earlier and how this might have impacted the number of individuals considered to be at risk of developing vCJD.

694. I will discuss three major decisions which impacted on vCJD safety: universal leucocyte depletion, withdrawal of UK plasma from fractionation, and importation of FFP.

1. **Universal leucocyte depletion.**

i. Considering there was no evidence till 2003 that vCJD could be transmitted through transfusion, decision making on leucocyte depletion (as explained above, the removal of white blood cells from blood components using specific commercially available filters) was straightforward. From a realisation during 1997 that prion infections in animals could reside in plasma and leucocytes, NBS produced a

feasibility report in three months and submitted it to DH in February 1998. This led to the Secretary of State's announcement in July 1998. This was a high cost, highly precautionary decision.

ii. Without a doubt, leucocyte depletion was the most complex programme undertaken by UK Blood Services. It required rebuilding at some centres, hiring of many new staff, re-engineering blood collection sessions and transport, developing methods that could be applied at scale for counting the low numbers of white cells left in the components, evaluating filters from several manufacturers, agreeing a specification, and devising statistical methods to provide a high degree of assurance that components sent to hospitals were in fact leucocyte depleted. Manufacturers had to develop/manufacture blood packs where filters were integral, rather than 'docked on', and there had to be a tendering exercise and contracts agreed. We also required manufacturers to provide filters to remove white cells from plasma, which had never been done before. Apheresis machines which removed leucocytes during platelet collection had to be evaluated, and contracts signed for those. Communications for staff, the public, donors, and hospitals had to be developed.

iii. Universal leucocyte depletion was in place across the UK by 1st November 1999, 16 months after the Secretary of State's announcement that it was to be implemented. The baseline figures for leucocyte depletion already in place to meet the needs of specific patients as recommended in the 1998 BCSH Leucocyte Depletion Guidelines Exhibit WITN0643040) were only 9% for red cells and 23% for platelets. Given the complexity of the project as described above, I do not think that this could have been achieved any more quickly.

2) Withdrawal of UK plasma from fractionation.

iv. This decision was taken by CPMP in February 1998 [MHRA0009439]. Again, considering the limited state of knowledge

of risk, this was a high cost, highly precautionary decision. No recipient of a plasma product had developed vCJD by that point. In my view, this was a timely and appropriate decision.

695. **Importation of FFP.** Reaching a decision and implementation on this issue was complex, I think for several reasons:

(1) International demand for plasma was high, driven by the needs of commercial and public fractionators. During 2000, NBS investigated possible sources of plasma, and it soon became clear that we were unlikely to find sufficient volumes of plasma to replace the entire FFP supply. Importation might have to involve paid donors, which to us was highly undesirable. It, therefore, appeared that importation would have to be selective, i.e. for certain groups of patients only. Therefore, a decision had to be made as to who should receive it. It was suggested, but I cannot recall precisely when or by whom, that patients born on or after the date by which the UK food supply was 'BSE-safe' (1st January 1996), would be a logical group to protect, at least to begin with.

(2) FFP had other risks associated with it, such as viruses and Transfusion-Related Acute Lung Injury (TRALI), a serious immune reaction causing breathlessness and low oxygen levels. SHOT had begun to collect cases of infection and TRALI in 1996, so initially, there was not much data to consider. However, regarding importation, it was of great concern that the rates of HIV and hepatitis in the USA population were 4-9 times higher than in the UK (data from Kate Soldan). Therefore, if we were not to be replacing one infectious risk with another, imported plasma would have to be subjected to a virus reduction step. NBS was already investigating SDFFP and MBFFP as possible steps to apply to UK plasma, but neither method was licensed until 1998, and there were concerns about each (see section 13 for details).

696. The NBA Executive had agreed that implementation of UK MBFFP for children should be done as an initial step, with a switch to USA plasma when this became available. Initially, MBFFP rollout was to be managed along with leucocyte depletion during 1999, but in practice, it was not implemented until 2000. I have discussed virus inactivated plasma in more detail in section 13, Q116-136.

697. At the same time, SHOT data were showing that TRALI occurred far more often from FFP and platelets than from red cells and cryoprecipitate, which contain far less plasma. Evidence emerged that a major cause of TRALI was the presence of Human Leucocyte Antibodies in the donor plasma, along with the fact that these were generally produced as a result of pregnancies. Therefore, NBS was considering whether all FFP should be manufactured from male donors only, but we were unlikely to obtain enough 'male only' plasma from the USA or anywhere else.

698. The need to balance the various risks associated with FFP was therefore complicated, and this possibly may have been a factor in the time taken to implement importation.

699. (3) Because of the instructions from DH regarding implementation of leucocyte depletion, this was given top priority in 1998/9. NBS had no corresponding instruction between 1999 - 2002 regarding importation of FFP.

700. (4) From the minutes, it appears that a recommendation on importation of FFP was reached by MSBT on 22nd October 2002 [NHBT0034821], with a DH announcement on 16th August 2003. I am not clear why there was this long gap. NBS then implemented this project within 10 months. This is not unreasonable, given the need to arrange contracts with US suppliers, organise regular shipping and storage, to build up stock, modify IT systems, scale-up quality control procedures, and produce communications for donors, hospitals and the public.

189. On 24 October 1997, the SEAC revisited the safety of blood and recommended that leucodepletion should be increased and the risks of transmitted vCJD through human blood should be assessed. The Inquiry understands that you made a framework proposal to SEAC on this question. (NHBT0004573_001). Please describe what was the role of the leucodepletion in reducing risk of vCJD transmission through human blood.

190. When was leucodepletion implemented in the UK? (NHBT0010689_019) What is the difference between selective and universal leucodepletion? Which method was implemented in the UK and why? You may find these documents helpful in answering the above questions on leucodepletion: NHBT0004564, NHBT0001257, DHSC0004805_254, NHBT0007051_004, NHBT0041015 page 3, NHBT0009286_002.

701. I will answer Q189 and Q190 together to provide a chronological account.

702. The evidence that leucocyte depletion would reduce the risk of vCJD came from animal studies done outside the UK and described in Q180 above. This evidence fed into the DH risk assessment conducted by DNV and which calculated how many vCJD cases might occur with and without leucodepletion.

703. In November 1997, DH asked NBS to prepare a costed implementation plan, within 3 months, describing how leucocyte depletion of all blood components, i.e. 'universal leucodepletion' could be achieved. (This contrasted with the policy in place at that time of 'selective leucodepletion' i.e. providing leucocyte depleted blood components only for patients who specifically needed them to prevent febrile reactions or to prevent HLA immunisation as per BCSH Guidelines). This implementation plan was produced by a small group, the NBS Leucodepletion Steering Group, chaired by Dr Tim Wallington, of which I

was a member. It was provided to DH by the end of February 1998, with an estimated cost of £80 million/year and a 12-month lead time from instruction to completion. I attended MSBT on 26th February 1998, with Philip Comer from DNV, to present the report.

704. On 17th July 1998, the then Secretary of State for Health, Frank Dobson, announced that universal leucodepletion would be adopted. The Steering Group then expanded to become the NBS Leucodepletion Implementation Group, with different sub-groups to lead on different aspects.

705. I chaired the Quality/ R&D sub-group, which initially focussed on the issue of white cell counting and statistical assurance (Exhibit WITN0643041) since these were on the critical path to implementation. There were also many unanswered research questions to be investigated in parallel to implementation, e.g. would there be any detriment to the quality of FFP, which had not been leucocyte depleted up till then (Exhibit WITN0643042); what types of white cells did filters remove and how could we count these different types (Exhibit WITN0643043); whether white cell filters might generate red cell fragments (Exhibit WITN0643044); whether blood from donors carrying the haemoglobin sickle gene would filter (Exhibit WITN0643045); was blood now sufficiently safe from white-cell associated viruses, e.g. cytomegalovirus (CMV, Exhibit: WITN0643018), for which we were testing for vulnerable patients, and HTLV I and II (Exhibit: WITN0643017), for which testing was being considered. We worked on these up to and beyond implementation, presenting the findings to relevant decision-making groups and publishing the findings.

706. Because it was not practical to count the leucocytes in every component produced, a sampling schedule was derived that would provide a high degree of assurance that the required degree of leucocyte removal had been achieved. The specification, therefore, agreed by JPAC for leucocyte depleted components was that 99% of components must

contain fewer than 5 million leucocytes and that this needed to be established with at least 95% statistical confidence.

707. This reflected the capability of filter and apheresis techniques for leucocyte removal. We saw no significant differences in capability between technologies from different manufacturers, enabling us to award contracts to multiple providers and thus minimise the risk of supply problems with key consumables.

708. In 2011, SaBTO recommended that CMV testing be discontinued, as there was now enough evidence on the CMV safety of leucocyte depleted components.

Your role in various committees and groups related to this section

191. The Inquiry understands that you were involved with committees and groups related to vCJD risk, leucodepletion and prion removal. For each of the following committees and groups, please explain their remit and your involvement:

a. NBS vCJD Steering Group;
b. SACTTI Working Group on vCJD;
c. Universal Leucodepletion Programme Implementation Board; and
d. NBS Leucodepletion Project Steering Group.

You may find the following documents of assistance in answering this questions: NHBT0060302, NHBT0060308, NHBT0002141_001, JPAC0000051_020, JPAC0000051_021, JPAC0000051_053, NHBT0000766, NHBT0000767, NHBT0000769, NHBT0002384, NHBT0045664, NHBT0010689_019, NHBT0052138.

192. What were the respective responsibilities of the above groups in respect to policy decisions relating to vCJD? Did both groups advise the DoH?

709. I will address questions 191 and 192 together.

710. I have described the roles of the NBS Leucocyte Depletion Steering Group and Implementation Groups above under Q188/189, and the NBS vCJD Steering Group above under Q184b. The SACTTI vCJD working group was created in 1999 to monitor the field for screening tests for vCJD. Its advisory role was through the UK Blood Services, as described in Section 10. It was later replaced by the UK Blood Services Prion Assay Working Group, chaired by Professor Marc Turner.

711. None of these groups provided advice to DH. The main group advising DH on prion safety of the blood supply was SaBTO, with input from SEAC.

Prion filtration

712. For completeness, I give here a short account of the NBS's role in evaluating commercially developed prion filters. I regret I do not have the papers which would give precise dates of some of these actions. Much of the material is covered in my Statement before the House of Commons Science and Technology Committee in 2014 [TSTC0000047].

713. In the mid-2000s, NBS was approached by 2 manufacturers who claimed to have developed filters which could specifically remove prions from blood components. One was the Leukotrap combined leucocyte and prion removal filter from Pall Biomedical, supported by published data (Sowemimo-Coker et al, Transfusion, 10 October 2005). This filter ultimately did not progress, although I cannot recall precisely why. The other was the P-Capt filter, developed by a company called ProMetic, which partnered with the blood pack/white cell filter manufacturer Macopharma.

714. In 2006, the UK Blood Services created the Prion Reduction Working Group (PRWG), accountable to the UK Forum (Chief Executives and

Medical Directors) to develop an assessment plan for such filters and liaise with the manufacturers. I chaired that group from its inception till it was merged sometime before 2012 with the Prion Assay Working Group created in parallel and chaired by Professor Marc Turner to form a single Prion Working Group, again chaired by Professor Turner.

715. To ensure a level playing field for all manufacturers, PRWG produced a protocol for evaluation of candidate prion filters.

716. It was recommended by SEAC that such filters should undergo an independent assessment. This was particularly relevant for P-Capt, since the manufacturer's data on P-Capt were on a prototype resin column only. SEAC declined to review manufacturers' data, as this was outside their remit but did agree to review the results of the independent evaluation. We then began discussions with the Health Protection Agency (HPA) for the independent evaluation. This would have to be carried out under strict biological containment, and we knew that their Porton Down facility would be a suitable environment.

717. These studies would involve small animal studies to a design recommended by SEAC. The first studies would involve blood spiked with prions from the brain or spleen of infected animals, then passed through the filter. The requirement specified by SEAC was for a 1000-fold (3 log) reduction in prion levels. If successful, this would be followed by a study filtering blood from prion infected animals. These studies were subject to the OJEU tender process, which took 3 months and we knew that the studies themselves would take at least 12 months to complete since they depend on the development of infections in recipient animals,

718. The results were not presented to the Select Committee in an open forum since they were commercial in confidence. They were, however, provided to the committee in written form.

