Witness Name: Dr Angela Robinson
Statement No.: WITN6926001
Exhibits: WITN6926002
Dated:

INFECTED BLOOD INQUIRY

WRITTEN STATEMENT OF DR ANGELA ROBINSON

I, Dr Angela Robinson will say as follows:

Section 1: Introduction

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

    1. My name is Dr Elizabeth Angela Eleanor Robinson.

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

    3. My date of birth is GRO-C 1942.

    4. I attach a copy of my curriculum vitae at exhibit 'WITN6926002' setting out my professional qualifications.

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

    5. Please refer to my CV at exhibit WITN6926002 .

6. I specialised in haematology and my first appointment as a consultant was a joint post between the Transfusion Centre and Seacroft Hospital in Leeds. Seacroft Hospital was the regional centre for infectious diseases and for paediatric oncology. I became involved in the diagnosis and management of children with cancer and leukaemia and the need for specialised blood components soon became apparent. My joint post enabled me to develop resources within the Transfusion Centre which led me into the field of cell separation and apheresis. I became a national and internationally recognised expert in both donor and therapeutic apheresis and introduced the first voluntary donor automated plasmapheresis centre in the world in Bradford in 1982.

7. I relinquished my position as medical director of the National Blood Authority in April 2007.

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.

8. Please refer to my CV at exhibit WITN6926002 .

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

9. In medicine there is a system of continuing professional development (CPD) which I engaged in. Courses were run by the College and I undertook and participated in reading and meetings.

10. I subscribed to the British Journal of Haematology, The British Journal of Blood Transfusion, Vox Sanguinis and the American Journal 'Transfusion' and various specialist apheresis journals, two of which I jointly edited. I read the BMJ, the Lancet and the New England Journal. I was a reviewer for some of these publications.

11. We had a library at the Yorkshire Regional Transfusion Centre (YRTC) which stocked many of these journals.

12. I would focus my reading and research on the particular speciality of the topic that I was dealing with at the relevant time.

13. I attended various symposiums, one example being in Boston USA in 1982 which was an advanced apheresis symposium. It was at this meeting that I first became aware that HIV might not just be confined to the gay community as cases had been found amongst haemophiliacs in the USA and the possibility that HIV could be a transfusion transmitted disease was raised.

14. I attended most meetings of the American Association of Blood Banks, the British Society of Haematology, the British Blood Transfusion Society, and the International Blood Transfusion Society.

15. The expertise surrounding blood transfusion medicine is a fairly small world and, therefore, by attending these meetings there was a lot of information sharing and I was able to keep up-to-date with who was a specialist and in what field.

16. When I became the director of the National Blood Authority in 1994, I began to read the MMWR, although I was aware of its existence and had access to copies before that time.

5. 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.

17. This statement should be read in conjunction with my response to the Amended Rule 9 Request, dated 14 August 2020 – the Lookback request.

18. No. I have not been involved in any inquiries, criminal or civil litigation in relation to HIV, HBV, HCV or vCJD.

19. With respect to investigations, I was heavily involved with the HCV lookback exercise and vCJD investigation. I was also involved with the HIV lookback exercise and recall sending our donor care Associate Specialist Dr Alison Townley to a national training course in London to learn how to counsel donors who proved to be HIV positive. With respect to Hepatitis B, I was not in the transfusion service when testing began for this virus and I do not have any memory of a formal HIV lookback exercise.

Section 2: Your role at the Yorkshire Blood Transfusion Service

6. Please describe the roles, functions and responsibilities you had at the Yorkshire Regional Blood Transfusion Centre ("YRTC") during your period as:

a) Consultant Haematologist; and

20. I had 11 sessions split between the Seacroft Hospital and the Transfusion Service. I believe that I had six sessions with the Seacroft Hospital and five sessions with the Transfusion Service. This is how my consultant rota was split.