719. As well as uncertainty about the filters' efficacy, we had some safety concerns. Since normal prion protein is a constituent of the red cell membrane, passage through the filters could alter the structure or function of the membrane. This, in turn, could either impair the capacity of red cells to withstand the 35 days storage in the fridge or even worse, cause the recipient to make antibodies against all red cells. In a worst-case scenario, patients would then destroy the red cells from any future transfusions. For patients dependent on regular transfusions, such as those with sickle cell anaemia or thalassaemia, this would be catastrophic.

720. Prion filters, like white cell filters, are licensed through the CE marking scheme, which I have described in Section 13 in relation to systems for the manufacture of MBFFP. There is a requirement to show biocompatibility, but clinical trials on safety are not necessary. There is no agreed standard for CE marked medical devices; provided the manufacturer can provide data to back up its claims, a CE mark will be awarded. Dr Chris Prowse (SNBTS) and I felt that this was a weakness in the regulations and met with the MHRA to discuss this issue, but no change to requirements was made.

721. We, therefore, conducted detailed laboratory studies on red cells which had passed through the P-Capt filter, examining in detail the membranes of the cells and the antigens which are part of them. This work was conducted by Professor David Anstee's team at the International Blood Group Reference laboratory at NHSBT Bristol. No worrying features were seen.

722. In parallel with the independent evaluation, we developed and ran a safety study (PRISM A) in patients having planned surgery to look for reactions and development of red cell antibodies. Four hundred surgical patients were randomised to receive either standard leucocyte depleted red cells or red cells, which had also been prion filtered. There was no difference in reactions or production of red cell antibodies between the

two groups (Exhibit WITN0643046) We also considered a further study in multi-transfused patients (PRISM B), which in the end was not needed.

723. These studies were performed at a point when vCJD cases in the UK were falling, and the ACDP Risk Assessment Sub-group was revising downwards its estimations of blood infectivity. However, since we were conscious of the time which these studies would take, Professor Turner and I also agreed to ask SaBTO what minimum data set would be adequate for implementation, should vCJD cases in the UK again begin to rise.

724. Here is an extract from the minutes of the SaBTO meeting on 12th December 2012. (Exhibit WITN0643047)

'SaBTO considered the evidence currently available and expert advice from the SaBTO Prion Sub Group. The Sub Group had worked closely with other relevant groups and specialists including the UK Blood Services Prion Working Group and the Advisory Committee on Dangerous Pathogens Transmissible Spongiform Encephalopathies Risk Assessment Sub Group. Following this consideration, SaBTO concluded that the evidence did not currently support the introduction of this filter, and the provisional recommendation it made in 2009 should be rescinded. SaBTO would consider re-evaluation of this conclusion if further evidence became available about this filter. SaBTO agreed to consider other filter technologies if evidence should become available. NOTE: Some material has been redacted for legal reasons. SaBTO may be in a position to publish this at a later date'.*

**This was a recommendation to introduce prion filters for neonates and children born on or after 1st January 1996, provided the safety study was satisfactory'.*

725. As I stated to the House of Commons Science and Technology Committee, an important finding in the assessment of efficacy of the

prion filters was that leucocyte depletion alone gave a very high degree of prion removal [TSTC0000047].

Section 18: Other matters

193. What was the impact on you and on others at the EABTC of the criminal prosecution of Professor Allain during the time he was the Director?

726. **Imprisonment of Professor Allain.** Naturally, the events in France came as a great shock to myself and others at EABTC. Professor Allain was the first Professor of Transfusion Medicine in Cambridge and Director of the Centre. With the appointment of Dr Willem Ouwehand and myself as new University Lecturers/Consultants, we were excited about the future of EABTC in making first-class contributions to both the national transfusion effort and to research for the benefit of patients. We were also concerned for Professor Allain personally as a colleague. It is my understanding that Professor Allain was imprisoned after a civil prosecution, not a criminal one.

727. On a day to day basis, our top priority was to keep the centre running smoothly, providing our usual high quality of service to donors and hospitals. On a practical level, the East Anglian Regional Health Authority appointed a Public Health physician, Dr Morton McDougall, as Acting Director of EABTC. I took over management of the donation screening laboratory (which had been managed by Professor Allain) and supported Dr McDougall when he needed advice from a haematologist. We also had to deal with a certain amount of media attention, and we were concerned that donors would be deterred from attending by the publicity. Fortunately, this was not the case, and blood stocks remained good. Overall, EABTC continued to run smoothly, thanks to the professionalism of our medical, nursing, laboratory and administrative staff.

194. Did you agree with the Warnock report and the decision to reinstate Professor Allain after he was found guilty of the offence of deceit in France?

728. **Warnock report.** Thirty years after its publication, I do not feel I can sensibly comment on Dame Mary Warnock's report. The question asks for my views on 'the decision to reinstate Professor Allain'. This is factually incorrect: Professor Allain was suspended from the NHS immediately after he was charged in France and was never reinstated to an NHS post. The University, I believe, did not suspend him from his Chair at any point. Therefore, reinstatement does not apply in either case.

729. There was a great deal of concern about the possible negative impact on the reputation of the blood service were Professor Allain to become an NHS employee again on his return from France. Again, the possible deterrent effect on donors was considered. Whatever we felt about the outcome of the case in France, and for Professor Allain as a colleague, the priority of the Blood Service had to be to our patients and donors. The University had more flexibility in accommodating Professor Allain. The solution which was adopted, i.e. that he kept his University Professorship, allowed Professor Allain to carry on his top quality research into blood safety. The National Blood Service was thereafter a willing research collaborator supporting studies on anti-HCV testing (16) and anti-hepatitis B core testing (Exhibit WITN0643029) and [NHBT0000112_034]

195. During Parliamentary questions on 10th December 1985, Mr Hayhoe stated that 'supplies of whole blood are not imported since the United Kingdom is self-sufficient in its needs for blood for transfusions; it is only certain blood products which are imported' (HSOC0018830). To your knowledge, was the UK self-sufficient in its need for whole blood for transfusions?

730. I entered transfusion medicine as a trainee in Sheffield in 1985. Ever since then, I am not aware of any imports of red cells from outside the UK because of shortage of supply. The UK was always self-sufficient in whole blood. I have had no personal involvement in any importation of whole blood, red cells or platelets.

196. During your tenure at EABTC, were you aware of patients being given blood transfusions with red blood cells imported from the USA? If so, was there any concern about its use at the time?

731. There may have been an occasional UK patient requiring very rare blood who had to have a donation from outside the UK. Frozen stocks of blood of rare types are held for international use, e.g. in The Netherlands, and we may have occasionally called on them to help with a patient for whom no suitable blood was available in the UK.

732. I believe there was also an agreement between NHSBT and Sanquin (the blood service of the Netherlands), I think in the early 2000s, for mutual support in the event of terrorism or a pandemic having a major impact on supply. Thankfully, this has never had to be activated.

197. Please provide a list of any articles you have had published relevant to the terms of reference.

733. **Publications.** I have provided lists of relevant publications, both chronologically (the numbers referred to in the text) and by theme.

198. Please explain, in as much detail as you are able to, any other issues that you believe may be of relevance to the Infected Blood Inquiry. To assist, we have provided a list of issues (attached).

734. I would like to reflect on three interlinked changes during my years in the National Blood Service, which I think have been transformative for the safety of transfused patients: structured policy making, safe delivery of

blood to patients, and production of data to inform policy. I refer specifically to (1) replacement of MSBT by SaBTO and the role of JPAC (2) creation of the NBA (later NHSBT) and (3) establishing the reporting system SHOT and, in particular, the NBS/PHLA/CDSC collaboration.

735. I include them because I think they are pertinent to one of the issues at the heart of the Inquiry's work, i.e. how can we ensure that decisions regarding patient safety are taken and enacted in a data-driven, transparent and timely manner. I refer to the patient rather than blood safety because decision-makers need to concern themselves with the whole journey of the altruistic donation all the way to the patient, i.e. 'vein-to-vein'. As we know only too well, efforts to ensure the safest product possible can be wiped out if that safe bag of blood is given to the wrong patient. I will discuss policy making first.

Setting safety policy: SaBTO and JPAC

736. Recalling the discussions in the 1990s on various safety policies and reading minutes of MSBT meetings have led me to reflect on the hugely improved way policy-making has operated since SaBTO was created.

737. During the 1990s, it was not always clear what MSBT had decided and, in particular, why certain decisions had been taken. Although Dr Robinson did her best to give feedback on these decisions to her senior team, I had a sense that there was a tension between her intrinsic wish to be open and her obligation to retain the confidentiality that MSBT required.

738. From 2008 onwards, with the creation of SaBTO, it was as if the fog had cleared. I accept that this may have been partly because I became an NHSBT Board member in 2007 and also a member of SaBTO, but for the first time, I could see a transparent and open process for important safety decisions. I would like to set out for the Inquiry some of the essential elements of this as I saw them between 2008 and 2016.

739. The most important change was that SaBTO's remit covered all aspects of blood safety, not just the microbiological ones. SaBTO was now the single committee with the over-arching view of blood safety which SHOT had been calling for since its first annual report in 1997. I thought it very helpful that the safety of organs and tissues was also considered in parallel, not just because it mirrored NHSBT's responsibilities, but to give a sense of perspective on the risks of blood.

740. There was also now greater clarity about the respective roles of SaBTO and JPAC with its supporting SACs (see paras 18-22 below for reflections on JPAC), with the chair of JPAC a SaBTO observer. In particular, this move provided clarity on how the work of SACTTI could feed into that of SaBTO. SaBTO has also welcomed input from other organisations with a focus on the safety of transfused patients, such as SHOT and the NBTC.

741. When I was a member, SaBTO had a wide membership from the medical, scientific and nursing professions from hospitals, Health Protection England, and academia. Transfusion Services members were only a small minority. The appointment of a practising clinician, independent of DH and the Transfusion Services, as chair (initially Professor John Forsythe, Transplant Surgeon) was a great step forward, as was inclusion of patient representatives.

742. There was much more collaborative working with the Blood Services, who had previously been rather at arm's length. This included a clear process for Blood Services to bring items for possible inclusion on the SaBTO agenda, and there was secondment of an NHSBT scientist to the SaBTO secretariat. I acted as the senior Blood Services link to the DH scientific officials supporting SaBTO, which I think was useful.

743. There was a clear process for SaBTO to reach decisions about the agreed issues. Generally, a Working Party would be formed, chaired by

one of the members, but able to recruit external experts as necessary. The Working Party would have agreed Terms of Reference and a deadline for production of a report. Some final recommendations were reached after considerable external consultation once preliminary conclusions had been drawn.

744. The Chair of the Working Party would present the conclusions and recommendations of the report to a meeting of the full SaBTO, where there would be open debate and a consensus recommendation reached. It was seen as important to reach a consensus, and I do not recall ever having a vote. SaBTO's recommendations went to the four UK Departments of Health, who might then undertake an Impact Assessment if large costs were required. They would then make a final recommendation to their Chief Medical Officer or Health Ministers.

745. I would like to say a little more about the factors taken into account when SaBTO were considering an issue. When SaBTO was formed in 2008, the members were introduced to the decision-making framework to be used, which included elements such as benefits and risks to patients of the proposed measure, interactions with other safety measures, impact on donors and the public, operational impact on blood services and hospitals, and cost.

746. SaBTO later adopted the international blood services risk-based decision-making framework, which had been devised by the ABO group after a consensus conference (Exhibit: WITN0643048). At its meeting on 29th April 2014, (Exhibit WITN0643049) SABTO agreed that this framework could be trialled in its assessment of hepatitis E screening, commissioned at the same meeting. At its meeting on 14th April 2014, SaBTO agreed to adopt this new framework. The minutes confirming these decisions are on the SaBTO website.

747. When I was a member, there was always a health economist as a full member, and the committee was supported by the DH's excellent

Economic, Statistics and Operational Research team (ESOR). In considering costs and cost-effectiveness of any measure, mention would be made of the benchmark used by NICE when they consider whether the NHS can make new medicines available. I think this started at £30,000/quality adjusted life year and may have reduced to £20,000/quality adjusted life year. The SaBTO chair, however, was always keen to point out that whilst we could be guided by this figure, it was far from an absolute, and we should be mindful of the many other impacts of our decisions. We were considering steps to avoid harm, a different exercise from approving new treatment.

748. There was total transparency in sharing SaBTO's work. The minutes, once agreed, and papers setting out the logic behind the decisions were put on the SaBTO website, except when we were bound by 'commercial in confidence' requirements.

749. Although the safety agenda continued, correctly in my view, to place high emphasis on new infectious threats to the blood supply, time was given to discuss other issues, e.g. TRALI prevention measures and findings from SHOT reports.

750. In conclusion, I would like to say how much difference the open and systematic approach of SaBTO has made to high-level policy setting on blood safety.

JPAC

751. I will now turn to JPAC and its Standing Advisory Committees, who act as the producers of the UK Guidelines for the Transfusion Services, as well as the advisory machinery for the UK Blood Services on matters below the level of SaBTO decision making.

752. It was usually obvious whether an issue could be decided at JPAC/UK Blood Service level or whether referral to SABTO was appropriate, mainly based on level of cost and impact. Usually, but not always,

decisions on testing for new viruses would be taken by SaBTO. One exception was when the Blood Services took the decision to substitute West Nile Virus (WNV) testing for deferral of travellers to WNV areas to minimise loss of donations.

753. In contrast, in the 1990s, it was not clear how the work of SACTTI in particular dovetailed with that of MSBT. It is now much clearer that SACTTI/JPAC advises the Blood Services and that JPAC/SACs can be a resource on which SaBTO can call.

754. It should be noted that SACTTI/JPAC themselves contribute significantly to infection safety by holding the Geographical Risk Index for deferral of returning travellers from either new areas of long standing infections, e.g. malaria, or hotspots for new infections, e.g. Zika virus. This is complemented by horizon scanning for new threats and through maintenance by SACTTI/JPAC of a list of animal and human infections which are monitored for their potential risk to the UK blood supply.

755. I would like to emphasise, at the end of this section, that the days of policy being set by any one individual in the transfusion landscape are firmly over. These sometimes difficult decisions are now always taken by the appropriate committee after consideration of a range of clinical and lay views, and I would not like to see this eroded.

Creation of the National Blood Authority.

756. There is no doubt that creation of the NBA was absolutely the right decision. I would like to reflect on the many benefits for patients that this national organisation has brought.

757. For me, the biggest change brought about by the NBA was the creation of a clear line of sight to the patient. In the past, the responsibility of RTCs in England ended when the blood arrived at the hospital, and there was varying interest within RTCs in what happened to it after that. I was

a medical student in Edinburgh, where SNBTS ran the hospital blood bank, and where SNBTS consultants were based in the hospital.

758. When I started work at the Sheffield RTC, I was very struck by the different models in England, despite Sheffield RTC having joint meetings with local consultants and a joint post with Sheffield Children's Hospital.

759. Even more striking was that there had been no such moves at EABTC by 1988, despite it being on the hospital campus, and relationships with transfusion staff at Addenbrookes Hospital were best described as cool. The appointment of the new Professor/Director (Professor Allain) and two new lecturers/consultants (Dr Ouwehand and myself) in 1989-91 began to change that, and creation of the NBA in 1994 was the next big step change.

760. The vision of those in NBS senior management who saw the need for greater involvement with hospitals cannot be overstated. Certainly, it was partly driven by vCJD, but I think it would have happened anyway. Recruitment of Professor Mike Murphy to lead a team of joint consultants across major hospitals provided a means of driving appropriate blood use as later defined through the Better Blood Management Health Service Circulars, the production of which was largely by NBS clinicians. An example of a Health Service Circular can be seen in document [NHBT0062177_001], which has been provided to me.

761. The creation of joint posts offered an interesting career option for talented haematology trainees or for people who had previously worked as a hospital consultant haematologist. In fact, most NBS consultants are fully trained haematologists (some are immunologists or virologists) and will have worked, as I did, for up to 10 years in hospitals before joining the Blood Service. Their engrained focus on the patient is exactly what a Blood Service needs.

762. Working alongside the medical staff, a team of nurses was created, linked to hospitals within a region, to focus on education. This created a route by which SHOT recommendations and BCSH guidance on safe transfusion reached all the relevant hospital staff. They could also promulgate information leaflets for patients, though it is the hospital's responsibility to make sure that these reached the patient.

763. Development of the Blood Stocks Management Scheme caused acceptance that hospital and Blood Service blood stocks were, in fact, a single national resource to be managed jointly and with care. It was not unknown in the early 1990s for RTCs to 'hide' some of their stock when making returns to the national directorate.

764. The creation of the CMOs National Blood Transfusion Committee has been another asset, with regional and local transfusion committees bringing together blood providers and users. This also gave a voice to lay people, whose input has been invaluable.

765. The NBA created a national infrastructure for real innovation, such as red cells and platelets derived from stem cells. There is a national Component Development Laboratory, joint research posts with top Universities, and a route for obtaining research funding. These are complemented by a Clinical Studies Unit and a Systematic Reviews Initiative to produce gold-standard evidence for the use of blood components and alternatives.

766. The NBA has benefitted from the recruitment of senior staff with commercial experience. Blood, however, is not widgets, it is a life-saving medical treatment, without which the NHS could not function. I recall a robust conversation with a former chairman who was asserting that the NBS would perform better if only we had competition and shareholders to whom we had to be accountable. I pointed out that *'we certainly do have shareholders, they're lying in hospital beds'.* A blood service that is

to thrive and deliver for patients must remain an integral part of the health care system and retain a strong patient focus.

767. Compared to the relative isolation of the 1970s and 80s, the UK Transfusion Services are leaders in new international groupings such as the European Blood Alliance (EBA). The regard in which we are held is reflected in the fact that the EBA modified its statutes to allow the UK Transfusion Services to remain as members after the UK had left the EU.

768. In addition, the NBA was instrumental in establishing the Alliance of Blood Operators (ABO), a global grouping of blood service providers. Membership of both EBA and ABO allowed the UK Transfusion Services to benefit from the experiences of others in dealing with many of the same issues as the UK.

769. As well as a much-improved organisational structure, I believe that the creation of the NBA allowed a culture of continuous quality improvement to flourish. With encouragement of 'fair blame' open reporting of errors and incidents, and information sharing through clinical governance arrangements, there was when I retired in 2016 an environment with a drive to always get better.

770. I would like to end my reflections on the NBA with some thoughts on provision of plasma to BPL. The documents provided by the Inquiry relating to RTD discussions in the 1980s do not always make comfortable reading. This seems particularly true in relation to the supply of plasma to BPL. I can recall, from my time as a consultant at EABTC in the early 1990s, and prompted by documents provided by the Inquiry, that there could be tensions between our responsibility in providing components to regional hospitals and the supply of plasma to BPL. We were essentially trying to serve two masters at the same time. Equally, we sometimes had to have difficult conversations with hospital colleagues when BPL products were in short supply, something for which EABTC had no responsibility.

771. The creation of the NBA brought BPL and the RTCs together, so that for the first time, we could coalesce around a shared vision and priorities. Success for BPL meant success for the whole organisation. BPL was certainly a changed organisation by the time vCJD appeared, unfortunately resulting in a ban on UK plasma being made into products. Now that UK plasma is again going to be fractionated, but with BPL no longer part of the NHS, efforts must be made to bring it back close to its plasma supplier, the NBS. There is a generation of staff in both organisations who will not know much, if anything, about the other. It concerns me greatly that we could return to those days when BPL was sometimes seen as a distant irritant rather than the partner that it should be in providing safe, high-quality medicines for patient benefit.

Availability of data to inform policy making.

772. I have discussed SHOT in detail in Section 10 and do not intend to go over its merits and limitations again. However, the importance of real-time data on transfusion risks cannot be overstated. The rapid availability of up-to-date information on new infections across the world was simply not available to the decision-makers of the 1980s, in the pre-digital era. There were no personal computers and no email, internet or smartphones. Written communication was by letter, typed up by a secretary and sent in the post. Information from a conference would depend on the returning delegate having notes typed up and circulated.

773. We now take for granted the rapid exchange of information across the globe. With climate change and global travel potentially bringing new blood-borne infections to the UK, ongoing horizon scanning is essential. Strong links between the Blood Services and PHLS, particularly CDSC, must be maintained. This should include links to the veterinary world. We are fortunate that it was clear early on that Covid did not pose a risk to the blood supply.

774. When vCJD emerged, huge, costly decisions were taken before its potential for harm through transfusion was known. Thankfully, the spectre of hundreds of patients infected through transfusion did not materialise. Whether this was due to the steps taken and/or the low probability of transmission is not entirely clear. However, this use of the Precautionary Principle when data were very limited saved many months of debate, and must be called upon as needed for the threats of the future.

Informed consent for blood transfusion and clinical trials

775. I would like to review the situation regarding informed consent in two situations which I think are relevant for the Inquiry (1) prior to blood transfusion and (2) for clinical trials of transfusions and alternatives.

(1). **Blood transfusion**

776. Blood transfusion was developed as a life-saving treatment for major bleeding after trauma and childbirth. Its use expanded to allow major planned surgery and to treat patients with chronic anaemias like sickle cell disease and thalassaemia, where again it is life-saving. Blood and its components have never been licensed as medicines, partly because every donation is unique, unlike a batch of pills.

777. Many transfusion recipients are conscious and aware they are being transfused, but some may be too ill or admitted to the hospital unconscious and have to be transfused urgently. The HCV lookback revealed that some patients who had planned surgery did not know whether or not they had been transfused while under anaesthetic. The rules of Good Medical Practice, as laid down by the General Medical Council, now dictate that a doctor should always explain a treatment to a patient and record a decision to prescribe it in the case records. Unlike surgery, however, no specific written consent is required for transfusion.

778. In spring 2010, SaBTO convened a working group to investigate the consent for transfusion. They conducted a wide-ranging consultation with the medical and nursing professions and with laypeople to seek a preference for one of two options (1) verbal consent recorded in the case records by a healthcare professional (2) documentation signed by the patient. More than 800 people responded to the survey and were evenly split in favouring each option.

779. On 11th October 2011, SaBTO presented the survey results to an Open Meeting, along with the conclusion that *'mandating written consent would not improve the level of valid consent'*. The key issue was what information the patient was given, not simply whether they had signed a consent form. As an alternative to signed consent, SaBTO recommended that the reason for the transfusion should always be recorded in the case notes. Importantly, a discussion should be had with the patient regarding the need for transfusion, its benefits and risks, and whether any alternatives might be possible. This discussion should also be recorded in the case notes.

780. These general recommendations were underpinned by 14 specific recommendations covering clinical practice, governance of the process and education. These were designed to facilitate the obtaining of informed consent in as many circumstances as possible. The clinical practice recommendations included: *'There should be a modified form of consent for long term multi-transfused patients', 'Patients who have received a blood transfusion and who were not able to give valid consent prior to the transfusion should be provided with information retrospectively',* and *'There should be a standardised source of information for patients who may receive a transfusion in the UK'*.

781. Recommendations on governance included UK adoption of a consent standard developed by Health Improvement Scotland, conducting a national audit of transfusion consent through the Royal College of

Physicians National Comparative Audit programme, and involvement of patient groups in providing oversight.

782. Recommendations on education included *'UK Blood Services should have an ongoing programme for educating patients and the public about blood transfusion as part of their respective 'Better Blood Transfusion' strategies*', as well as e-learning packages for all staff involved in the transfusion process and in undergraduate curricula.

783. Many of these recommendations, particularly on education, were already under development through the Better Blood Transfusion toolkit. This area is now covered in the Transfusion Practice section of the JPAC website http://www.transfusionguidelines.org.uk/transfusion-practice/consent-for-blood-transfusion.