21. The Seacroft Hospital was a regional centre for infectious diseases and I supervised the laboratory haematology screening of infectious disease patients. This is where I became more acquainted with infectious disease medicine although I had had 6 months basic training in microbiology including 1 month at the PHLS Leeds as part of my SHO rotational training scheme.

22. During my split role with the Transfusion Service, I was particularly concerned with the provision of specialist blood components for paediatric

cancer and leukemic patients such as platelets, white cell transfusions and specific immunoglobulins e.g. anti-varicella (chickenpox).

23. At the time the Hospital Haematology department and the Transfusion Centre were located in the same building making it possible for me to satisfactorily undertake my joint consultant role. Each session would last approximately half a day.

b) Director and explain how these changed over time.

24. When I became director, I retained three clinical sessions, but appointed consultant haematologist Peter Flanagan to take over my paediatric haematology patients.

7. Please describe the organisation of the YRTC during the time you worked there, including:

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

25. I refer the Inquiry to the 1991/92 business plan for the YRTC under URN NHBT0097056_002.

26. When I started at the YRTC it was managed by the Yorkshire Regional Health Authority, so the organisation was accountable to the Chair of the Regional Health Authority. In most circumstances we reported to the Chief Scientific Officer for the region. An annual budget was allocated which was managed by a general administrator. The budget was not broken down and was rather simplistic. The administrator would manage the budget and produce annual forecasts.

27. After my appointment as Director in 1988 the organisation became more complex and accountable. I had to manage staff budgets and HR issues and produce an annual business plan and annual forecasts. I appointed a business manager to assist and we introduced computerisation of all our donor and laboratory records

28. Eventually, in order to balance my managerial and clinical responsibilities, I appointed consultant Dr Moji Gesinde to take over the apheresis services and Dr Peter Flanagan to take responsibility for managing the laboratory and microbiology testing services

29. My role became predominantly Chief Executive rather than medical director, which is why I ended up splitting responsibilities between Dr Peter Flanagan who became Clinical Director and my business manager Mr Tony Heywood.

30. When there were competing clinical and budgetary issues Dr Peter Flanagan as Clinical Director would debate the issues with our business manager so that I could take a step back, enabling me to make an informed decision based on the arguments presented by both of them.

31. From an old annual report I found (1988/1989) it states that the YRTC employed approximately 300 staff.

b. how the YRTC was funded and how this changed (you may find NHBT0027504 useful);

32. When I was appointed as Director in 1988, I had never been presented with a budget sheet before and I had to appoint a business manager, Mr Tony Heywood to understand how the budget allocated was dispersed to fund the organisation. When the budget was devolved in 1992, we had to work out a unit price for the cost of collecting and testing 1 unit of whole blood and then apportion this between red cells, platelets, cryoprecipitate and/plasma and a similar exercise had to be done for apheresis plasma. This was an arithmetical exercise undertaken to ensure that whatever we charged for a particular unit (red cells/platelets/cryo/plasma) the costs added up to a sufficient sum to cover the running costs of the organisation

33. Initially BPL did not pay for the plasma it received from RTC's but worked on a system of 'pro rata' return. This worked well for YRTC as the volume

of both recovered and apheresis plasma sent to BPL meant that the pro rata return of plasma products e.g. F VIII and human albumin solution (HAS) was sufficient to meet the region's requirement. Later on, BPL set up a national pricing structure for a unit of recovered plasma and apheresis plasma. The price for a unit of apheresis plasma proved to be insufficient to cover the cost of producing it at the YRTC.

34. When I joined the YRTC as a senior registrar in 1971, blood was still being collected into glass bottles making separation into its components difficult as the integrity of the seal had to be broken, risking potential contamination. With the introduction of plastic packs, it became possible to introduce integral triple packs. This made the separation of whole blood into its component parts, red cells, platelets and plasma within a closed system possible. This was a major breakthrough in blood banking and blood component therapy. Recovering plasma in this way was relatively cheap as two other products were obtained at the same time and triple plastic blood packs were much cheaper than the plasmapheresis harnesses which included an integrated centrifuge bowl with a closed rotating seal. Although we could obtain almost three times as much plasma from one plasmapheresis donation compared to that obtained from one unit of whole blood, because the harness was so much more expensive, the resulting plasma was more costly.