784. On 17th December 2020, SaBTO published updated guidance, reinforcing the principles of the 2011 recommendations, and providing more specific actions to be taken in certain situations. In summary, they are:

"We recommend that:

i. Informed and valid consent for transfusion is completed for all patients who will likely, or definitely, receive a transfusion. These recommendations apply to transfusion of whole blood, red blood cells, platelets, fresh-frozen plasma (FFP), cryoprecipitate and granulocytes, as well as those who are exposed to blood or blood components. These recommendations also apply to where transfusion might occur during a procedure where the patient is incapacitated, for example, where blood is routinely requested prior to surgery or where a 'group and save' or 'cross-match' sample is taken pre-procedure. Such shared decision-making discussions should be documented in the patient's clinical record.

ii. Patients who have a been given a blood transfusion and were not able to give informed and valid consent prior to the transfusion

are informed of the transfusion prior to discharge and provided with relevant paper or electronic information.

iii. All patients who have received a transfusion have details of the transfusion (type[s] of component), together with any adverse events associated with the transfusion, included in their hospital discharge summary to ensure both the patient and their family doctor are aware. The patient should also be informed that they are no longer eligible to donate blood (with the exception of individuals who have received Convalescent Plasma from donating Convalescent Plasma to treat individuals with SARS-CoV-2).

iv. The UK Blood Services provide a standardised source of information for patients who may receive a blood transfusion in the UK.

v. Training in consent for transfusion is included in all relevant undergraduate healthcare practitioners training, followed by continuous, regular knowledge updates (minimum 3-yearly) for all healthcare practitioners involved in the consent for transfusion process.

vi. There is a centralised UK-wide information resource for healthcare practitioners to facilitate consent for transfusion discussions, indicating the key issues to be discussed when obtaining informed and valid consent for a blood transfusion, and providing up-to-date information on the risks of transfusion. This resource should be provided by the UK Blood Services. The feasibility of developing and maintaining this resource should be completed by the UK Blood Services within 6 months of the publication of these recommendations.

vii. All UK healthcare organisations who provide blood transfusions employ mechanisms (such as audit) to monitor the implementation and compliance with these SaBTO recommendations, with subsequent improvement plans developed and implemented if indicated'.

785. The summary also states, *'It should be noted that SaBTO is an independent advisory body. DHSC has not mandated the recommendations, and it is for the NHS and other UK healthcare bodies locally to decide on their implementation'.*

786. It is my view that providing information and informed consent for patients who will (or might) receive blood components is an essential part of clinical care. The NHS is obviously under huge pressure, but I would not like this precious issue to be lost in the coming years. Our patients deserve nothing less.

(2) Consent for clinical trials in transfusion

787. During the 1990s, it became clear that there was probably overuse of blood components and that prescribing them only when appropriate was going to be an important plank in the safety measures taken to minimise the risk of vCJD.

788. Since blood components are not licensed medicines, however, there has never been a regulatory requirement to conduct clinical trials on either their safety or effectiveness in improving the patient's outcome. This meant that there had been relatively few high-quality trials of blood components, making it difficult to produce definitive recommendations for their use.

789. In the 1990s, Professor Mike Murphy and I made a successful bid to establish a Clinical Studies Unit for the NBS, which was strongly supported by Professor Marcela Contreras, then the national Director of Diagnostics, Development and Research. To ensure that this unit was established and run to the highest standards, we were able to establish a partnership with the MRC Clinical Trials Unit in London. At some point, the (by then) NHSBT Clinical Studies Unit (CSU) became registered in its own right.

790. Although there were no specific regulatory requirements covering trials in blood components, we aimed as far as sensibly possible to work to the Good Clinical Practice standards required for licensed medicines. Patient consent for trials is required under the Declaration of Helsinki, the first version of which was published in 1964, and which has been updated

seven times since, the most recent update being in 2013. We, therefore, incorporated patient information and written consent into our standard operating procedures from the outset.

791. I can therefore provide assurance to the Inquiry that all clinical trials conducted by the CSU have been carried out with Ethics Committee permission and with the written consent of the patient, obtained after providing full information about the trial. The patient information leaflet also has to be approved by the Ethics Committee as part of their approval process. Written consent was always obtained, even when the intervention under investigation was 'no transfusion', in settings where the giving of a transfusion was standard practice (Exhibit WITN0643049).

792. I was involved in several studies in patients before the establishment of the CSU, covering leucocyte depletion (Exhibit WITN0643016) SDFFP (Exhibit WITN0643019 and WITN0643020), and transmission of hepatitis B (NHBT0000112_034). Again, all these studies were performed with Ethics Approval and written patient consent.

793. Similarly, studies of infectious disease markers in donors (refs 10, 15 and 36) were covered by the standard donor consent procedures in place when the studies were performed.

Personal remarks

794. Providing evidence for the Inquiry has caused me to reflect a great deal on this dreadful tragedy, so I have begun my statement (in section 1) with some thoughts of my own, which I hope convey my personal reactions, thoughts and hopes for the Inquiry's work and those who have been affected by it.

Statement of Truth

I believe that the facts stated in this witness statement are true.

Signed GRO-C

Dated 21st November 2021

Table of exhibits:

Date	Notes/ Description	Exhibit number
N/A	CV of Dr Lorna Williamson	WITN0643011
N/A	List of publications	WITN0643012
01/01/2015	A clinical governance framework for blood services' by L.M. Williamson, R.J. Benjamin, D.V. Devine, L.M. Katz, J. Pink	WITN0672072
07/05/1994	British Medical Journal, Vol 308, 1994, 'Errors in blood transfusion in Britain: survey of hospital haematology departments' by D. McClelland and P. Phillips. Contains survey responses from 245 hospitals which suggests that the lack of a centralised system for collecting data means failures go unrecorded. Includes a table on the number of incidents.	NHBT0000032_001
05/2012	Scully M et al., Diagnosis and Management of TTP and other thrombotic	WITN0643013

Signed _____

Dated _____

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05/2012	Scully M et al., Diagnosis and Management of TTP and other thrombotic microangiopathies	WITN0643013
26/02/1997	Minutes of the Anti-HBc Screening Project Study Group Meeting 26 February 1997.	NHBT0042349
2002	Cardigan R et al Levels of von Willebrand	WITN0643014

	factor cleaving protease are normal in methylene blue treated plasma.	
09/2003	Garwood M et al The effect of methylene blue photoinactivation and methylene blue removal on the quality of fresh frozen plasma.	WITN0643015
01/01/2015	Journal Article titled 'A clinical governance framework for blood services' by L.M. Williamson, R.J. Benjamin, D.V. Devine, L.M. Katz, J. Pink and for the Alliance of Blood Operators Medical Directors Group	TSTC0000047
29/09/1994	Minutes of Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation 3rd meeting, 29 September 1994.	PRSE0000189
13/10/1995	Minutes of Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation, 13 October 1995.	PRSE0004758
26/08/1998	Leucodepletion Newsletter, from the National Blood Service, regarding updates and progress so far as the implementation of the Leucodepletion Programme continues.	NHBT0010585_002
01/03/2000	Witness statement of Dr Lorna Williamson provided as part of the Hepatitis C litigation, A and Other and The National Blood Authority re: methods of virus inactivation of fresh frozen plasma, solvent detergent treatment and methylene blue photochemical inactivation.	NHBT0000026_009

02/06/1993	Minutes of the BTS Executive Meeting, 24th May, 1993.	NHBT0041409_002
27/07/1993	Minutes of the BTS executive meeting, 26 July 1993. Attendees: Dr. McDougall, Dr. Williamson, Dr. Caffrey	NHBT0041398
30/11/1992	'- Agenda for Executive Committee meeting on 7 December 1992 - Minutes of BTS Executive meeting, 30 November 1992.	NHBT0035813
11/12/1996	Memorandum from Dr J S Metters to Dr A Wight, re: framework proposal to SEAC on experimental approaches to the transmissibility of TSE by blood and the effect of leucodepletion	DHSC0004239_017
21/07/1997	Letter from Dr. Lorna Williamson to Dr. W. M. McClelland, Northern Ireland Blood Transfusion Service re: Solvent Detergent FFP	NHBT0041413
24/11/1995	Letter from Alan Slopecki and Kate Soldan to Dr L Williamson re: NBA/PHLS-CDSC surveillance of transfusion transmissible infections.	NHBT0041418
10/11/1997	Notes on NBA Virally Inactivated FFP Group: Watford 7-11-97.	NHBT0006237
14/03/1991	Notes of the management group meeting, 11 March 1991.	NHBT0041282_003
05/1994	Williamson et al. Bedside filtration of blood products in the prevention of HLA alloimmunisation	WITN0643016
07/2002	Pennington et al Persistence of HTLV in blood donations after leucocyte depletion	WITN0643017
02/2004	Visconti MR et al Assessment of removal of human cytomegalovirus from blood	WITN0643018

	components by leukocyte depletion filters using real-time quantitative PCR.pdf	
15/05/1989	Internal Departmental Memorandum of the National Blood Transfusion Service (NBTS) from Mr Howell to Mrs Poole et al. regarding Re-introduction of the 'J' donor system.	NHBT0005103_009
1999	Evans G et al Solvent/detergent fresh frozen plasma as primary treatment of acute thrombotic thrombocytopenic purpura.	WITN0643019
12/1999	Williamson LM, et al A randomised trial of SDFFP	WITN0643020
08/2007	Williamson et al 2007 Universal leucocyte depletion and PTP etc	WITN0643021
03/2009	Chapman et al 2009 Haemovigilance reports of TRALI	WITN0643022
08/02/1996	Guidelines, on Gamma irradiation of blood components for the prevention of transfusion- associated graft- versus-host disease, by BCSH Blood Transfusion Task Force (Chairman: D. Voak), 21/12/1995, published on 08/02/1996.	BSHA0000003_023
21/10/1996	Letter from Dr E Angela E Robinson, National Blood Service, to Dr Luc Noel, Centre de Transfusion des Yvelines. Re: info about the "SHOT initiative"	NHBT0007051_004
31/07/1991	NOTES OF THE EXECUTIVE COMMITTEE MEETING Monday, 29 July 1991 Present: Dr McDougall Dr Ouwehand Dr Williamson Mr Hawdon Apologies: Professor J P Allain	NHBT0041285_004

10/10/1990	'- Agenda items of Management Group Meeting as well as minutes of the meeting. - Minutes of Management Group meeting, Wednesday 10 October 1990.	NHBT0041230_001
10/06/1991	Minutes of Executive meeting on 10 June 1991.	NHBT0041234_002
1/11/1997	November 1997 SACTTI Update (Standing Advisory Committee on Transfusion Transmitted Infection)	NHBT0008628_001
15/12/1999	Minutes of UKBTS/NIBSC Standing Advisory Committee on Blood Components (SACBC) Meeting on 15 December 1999 at West End Donor Centre, London. HCV, NAT.	NHBT0002534
20/05/1991	Minutes of the Executive meeting, 20 May 1991.	NHBT0041235
18/02/1991	Notes of a Management Group Meeting held on 18 February 1991. Chair: Dr. McDougall, Attendees: Dr Williamson, Mr Hawdon, Dr Rankin	NHBT0041284
02/05/1996	Minutes of Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation meeting, 2 May 1996.	SBTS0000516_001
18/08/1993	Minutes of the BTS Executive Meeting, 16 august 1993.	NHBT0041396
12/08/1994	Agenda for meeting of the executive committee on 15 August 1994 followed by minutes with actions	NHBT0037680
04/03/1991	Notes on the Management Group Meeting, 4 March 1991.	NHBT0041283_002
14/05/1992	Notes of the Executive Committee Meeting, 11th May 1992.	NHBT0035847

07/02/2001	Briefing Paper from Lorna Williamson to Dr Virge James, for the next Joint Executive Liaison Committee meeting on 14 February 2001.	NHBT0003342
29/03/2001	Report from Serious Hazards of Transfusion (SHOT), re: Annual Report 1999 - 2000.	NHBT0057426_002
23/10/1992	Agenda and minutes of the BTS Executive meeting on Monday 12 October 1992.	NHBT0035837
09/07/1993	Minutes of the Executive Meeting on 5th July 1993.	NHBT0041403
01/03/1981	Minutes of the second meeting of the Advisory Committee on the National Blood Transfusion Service.	CBLA0001287
26/09/1994	Meeting minutes of the Executive Committee.	NHBT0035861
14/08/1992	Agenda of the Executive Committee Meeting held in the Committee Room on Monday, 17 August 1992; and Minutes of the BTS Executive Meeting 10 August 1992	NHBT0035842
22/09/1997	Email from Carol Holmes to number of recipients re NBS/Octapharma mtg	NHBT0001565
10/11/1994	Discussion paper by Dr JD Cash on HCV Lookback titled "Recommendations of the Standing Advisory Committee on Transfusion-Transmitted Infection to the MSBT Concerning the Merits of Adopting an HCV Look-Back Policy". Concludes that there is "a serious case for considering a look-back policy for HCV".	NHBT0118144
22/04/1998	Minutes of UK/BTS/NIBSC Standing	NHBT0042773

	Advisory Committee on Blood Components, 22th April 1998	
18/03/1998	Serious Hazards of Transfusion (SHOT) Annual Report, 1996-1997, by Dr. L.M. Williamson, S. Lowe, Dr. E. Love, Dr. H. Cohen, K. Soldan, Dr. D.B.L. McClelland, Dr. P. Skacel and Dr. J.A.J. Barbara	NHBT0057381_004
15/12/2000	National Blood Service, Safer Plasma in Components, Phase 1 : Evaluation and Feasibility Study, Stage 1: Frozen Plasma Components - Section 4: Methylene Blue Feasibility and Pilot Study	NHBT0016087
09/01/1992	Minutes of the Eastern Division meeting, 09 January 1992 at the North London BTS Colindale.	NHBT0097463_001
14/08/1991	Minutes of the meeting of the Eastern Division consultants held at Cambridge BTC on 14 August 1991.	NHBT0097468_001
31/01/1991	Minutes of Eastern Division of Consultants in Blood Transfusion meeting, 31 January 1991 at Royal Free London Hospital UK.	NHBT0097469_018
11/03/1991	Minutes of Eastern Division Meeting, 11 April 1991 at the South London Regional Transfusion Centre.	NHBT0097471_029
10/09/1998	Minute of UKBTS/NIBSC, standing advisory committee on blood components meeting, 10/09/1998 at SNBTS PFC Edinburgh.	NHBT0097472_009
28/02/1996	Minutes of the Anti-HBc Screening Project Study Group, 28/02/1996.	NHBT0097473_029
09/04/2002	Serious Hazards of Transfusion (SHOT) Annual Report, 2000-2001, by D. Asher	SBTS0000523

	et al. on behalf of the SHOT Steering Group	
20/09/1995	Letter from Dr. E. Angela Robinson, National Blood Service (NBS) to Dr. Jeremy Metters, Department of Health (DOH), re: relationship of Standing Advisory Committee on Transfusion Transmitted Infections (SACTTI) to the UK Transfusion Services .	DHSC0006195_003
28/09/2000	Email from Charles Lister to Mike McGovern, re: Octapharma's press release on FFP/Octaplas,with a reminder to the Department that Octapharma are ready to supply the NHS need for FFP	DHSC0014973_005
27/11/1992	Minutes of a meeting of medical consultants and business managers from the North East Thames BTS on Tuesday, 3rd November 1992 at the Brentwood Centre.	NHBT0002418_003
25/02/2010	Journal of Haemophilia, "Variant CJD infection in the spleen of a neurologically asymptomatic UK adult patient with haemophilia", by A. Peden, et al. 2010	DHSC0038559_047
2/10/1997	Transmissions to mice indicate that 'new variant' CJD is caused by the BSE agent, M. E. Bruce, R. G. Will, J. W. Ironside, I. McConnell, D. Drummond, A. Suttie, L. McCardle, A. Chree, J. Hope, C. Birkett, S. Cousens, H. Fraser & C. J. Bostock	DHSC0004026_032
13/09/1983	Results of telephoned survey conducted by East of Scotland Blood Transfusion Service regarding use of prisons as a source of donor blood at English and	NHBT0008129

	Welsh Regional Transfusion Centres. Refers to a meeting of Scottish Transfusion Directors on 13 September 1983.	
22/12/1995	Letter from Dr Lorna Williamson to Dr Julia Heptonstall, PHLS, regarding setting up a national system for reporting serious complications of blood transfusion.	NHBT0007853_001
21/12/1994	Minutes of the first meeting of the Serious Hazards of Transfusion Working Group on 21 December 1994 at NBA Headquarters, Watford.	NHBT0007848_002
26/1/1995	A summary from Dr. Hewitt to Dr. Lorna Williamson (Cambridge) ,Dr. Angela Gorman (Brentwood), Dr.Sue Knowles,(STBTS); RE: Anti-HCV Look-back	NHBT0019435_010
19/04/2001	Summary of The Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation meeting, 19 April 2001, with paper on 'Notes to Editors', attached.	NHBT0007858_002
23/11/1995	Serious Hazards of Transfusion Working Party- Funding Proposal.	NHBT0017300
08/05/1996	Minutes of Meeting, Serious Hazards of Transfusion Steering Group, 8 May 1996 at St. Mary's Hospital, London.	NHBT0017298_001
04/07/2011	Email from Gemma Lovell (Penrose Inquiry) to (redacted) regarding the task of identifying former NBTS employees to provide statements to the Inquiry, dated 4th July 2011	NHBT0118019
12/09/1994	Recommendations of the Standing	NHBT0085385

	Advisory Committee on Transfusion-Transmitted Infection to the MSBT Concerning the Merits of Adopting an HCV "Look-Back" Policy, by Dr F. A. Ala, 1994	
28/04/1999	Minutes for the Serious Hazards of Transfusion National Steering Group meeting, 18 Janaury 1999 at the Royal College of Pathologists.	NHBT0085384
28/04/1999	Minutes of SHOT Standing Working Group, meeting number [unknown], 28th April 1999 at University College Hospital.	NHBT0085383
26/11/1992	Minutes of the Eastern Division meeting on 26 November 1992 at Cambridge BTS.	NHBT0085386
1996	Williamson et al A SHOT in the arm for safer blood transfusion. A new surveillance system for transfusion hazards	WITN0643051
23/01/1992	Preliminary Discussion Paper for ACTTD: Two topics related to transfusion safety by Dr Marcela Contreras and Dr John Barbara (North London Blood Transfusion Service).	NHBT0000037_022
27/05/1999	Minutes of the Shot Standing Working Group meeting, 27 May 1999 at University College Hospital.	NHBT0077594_005
01/10/2002	Written Statement, re: United Kingdom Blood Transfusion Services Position Statement: Creutzfeldt-Jakob Disease, by the vCJD Working Party of the Standing Advisory Committee on Transfusion Transmitted Infections, 2002.	NHBT0007367

17/07/2003	SHOT (Serious Hazards of Transfusion) Summary of Annual Report 2001-2002 (Published 17th July 2003). Report by D. Stainsby, H. Cohen, H. Jones, A. Todd, S Knowles, C Taylor, C. Beatty, K. Davison, J. Revill, D.R Norfolk. Discusses the key observations and recommendations.	NHBT0057437_001
28/10/2021	Written Statement of Dr Lorna Williamson	SHOT0000020
01/03/1995	Application to the Local Research Ethics Committee. The relevant applicant is Dr Lorna Williamson.	NHBT0040229_001
17/07/2003	Report from D. Stainsby, H. Cohen, H. Jones, A. Todd, S Knowles, C Taylor, C. Beatty, K. Davison, J. Revill, D.R Norfolk, Serious Hazards of Transfusion (SHOT), re: Annual Report 2001 - 2002.	NHBT0057438_002
12/06/1998	Minutes of UKBTS/NIBSC Standing Advisory Committee 5th meeting, 12 June 1998 at Royal College of Pathologists London Hospital UK.	NHBT0057439_001
15/10/2001	Minutes of NBS vCJD 'Steering Group', on 15/10/2001 at West End Donor Centre.	NHBT0057439_002
01/04/2014	House of Commons Science and Technology Committee Oral evidence regarding the risk of prion transmission	SHOT0000016
1999	Williamson et al. The Serious Hazards of Transfusion (SHOT) Initiative – Analysis of the First Two Annual Reports	WITN0643052
01/01/1999	Guidelines on 'The Administration of Blood and Blood Components and the Management of Transfused Patients', M. F. Murphy, et al., 1999.	AHCH0000049

05/05/1999	UKBTS/NIBSC Standing Advisory Committee on SACTTI meeting minutes held on 5 May 1999 at the North London Centre.	NHBT0017307_001
18/9/1995	Minutes of the fifth meeting of the Serious Hazards of Transfusion Working Group, on 12th July 1995 at the West End Donor Centre.	NHBT0007856
28/06/1999	Minutes of meeting of Serious Hazards of Transfusion National Steering Group, on 28 June 1999 at The Royal College.	NHBT0062177_001
22/1/2001	Minutes of Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation meeting at Wellington House, 22 January 2001.	DHSC0006906_013
19/10/1994	Minutes of the UK BTS/NIBSC Standing Advisory Committee on Transfusion Transmitted Infections meeting on 19 October 1994.	NHBT0000088_006
13/02/1995	Minutes of UK BTS/NIBSC Standing Advisory Committee on Transfusion Transmitted Infection (SACTTI) held on 13 February 1995 at Colindale.	NHBT0000088_008
12/06/1995	Minutes of UK BTS/NIBSC Standing Advisory Committee on Transfusion Transmitted Infections (ACTTI) Meeting on 12 June 1995, at WMBTC, Birmingham.	NHBT0000088_009
15/11/1995	Minutes of UK BTS/NIBSC Standing Advisory Committee on Transfusion Transmitted Infections (ACTTI), held on 18 October 1995, at NLBTC Colindale.	NHBT0000088_010
18/2/1997	Minutes of UK BTS/NIBSC Standing	NHBT0000088_013

	Advisory Committee on Transfusion Transmitted Infections Meeting on 30 January 1997, at North London Blood Centre.	
16/5/1997	Meeting minutes of UK BTS/NIBSC Standing Advisory Committee on Transfusion Transmitted Infections (SACTTI) held on 14 May 1997 at North London Centre.	NHBT0000088_016
29/09/1998	Minutes of UK BTS/NIBSC Standing Advisory Committee on Transfusion Transmitted Infections (SACTTI), meeting on 29 September 1998, at North London Centre.	NHBT0000088_022
29/09/1998	Article from British Journal of Haematology, 'Evidence that anti-HBc but not HBV DNA testing may prevent some HBV transmission by transfusion'.	NHBT0000088_023
20/08/1997	Letter from Dr Lorna Williamson to Dr A Yardumian re Viral Inactivated Solvent Detergent Treated Fresh Frozen Plasma	NHBT0001972
14/07/2003	Email from J .Taylor to A. Robinson attaching Minutes of Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation Meeting on 10 June 2003 at Skipton House.	NHBT0005590
02/02/1990	Report, "The East Anglian BTS, towards the year 2000, a personal view", by Willem H. Ouwehand, February 1990.	NHBT0009458_002
07/07/1997	Minutes of UKBTS/NIBSC Executive Committee Meeting.	NHBT0010921
18/01/1995	Letter from Dr. E. Angela Robinson (Medical Director, National Blood	NHBT0010970

	Authority) to Dr. Jean F. Harrison (Medical Director, North East Thames RHA); re: HCV Look Back - action to be undertaken by RTC, including attachment of actions to be undertaken.	
26/10/1996	Minutes of the meeting of Serious Hazards of Transfusion (SHOT) Executive Group Meeting, 30 August 1996 at the West End Donor Centre	NHBT0017284
16/07/1997	Minutes for meeting on Implementation of Solvent/Detergent FFP Group, 16th July 1997, Copenhagen	NHBT0000236_024
25/07/1995	Minutes of the fourth meeting of the Serious Hazards of Transfusion Working Group, on 12th July 1995 at the West End Donor Centre.	NHBT0017405_001
09/05/1995	Letter from Dr L. M. Williamson, National Blood Transfusion Service, to Dr A. Robinson, National Blood Authority, re: HCV Look Back. Dr Williamson asks for clarification on how important it is that the cause of death be notified on all HCV Look back forms.	NHBT0005734
10/05/1993	Minutes of the UK Advisory Committee on Transfusion Transmitted Diseases sixteenth meeting on Tuesday 20 April 1993 at NLBTC.	JPAC0000029_158
02/04/2001	Minutes of the second meeting of the NBS vCJD Steering Group, held 2nd April 2001, at the Oak House.	NHBT0059328
15/12/1999	Minutes of UK Blood Transfusion Service (UKBTS)/National Institute for Biological Standards and Control (NIBSC) Standing	JPAC0000026_144

	Advisory Committee on Blood Components Meeting, at West End Donor Centre, 15 December 1999.	
26/11/2001	Joint meeting of the UKBTS/NIBSC Standing Advisory Committee on Blood Components and Transfusion Transmitted Infections, held at the University of Manchester on 26 November 2001.	JPAC0000028_170
15/09/1999	Minutes of UKBTS/NIBSC Standing Advisory Committee on Blood Components meeting, 15 September 1999 at Blood Transfusion Service, Edinburgh.	NHBT0002620
18/01/1995	Sample letter from Dr E Angela Robinson to multiple recipients re HCV Look Back. Document titled 'HCV Look Back - Action by RTC'. Provides definitive version of guidance of the steps to be taken by Regional Transfusion Centres in relation to the tracing of recipients of blood donated by HCV antibody positive donors.	NHBT0002642
12/12/1997	Minutes of the UKBTS/NIBSC Standing Advisory Committee on Blood Components meeting, held on 12 December 1997, Newcastle Blood Centre.	NHBT0010943
19/10/1994	Minutes of UKBTS/NIBSC Standing Advisory Committee on Transfusion Transmitted Infections (SCTTI) on 19th October 1994 at Birmingham.	NHBT0010964
03/03/1995	Minutes of SACTTI special meeting held	NHBT0016319_001

	on 3 March 1995 at Birmingham BTS.	
26/11/2001	Joint Meeting Of The UKBTS/NIBSC Standing Advisory Committee On Blood Components And Transfusion Transmitted Infections University Of Manchester, 26 November 2001.	NHBT0041167_002
12/11/2001	UKBTS/NIBSC Standing advisory committee on blood components.	NHBT0041167_005
20/03/2000	UKBTS/NIBSC Standing advisory committee on blood components.	NHBT0041167_020
10/06/1999	Minutes of the UKBTS/NIBSC Standing Advisory committee on Blood Components meeting, 10 June 1999, West End Donor Centre London; re: blood preparation and blood bags. Chairperson: Dr. L. Williamson. Secretary: M Bruce. Attendees: Dr. K. Forman, P. Garwood, Dr. P. Metcalfe, Dr. D. Pamphilon and Dr. C. V. Prowse.	NHBT0041168
20/03/1999	Minutes of a Meeting of Standing Advisory Committee on Blood Components, held on 10011/03/1999 at Newcastle Blood Centre. Matters covered included: Leucocyte Depletion; New Proposals for Component Base Levels; Re-Issue of Blood Components; Issue of Untested Granulocytes; CMV Testing of Skin Donors.	NHBT0041172
12/2/1991	Notes marked: 'Gulf Crisis' and 'Anti-HCV testing'. Notes of a Management Group Meeting, 11 February 1991, [unknown location]; re: gulf crisis and anti-HCV testing. Chairperson: Dr. McDougall.	NHBT0041173_001

	Attendees: Dr. Ouwehand, Dr. Williamson, Mr Hawdon and Dr. Rankin.	
07/01/1991	Minutes of a Management Group Meeting held on 07/01/1991. Present: Dr McDougall (Chairman), Dr Ouwehand, Dr Williamson, Mr Hawdon.	NHBT0041174_001
12/11/1998	Minutes of Universal Leucodepletion Programme Implementation Board Meeting, Thursday 12 November 1998 as a video conference.	NHBT0043199
18/1/1996	Minutes of Anti-HBc screening Project Study Group meeting held 17th January 1996.	NHBT0098059_0030
7/04/2000	Serious Hazards of Transfusion (SHOT), Annual Report, 1998-1999, by E. M. Love et al. on behalf of the SHOT Steering Group	NHBT0040170
09/2003	Williamson LM, Cardigan R, Prowse CV. Methylene blue treated fresh frozen plasma. Invited editorial	WITN0643023
14/01/1994	Minutes of the BTS Executive Meeting, 10th January, 1994, re: matters arising, TRACT Consortium, Purchaser Contracts, Returns of blood from sessions, annual report, donor questionnaire. Present: Dr. McDougall, Dr. Ouwehand, Dr. Williamson, Dr. Caffrey, Mr. Hawdon	NHBT0041286_003
17/05/2002	Minutes of Joint Meeting of the UKBTS/NBSC Standing Advisory Committee on Blood Components and Care and Selection of Donors, MRC Clinical Trials Unit, 17/05/2002.	NHBT004103

20/09/1993	Minutes of the BTS Executive meeting, 20 September 1993 at location unspecified. re: Brentwood Collaborations; NBA RTDs/Chief Executive Meeting.	NHBT0041354
29/01/1992	Minutes from the Executive Committee meeting on 27/01/1992 (page 2 - 6).	NHBT0035853
04/2004	Malfroy M, Using patient identifiable data for epidemiological research: problems and pitfalls	WITN0643024
04/2009	Llewelyn CA et al The EASTR study: a new approach to determine the reasons for transfusion in epidemiological studies	WITN0643025
11/2009	Wells AW et al The EASTR study: Indications for transfusion and estimates of transfusion recipient numbers in hospitals supplied by the National Blood Service.	WITN0643026
04/2016	Morley SL et al. Transfusion in adults 10 year survival of red cell, plasma and platelet recipients	WITN0643027
03/2016	Morley SL et al. Transfusion in children epidemiology and 10 survival of transfusion recipients	WITN0643028
06/11/1989	Minutes of Advisory Committee on the Virological Safety of Blood 4th meeting, 6 November 1989.	NHBT0004742_001
27/05/1997	Minutes of Anti-HBc Screening Projects Study Group Meeting, 21 May 1997 at EABC, re: Archive samples, Update on EABC Results, Presentation of Results and any other business. Attendees: Jean-Pierre Allain, Dr. Pat Hewitt, David	NHBT0041996_001

	Howell, Chris Parkhouse, Una Whicheloe and Dr. Lorna Williamson	
14/05/1996	Minutes of Standing Advisory Committee on Transfusion Transmitted Infection (SACTTI) Special Meeting to Consider HTLV and Blood Transfusion on 14 May 1996, at Leeds Blood Centre.	NHBT0005388
30/05/1995	Allain et al 1995, Feasibility and usefulness of an efficient anti-HBc screening programme in blood donors	WITN0643030
01/09/1989	Letter from H.H Gunson, National Director, National Blood Transfusion Service to Mr A Follet, Ortho Diagnostic Systems Limited regarding demonstrations to RTCs. Re: he had spoken to Dr.Robinson (Leeds), Dr. Ala (Birmingham) and Dr. Hewitt (N.London, Colindale) and they would welcome hosting Mr Follett's demonstration during the week commencing Monday 25th September 1989.	NHBT0000112_034
09/03/1999	Serious Hazards of Transfusion (SHOT) Annual Report, 1997-1998, by L. M. Williamson et al. on behalf of the SHOT Steering Group	SBTS0001120
07/07/1997	Minutes of "UK BTS/NIBSC Standing Advisory Committee on Blood Components". RE: - Virus inactivated plasma (VIP) - Solvent detergent (SD) treated plasma - Methylene blue (MB) treated plasma - Protocol for the evaluation of FFP and cyro - Preparation for review of quality monitoring -	NHBT0010936

	Accredited donor status; FFP/CRYO - Nucleic acid testing	
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	WITN0643031
14/6/1992	Agreement with Octapharma	BPLL0002893
12/03/1992	Letter from Dr Lorna Williamson to Dr Richard Lane, Bio Products Laboratory (BPL) et al., re. Solvent detergent FFP and the output of the participating centres.	BPLL0003377_002
03/06/1999	Minutes of Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation meeting, 3 June 1999.	NHBT0003749
10/03/1992	Application submitted by Professor Jean-Pierre Allain to the District Ethical Committee, for a Clinical Study of Solvent Detergent Treated Fresh Frozen Plasma.	NHBT0003745_001
01/11/1997	Information pages re: New Variant Creutzfeldt-Jakob Disease, by Pauline Banks, November 1997. Screening tests.	NHBT0000946
26/05/1992	Letter from Dr C. Prowse of the Scottish National Blood Transfusion Service to Dr R. Lane of Bio Products Laboratory re Virally Inactivated Plasma	BPLL0003518
10/07/1992	Letter from Dr Lorna Williamson to Dr Richard Lane, BPL, re. final version of the Clinical Protocol for the SD FFP Study.	BPLL0003548
24/11/1993	Letter from Dr Richard Lane to Dr Lorna Williamson re Octaplas CTX Application.	BPLL0003359
20/09/2005	Minutes of SACTTI Working Group on	JPAC0000036_104

	vCJD Prion Reduction Filter Efficacy Sub Group Meeting, 20 September 2005 at Postgraduate Education Centre, Royal Infirmary of Edinburgh.	
20/05/2003	Minutes of the UK BTS/NIBSC Standing Advisory Committee on Transfusion Transmitted Infections meeting, 20th May 2003 via video conference at Edinburgh, Manchester and Watford.	JPAC0000109_025
19/05/1998	Minutes of UK BTS/NIBSC Standing Advisory Committee on Transfusion Transmitted Infections (SACTTI) held on 19 May 1998 at North London Centre.	NHBT0000088_018
10/9/1996	Reports, "Provisional estimation of the risk of HIV, HCV and HBV infection in tested blood donations from repeat donors", by Kate Soldan; "NBA Octaplas Trial - Status as at 30th September 1996", by L. Williamson; and "Octaplas Data".	NHBT0006016
17/06/1998	Notes on the Annual Consultant's meeting on the 17 June 1998 in Birmingham - Feedback from 'Blood Matters'. The document addresses issues such as NBS finances, vCJD, and leucodepletion of blood.	NHBT0007035
18/05/1997	Minutes of the First Meeting, Implementation of Solvent/Detergent Fresh Frozen Plasma, 18th May 1997	NHBT0000723_001
15/09/1999	Minutes of the Universal Leucodepletion Programme Implementation Board Meeting on Wednesday, 14 July 1999 at the Postgraduate Medical Centre, Queen	NHBT0000723_004

	Elizabeth Hospital. Attendees include Alan Slopecki, Tim Wallington, Richard Bedford, Lorna Williamson, Peter Garwood, Neil Beckman, Terry Male, Angela Robinson and Steve Morgan	
12/02/2001	Meeting Minutes of the NBS vCJD Steering Group, regarding the terms of reference for the NBS vCJD Steering Group,' actions to minimise the risk that vCJD could be transmitted by transfusion, discussions with various sub-groups and discussions with other UK Blood Services.	NHBT0002083
15/09/1997	With Compliments Note from Dr. L. Williamson, University of Cambridge et al, to Dr. A. Robinson, re: Attached Letter, with letter (dated 15/09/1997) from Dr. L. Williamson, to Dr. C. A. Ludlam, The Royal Infirmary of Edinburgh, re: Solvent Detergent Fresh Frozen Plasma (Octaplas), attached. Enclosed information package, and product information sheet, and paper by Inbal et al, not found.	NHBT0001703
09/08/1994	Minutes of Ad Hoc Assembly to Consider the Merits of an HCV "Look-Back" Policy, held 5 August 1994 at West Midlands BTS Centre. Dr Ala was the Chair and attendees included Drs Barbara,Hewitt, Martlew, Robinson and Gillon along with Professors Cash, Tedder and Williamson.	NHBT0009347
31/01/2000	Journal of Haematology, "Coagulation factor content of cryoprecipitate prepared	NHBT0041966_009

	from methylene blue plus light virus-inactivated plasma", by Hornsey S. V., Krailadsiri P., MacDonald S., Seghatchian J., Williamson M. L., Prowse V. C., 2000	
16/11/2001	Meeting Minutes of the Blood and Tissue Safety Assurance Group Meeting, regarding HTVL testing, a vCJD Clinical Incident Panel, the suitability of plasma from mainland Europe, the Paul Ehrlich Institute vCJD risk analysis, and the exclusion of previously transfused donors.	NHBT0001709
2004	British Journal of Haematology, "Guidelines for the use of fresh-frozen plasma, cryoprecipitate and cryosupernatant", British Committee for Standards in Haematology, Blood Transfusion Task Force (J. Duguide et al.) 2004	BSHA0000045_001
31/01/2006	O'Shaugnessy D. www.dh.gov.uk Gateway ref 5999	WITN0643032
09/05/1997	Second draft of an information Sheet for Hospitals on Fresh Frozen Plasma, covering content of FFP, donor selection and testing, infectious risks and other side effects.	NHBT0009329
25/07/1990	Inspection Report, East Anglia Regional Transfusion Centre, 1990. Re: progress since previous inspection in 1988	NHBT0006031_001
12/10/1995	Fax from Keith Lawson to Dr A Robinson re: Octaplas (SD FFP) v Standard FFP Study Suspension	NHBT0009305
08/01/1996	Minutes of advisory committee on the	DHSC0017165

	microbiological safety of blood and tissues for transplantation (MSBT), on 8 January 1996.	
06/08/1997	Email from Lorna Williamson to David Wesley, Terry Snape, Barry Savery, Sue WIlliamson re Minutes of contract meeting with Octapharma 06/08/1997.	NHBT0002075
01/11/1997	Report from PD Minor and L Williamson, Standing Advisory Committee on Transfusion Transmitted Infection (SACTTI), entitled 'a framework proposal to SEAC on experimental approaches to the transmissibility of TSE by blood, and the effect of leucodepletion.'	NHBT0004564
01/10/1997	Report from Peter Flanagan, Brian McClelland and Lorna Williamson, entitled 'an assessment of strategies, including leucocyte depletion, to minimise the risk of transmission of new variant CJD by transmission.' Encloses three appendices	NHBT0004510
02/10/1997	Journal of Nature, Scientific correspondence, " The same prion strain causes vCJD and BSE" by Andrew F.Hill, Melanie Desbruslais, Susan Joiner, Katie C.L.Sidle, Ian Gowland, John Collinge, Prion Disease Group, Neurogenetics Unit, Imperial College School of Medicine at St Mary's, October 1997	DHNI0000041_123
13/01/1993	Letter from R. W. Carrell, University of Cambridge to R. Jefford, Cambridge Health Authority (CHA), re: comment on Professor Allain's performance in his post	DHSC0004125_011

	as Director of the Regional Transfusion Centre	
17/12/1998	Minutes of UKBTS/NIBSC Joint Meeting of the standing advisory committees on blood components and transfusion transmitted infections held on 17/12/1998.	NHBT0016299_001
10/10/1989	Report from H.H. Gunson outlining UK Advisory Committee on Transfusion Transmitted Diseases' (UKACTTD) position on anti-HCV testing and surrogate testing.	NHBT0000188_039
19/12/1994	Letter from Dr. Lorna Williamson, National Blood Transfusion Service (NBTS) to Dr. Angela Robinson, National Blood Authority (NBA), cc A. Slopecki, Dr. John Barbara, and David Wenham, re divergence in policy between SNBTS and NBTS as to handling of donors and donations likely to give repeatedly reactive results during Prism evaluation particularly for hepatitis B	NHBT0007771_001
10/02/1995	Minutes of the second meeting of the Serious Hazards of Transfusion Working Group on 8 February 1995 at West End Donor Centre. Chair: Dr Lorna Williamson. Attendees: Professor A. Waters, Dr Audrey Todd, Dr Angela Robinson, Dr Patricia Skacel, Dr A. Napier, Dr P. Mortimer	NHBT0007772_003
03/01/2000	Hepatitis Litigation (A and Ors.), Witness Statement of Harold Hastings Gunson, re: the organisation of the NBTS (1946-1993), the hepatitis C virus and its	NHBT0000015_106

	discovery, surrogate testing for hepatitis NANB and the introduction of the anti-HCV tests.	
08/01/1996	Minutes of Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation meeting, 8 January 1996.	PRSE0004824
10/11/1997	Document titled 'Universal Leucocyte Depletion' - Issues to Consider (and by whom) ' by Lorna Williamson. Discusses role of SAACTI, NBS, SACBC and Clinical Directors. Issues include methodologies, availability of equipment, logistics, quality control, Red Book component specifications, other testing programs and guidelines.	NHBT0008816_002
21/08/2006	Vox Sanguinis, "Creutzfeldt-Jakob disease and blood transfusion: results of the UK Transfusion Medicine Epidemiology Review study", by P.E. Hewitt, C.A. Llewelyn, J. Mackenzie, R.G. Will, 2006	MHRA0020214
02/03/1985	Article in the Lancet titled HTLV-III Antibody Screening of Blood Bank Donors	PRSE0003670
10/9/1996	'A Special Meeting of SACTTI to discuss Virally Safer Plasma' 10 September 1996. Discusses 'Virally inactivated FFP - A challenge to UK Transfusion Services' and 'Residual risk associated with tested frozen components'.	NHBT0000188_072
01/01/1997	Journal Article from D. M. Keeling et al, British Journal of Haematology, entitled	NHBT0005043

	'Cryoprecipitate prepared from plasma virally inactivated by the solvent detergent method.'	
02/07/1993	Minutes of BTS Executive meeting, 28 June 1993 at [location unspecified] re: BPL Products - HCV, Dr Williamson referred to recent correspondence from Dr Martlew and the press concerning blood products contaminated with the Hepatitis C virus, and questioned the action which should be taken to reassure hospitals and staff.	NHBT0041406_002
18/03/1991	Notes of management group meeting held on 18 Marc 1991. Chair: Dr McDougall, Attendees: Dr Williamson; Dr Ouwehand; Mr Hawdon; Dr Rankin.	NHBT0041278
03/12/1997	Minutes of meeting of National Blood Service Laucodepletion Steering Group, 3 December 1997, NBS Leucodepletion Project.	NHBT0045585
02/05/1991	Letter from Dr H L Lloyd to Dr H H Gunson, and Professor J D Cash, re: hepatitis C testing. Advises he has decided to commence testing by July 1, rather than the revised national date of September 1991. Expresses that his "personal view is that not to test now that we have the ability to test would be indefensible under the current Product Liability Legislation." Asks whether any Centre is carrying out any additional tests such as Hep B core, or ALT testing, and if so, which criteria are being used to select	NHBT0000073_065

	samples for testing.	
17/02/1994	Minutes of UK BTS/NIBSC Standing Advisory Committee on Transfusion Transmitted Infections (ACTTI) Meeting, 18 January 1994 at BLBTC, Colindale.	NHBT0000076_009
24/06/1991	Letter from H L Lloyd to Dr H HGunson re: Hepatitis C Testing. Concern that UK testing has not begun. Includes reference to the position internationally. Refers to reaction from other RTCs over decision to begin testing. Requests confirmation that staff will not be discriminated against for carrying out duties.	NHBT0000074_014
1996	Allain et al 1996 Anti hepatitis C screening	WITN0643029
10/04/1991	Notes on the Management Group Meeting, 8 April 1991; re: anti- HCV testing. Attendees: Pro. Allain, Dr. McDougall, Dr. Williamson, Dr. Ouwehand, Hawdon, Dr. Caffrey, Dr. Rankin and Dr. Voak.	NHBT0041277_002
15/03/1993	Agenda of a meeting of the Executive Committee, 15 march 1993. Minutes of the BTS Executive Meeting, 8 March 1993	NHBT0041410
29/10/1998	Minutes of the Advisory Committee on the Microbiological Safety of Blood and Tissue for Transplantation (MSBT) meeting, 29 October 1998.	DHSC0004026_032
03/04/1991	Letter from H. H. Gunson, National Blood Transfusion Service, to All RTDs - England and Wales, re: Anti-HCV Tests on Blood Donations.	NHBT0000044_095

21/03/1995	Memorandum from Dr. Sue Knowles, South Thames Blood Transfusion Service to Pat Hewitt, NLBTC, Lorna Williamson, Cambridge BTC, Angela Gorman, Brentwood BTC, Tony Martin, Tooting BTC re: HCV Look back - request for information on number of anti-HCV positive donors identified	NHBT0040583
24/08/2011	B4 - Email from Dr Lorna Willamson to Lovell G reference the Inquiry asking if she still needs evidence from Professor Barbara	PRSE0001236
25/03/1997	Minutes of Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation meeting, 25 March 1997.	NHBT0005879_017
12/06/1996	Minutes of UKBTS/NIBSC Standing Advisory Committee meeting, re: blood components evaluation of new fresh frozen plasma/cryoprecipitate components for transfusion	NHBT0039758_022
24/03/1995	Memorandum, from Dr. Sue Knowles, South Thames Blood Transfusion Service to Lorna Williamson - Cambridge BTC, Angela Gorman - Brentwood BTC and Sudha Young - Tooting BTC	NHBT0011115
22/10/2002	Minutes of Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation meeting, 22 October 2002 at Skipton House, UK.	NHBT0019915
18/09/1995	Letter, to Dr Pollock, East Anglian Blood Transfusion Centre, from Dr Angela Robinson re HCV Lookback Programme,	NHBT0002752

	concerning whether patient's next of kin should be informed if a patient is deemed unsuitable for counselling	
28/01/1993	Minutes of the Eastern Division Medical Meeting held at Colindale B.T.C. on Thursday 28 January 1993.	NHBT0012321_001
23/5/1996	Minutes of Anti-HBc Screening Project Study Group meeting, 22 May 1996, at East Anglian Blood Centre.	NHBT0040594_001
29/3/1995	Minutes of a preliminary discussion on the potential scientific outcome of the NBA HCV lookback (29 March 1995).	NHBT0040542_001
26/03/1992	Minutes of the Eastern Division Meeting held at Brentwood BTC on Thursday, 26 March 1992. Chairman: Dr J F Harrison. Attendees: Dr H Boralessa, Prof J P Allain, Dr R Brearley, Dr M Contreras, Dr E Caffrey, Dr M de Silva, Dr G Fryers, Dr A Gorman, Dr P Hewitt, Dr R Jones, Dr J Kemp, Dr S M McDougall, Dr E Ranasinghe, Dr M Thomas, Dr L Williamson.	NHBT0095526_0006
12/06/1996	Letter from Dr Lorna Williamson to [GRO-A] re: With permission of her GP, [GRO-A], if she is willing to help with a study carrying out on patients who have received blood transfusions in the last five years As she received blood in December 1993 which tested negative for hepatitis by the standard tests, there are a few donors who tested negative may still be hepatitis carriers, hence why they are studying an extra test for hepatitis.	NHBT0037682

	Informed her not to worry as they do not think that there is any risk that she have contracted hepatitis from the transfusion, but would like to offer her hepatitis B testing	
13/03/1991	Letter from Dr L. Williamson, National Blood Transfusion Service, to Dr R. J. Moore, North Western Regional Health Authority, re: Plasma Target 1991-92.	NHBT0002873_001
13/1/1995	Draft minutes of BTS Executive meeting, present includes Dr Williamson, Dr Ouwehand, Dr Caffrey, Pegler and Prof. Carrell. Matters discussed include Additional Bank signatories, Centrifuges, Stem Cell Laboratory, TUTA Packs and other related matters. Key date refers to when the meeting is to be held	NHBT0040540_001
31/01/1996	Minutes of the meeting of THE UK BTS/NIBSC STANDING ADVISORY COMMITTEE ON TRANSFUSION TRANSMITTED INFECTIONS (SACTTI), on 31st January 1996 at North London Transfusion Centre.	NHBT0009383
11/2016	Public Health Protection Unit Newsletter	WITN0643033
11/03/2004	Minutes of the Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation 32nd meeting, 11 March 2004.	DHSC0020692_118
26/02/1998	Minutes of Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation meeting, 26 February 1998.	SBTS0000518
01/10/1986	"Alanine amino-transferase (ALT) and	SBTS0000519

	hepatitis B-core (Anti-HBc) screening of blood donations" by H. H. Gunson.	
1/4/1996	Minutes of the Anti-HBc Screening Project study Group meeting, 29 March 1996, East Anglian Blood Centre; re: lookback EABC update and supplementary testing.	NHBT0040396_001
02/11/1995	Minutes of Anti-HBc Screening Project Study Group meeting, 1st November 1995.	NHBT0042751
21/10/1998	Minutes of the SHOT standing working group, on 21 October 1998, at the Manchester Blood Centre.	NHBT0114811
	Report, 'The Role of Leucodepletion in prevention of HTLV Transmission by Transfusion', by Dr. Lorna Williamson, National Blood Service	NHBT0040735
06/06/1990	Minutes of the meeting of the Eastern Division of Consultants in Blood Transfusion held at Cambridge RTC Thursday 24 May 1990.	NHBT0116043
26/11/1996	Minutes of anti HBc screening project study group meeting. on 20 November 1996, at NBS, East Anglia.	NHBT0042422_001
19/09/1996	Minutes of Anti-HBc Screening Project Study Group meeting East Anglian Blood Centre Present: Professor Jean-Pierre Allain Dr Loma Williamson Professor Richard Tedder Chris Parkhouse Dr Pat Hewitt Una Whicheloe Barbara Cant Joanna Griffiths Ian Reeves	NHBT0042424
23/04/1996	Letter from Dr Lorna Williamson to Dr Angela Robinson re: Anti-HBc Study.	NHBT0042691_001

	Details provided on the study, information requested for three donors who tested positive for HBA DNA.	
03/11/1995	Letter, from Dr Lorna Williamson, Dr Grimmer, East Suffolk Local Research Ethics Comittee, re clinic investigation of significance of anti HBC positivity in blood donors, mentions lifestyle study questionnaire was designed for routine donor counselling which will be regularly undertaken in the National Blood Service	NHBT0042707
19/10/1995	Letter from Patricia E. Hewitt, Acting Medial Director, to Professor Jean-Pierre Allain, Department of Haematology, re: Anti-HBc/Anti-HBs study at Cambridge and STBTS	NHBT0040649_001
11/07/1996	Minutes of meeting, re: Anti-HBc Screening Project Study Group Meeting	NHBT0040646
29/06/1995	Minutes of the coordination meeting of the Anti HBc Project re study update, testing, lookback protocol; Attendees: JP Allain, B Cant, R Challis, S Knowles, C Parkhouse, A Perigo, I Reeves, D Wenham and L Williamson	NHBT0040447_001
18/10/1995	Letter from Patricia E. Hewitt to Dr. Lorna M. Williamson, National Blood Transfusion Service, titled "Anti-HBc look-back study", re: ethics and the decision not to include children in the study	NHBT0114798
23/10/1997	Minutes of the Anti-HBc Screening Project Study Group meeting, on 24 September 1997, at EABC, re: Minutes of last meeting 21 May 1997.	NHBT0114800

23/05/1991	Costings for HCV Testing A letter from Jean- Pierre Allain to Dr J M O'Brien, Director of Public Health East Anglian Regional Health Authority, regarding budget projection of HVC screening and capital investment plan.	NHBT0042779_001
01/05/1995	Minutes of the management team meetin, 24 April 1995, [unknown location]; re: platelets. Attendees: Dr. Williamson, Dr. Ouwehand and Pegler.	NHBT0040453_001
26/08/1995	Minutes of meeting Anti-HBc Screening Project Study Group meeting Tuesday, 26th September 1995.	NHBT0040451_001
16/04/1996	Minutes of meeting 24/96 of UK BTS/NIBSC Standing Advisory Committee on Transfusion Transmitted Infections (SACTTI), held on 16/4/1996 at North London Transfusion Centre.	NHBT0000088_011
22/11/2000	Joint Meeting of the Standing Advisory Committees on Blood Components and Transfusion Transmitted Infections, held on 22 November 2000 at West End Donor Centre, London.	NHBT0001954_001
1996	Swann and Williamson Potassium loss from leucodepleted red cells following g-irradiation	WITN0643034
12/2001	Pennington et al 2001 Residual subset population analysis	WITN0643043
1995	Copplestone et al Wider benefits of leukodepletion	WITN0643035
05/2013	Bashir S et al Pathogen inactivation of platelets using ultraviolet C light effect on in vitro function and recovery and survival	WITN0643036

	of platelets.pdf	
06/04/1992	Letter from Dr L. Williamson, National Blood Transfusion Service, to Dr Nick Dodd, The Ipswich Hospital, et al., re: Solvent Detergent FFP.	NHBT0003473
25/02/1998	Minutes of meeting of UKBTS/NIBSC standing advisory committee on blood components, on 25 February 1998, at North London Blood Centre, Colindale.	JPAC0000007_095
2000	(Lancet 2000) F Houston et al Transmission of BSE by blood transfusion in sheep	WITN0643037
26/02/1993	Minutes of the BTS Executive Meeting, 22nd February 1993	NHBT0034821
01/01/1901	Report, "New variant CJD and Blood Transfusion Services - where is it all leading?", by Dr P. Flanagan.	NHBT0004351
18/02/2000	Minutes of Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation extraordinary meeting, 18 February 2000.	DHSC0006163_060
19/04/2001	Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation. Minutes of meeting held on 19/04/2001 in Wellington House.	NHBT0002411_003
09/08/1991	Letter from J. P. Allain (NBTS) to Dr. H. H. Gunson (The National Directorate), re: Ortho Test & Abbott Test.	NCRU0000197_005
10/12/1985	Hansard Material from Parliamentary Monitoring Services re Aids HoC Discussions	HCDO0000799
04/08/1987	Extract from draft report of meeting of	NHBT0008646

	Council of Europe Committee of Experts in Blood Transfusion and Immunohematology titled 'Non A, Non B Hepatitis - Testing of Blood for Indirect Evidence of Infectivity', produced by Dr H.H. Gunson.	
01/10/2001	Draft 2 - Final Version to be Signed off by vCJD Steering Group. Outline Paper for MSBT October 2001- Update on Actions Taken to Minimise Risks of Transfusion	NHBT0001804
19/03/2002	Minutes of the meeting held at WED on 19/03/2002 of the UK BTS/NIBSC Standing Advisory Committee on Transfusion transmitted Diseases (SACTII).	NHBT0001920
10/01/2002	Email from M. Slade, to M. Gorham et al, re: B&TSAG Agenda and Papers 16/01/2002, with minutes of the Blood & Tissues Safety Assurance Group's meeting, 14 December 2001 at West End Donor Centre, attached. Enclosed agenda, and item 9, and BTSAG material, not found.	NHBT0001900
08/07/1998	Notes of a special meeting of the UK Blood Transfusion Service/National Institute of Biological Standards and Control Standing Advisory Committee on Transfusion Transmitted Infections (SACTTI) held on 8th July 1998 at North London Centre.	NHBT0005599
01/07/1996	SACTTI meeting minutes from 1 July 1996, at the North London Blood Centre.	JPAC0000061_022
02/07/1996	Minutes of Advisory Committee on the	SBTS0000517

	Microbiological Safety of Blood and Tissues for Transplantation meeting, 2 July 1996.	
02/1999	Paul Hebert, et al A Multicenter, Randomised, controlled Clinical Trial of Transfusion Requirements in Critical Care	WITN0643038
05/11/1992	A letter from Dr Lorna Williamson, National Blood Transfusion Service, to Dr R. J. Moore, The National Directorate, regarding the production and utilisation of cryoprecipitate. There is an attached information page which details East Anglia's production of cryoprecipitate and cryo-poor plasma produced for year 1991/92. Response to cryoprecipitate survey NHBT0001560.	NHBT0001257
23/02/1995	Minutes of a meeting to discuss the proposed evaluation of Abbott Prism for the National Blood Service, held on 22 February 1995.	NHBT0007412
25/02/1998	CPMP position statement on nvCJD and plasma-derived medicinal products for a CPMP meeting in February 1998.	JPAC0000114_012
2007	S. Ballard,J. Staves,M. F. Murphy Changing indications for red cell transfusion	WITN0643039
1998	BCSH Leucocyte Depletion Guidelines	WITN0643040
04/10/1993	Draft minutes of Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation 1st meeting, 4 October 1993 at Skipton House.	MHRA0009439
03/11/1989	Letter from Janet Mortimer, PHLS to Dr Gunson, NBTS re three HIV positive US	NHBT0004573_001

	forces personnel. Letter shows they were not concerned with those known to have tested negative at least 6 months post donation. Also notes that the HIV database of positive blood donors at CDSC has many donors missing, or incomplete information and requests ways to receive this information. Letter acknowledges that Dr Gunson anxious that individual transfusion centres should not be identifiable in any output.	
4/11/1996	Minutes of the UK Standing Advisory Committee on Transfusion Transmitted Infections (SACTTI) on 4 November 1996, held at North London Blood Centre.	NHBT0010689_019
30/01/2002	Minutes of Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation on 30 January 2002.	DHSC0004805_254
12/09/2002	UKBTS/NIBSC Standing Advisory Committee on Blood Components SNBTS Protein Fractionation Centre, Ellens Glen Road, Edinburgh. Minutes of meeting held on 12/09/2002.	NHBT0041015
01/01/1994	Procedure document of Octopharma Pharmazeutika (OP) on "Clinical evaluation of solvent-detergent treated fresh frozen plasma ('Octaplas') in the management of thrombotic thrombocytopenic purpura, and in correction of coagulopathy due to either warfarin, liver disease of liver transplantation", includes sample forms	NHBT0009286_002

	and marked "protocol final version"	
2002	Beckman N et al Value of central analysis of leucocyte depletion quality control data within the National Blood Service, England	WITN0643041
2001	Cardigan R et al The effect of leucocyte depletion on the quality of fresh-frozen plasma (FFP)	WITN0643042
03/2006	Krailadsiri P, The effects of leucodepletion on the generation and removal of microvesicles and prion protein in blood components.	WITN0643044
03/2004	Beard MJ et al Variables determining blockage of leucocyte depleting filters by haemoglobin sickle cell donations	WITN0643045
4/7/2002	Health Service Circular, "Better Blood Transfusion, Appropriate Use of Blood", from Sir Liam Donaldson, Department of Health.	NHBT0060302
1/11/2001	Appendix 1, Serious Hazards of Transfusion (SHOT) Scheme, Terms of Reference, from the SHOT Annual Report, 2000-2001, by D. Asher et al. on behalf of the SHOT Steering Group	NHBT0060308
23/04/1998	Minutes of the Preliminary Meeting held on: Thursday 23 April 1998 - Oak House Watford Universal Leucodepletion Programme Implentation Board	NHBT0002141_001
13/10/2005	Minutes of SACTTI Working Group on vCJD, 7 November 2005 by Video Conference.	JPAC0000051_020
13/01/2005	Minutes of SACTTI Working Group on vCJD, 13 January 2005 by Video	JPAC0000051_021

	Conference.	
17/6/2005	Minutes of SACTTI vCJD Working Group Meeting, 17 June 2005 by video conference.	JPAC0000051_053
13/10/1999	Minutes for the universal leucodepletion programme implementation Board meeting on the 13 October 1999 at Queen Elizabeth Hospital	NHBT0000766
07/09/1999	Minutes of the Universal Leucodepletion Programme Implementation Board Meeting, Tuesday, 7 September 1999 at the Postgraduate Medical Centre, Queen Elizabeth Hospital.	NHBT0000767
01/01/1994	Report, re: Viral Inactivated Fresh Frozen Plasma (FFP), by Dr Gunson, 1994. Report considers a collaboration between NBA and Octapharma for a trial into solvent detergent treated plasma.	NHBT0000769
11/06/2001	Minutes of a Meeting of The Advisory Committee on Microbiological Safety of Blood and Tissue for Transplantation held in Richmond House	NHBT0002384
05/08/1994	Report of a Preliminary Position Paper. Discusses risk of Hepatitis C in Patients who Received Blood from Donors Subsequently shown to be carriers of Hepatitis C Virus. Notes that an ad-hoc assembly of experts was convened on behalf of the Standing Advisory Committee (SACTTI) to discuss the feasibility of introducing a HCV look-back.	NHBT0045664
03/12/1997	Proposal re: distribution of BPL products and supply of plasma to BPL: A new	NHBT0052138

	approach. Drawn up by group under DH chairmanship. Discusses objectives for the new approach, and other aspects including constraints, supply arrangements, plasma prices, method of settlement, resource distribution effects, and implementation date	
01/2013	Elebute et al 2013 Prion filtered red cells	WITN0643046
12/12/2012	SaBTO meeting	WITN0643047
04/12/2000	Email from Elizabeth Love, to Brian McClelland, Morris McClelland, Chris Prowse, Geoffrey Geddis, Graham Rowe, Geoffrey Schild, Henry Hambley, Ian Franklin, Jean-Pierre Allain, Martin Bruce, Michael Kavanagh, Dr. William Murphy, Paul Ashfrod, Neil Beckman,Dr. Elizbaeth Boxall, John Kurtz, Richard Bedford, Wendy Groves, Tim Wallington, Marcela Contreras, Peter Garwood, Hilary Hampson, Angela Robinson, Kate Soldan, Lorna Williamson, Mahes DeSilva, Roger Eglin, Carl McDonald, Ruth Warwick, David Anstree, SHeila MacLennan, Chris Hodson, Michelle Ashford, Virge James and Frank Boulton, re: Joint SACBC/SACTTI meeting 22 Novmber 2000: Proposal for vCJD workshop	HSOC0018830
04/2014	Menitove JE et al, How Safe is enough, who decides and how	WITN0643048
29/04/2014	SaBTO meeting	WITN0643049
16/03/2013	Howard et al 2013 Transfusion Alternatives in Sickle Cell Disease	WITN0643050

04/2004	Llewelyn C et al The effect of universal leucodepletion on postoperative infections and length of hospital stay	WITN0643053