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

35. The YRTC served the Yorkshire region North of the Humber. The population the YRTC had to serve based on geographical location was approximately 3,500,000.

d. its place in the 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 and Others v National Blood Authority and another*

[2001] 3 All E.R. 289 (A & Others) and explain whether you agree with what is said there (NHBT0000026_009);

36. The National Directorate was set up in 1988 but did not have any executive power. The National Directorate could influence and advise but could not determine how the budget was spent. My centre was still accountable to the Regional Health Authority. During 1988 the Regional Health Authority altered its structure so that my centre came under the Yorkshire Regional Services organisation, which included the Ambulance Service, NHS supplies and the Transfusion Service. I had much closer managerial scrutiny then, from the Regional Services organisation. This was quite a helpful relationship for me, because it allowed me to better understand the management of budgets and business planning, which I had not had a great deal of experience of up until then.

37. I have read paragraphs 14-16 of Dr Harold Gunson's statement in *A and Others – v – National Blood Authority and Another* and found this extremely helpful. I agree with Dr Gunson's summary.

e. whether the YRTC was associated or linked with other Regional Transfusion Centres ("RTCs") and, if so, how and for what purpose;

38. Not officially in any way, but we did have personal links with Sheffield because of the proximity of our centres. One example is that if we were ever short of donors, I used to do a radio appeal and sometimes would get a call from the Regional Director Bill Wagstaff at Sheffield, who was 30 miles away, 'complaining' that they weren't short of blood, but their sessions were getting oversubscribed because of my radio appeal which covered both of our areas. As a result, we kept quite close informal links with Sheffield.

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

39. We had the Medicines Inspectorate (MCA) and we were inspected by them before crown immunity was lifted in 1991. I recall that we had a laboratory in which we used to make our own sterile saline and anticoagulant solutions and the MCA insisted that this was closed down as it did not meet the regulatory standards

40. Dr Gunson introduced medical audits between the RTC's and I, together with Dr Tim Wallington (Bristol) and Dr Pat Hewitt (N. London) audited Tooting and Cambridge. This was to help establish the clinical involvement and expertise within each centre to understand how they were managed and what role the clinicians had within the centre, to encourage consistency and ensure standards were being maintained.

g. YRTC's relationship with the Blood Products Laboratory ("BPL") and any other laboratory involved in the production of blood products or processing of blood. In particular, please set out which of the two options you took as set out in the letter from Dr Cash dated 9 April 1992 (SBTS0000056_036). If it was to sign a confidentiality agreement, please set out what impact that had on your ability to carry out your role at the YRTC;

41. The YRTC produced whole blood, concentrated red cells, fresh frozen plasma, cryoprecipitate, and platelet concentrates; some plasma, platelet concentrates and occasional white cell concentrates were produced by apheresis

42. I assume we must have held and distributed the Factor VIII products received from BPL to hospital blood banks, but I can't remember. I recall that we were doing this for the anti-D and albumin, but I can't consciously remember doing this in relation to Factor VIII.

43. This would be a solely NHS product as I never had anything to do with commercial products.

44. I have read document SBTS0000056_036 and I do not recall being at this meeting or having read or signed this document. I do not now believe I would have signed any confidentiality agreement.

h. YRTC's relationship with any pharmaceutical companies involved with the production of blood products; and

45. I did not have any relationship with pharmaceutical companies *per se*. I did have a relationship with the companies who produced the apheresis machines and harnesses, such as Haemonetics, Baxter Travenol and IBM. Later Cobe laboratories took over the IBM cell separator.

46. This was not a paid relationship; it was a mutually beneficial relationship in which I advised them what was needed and they then developed products to meet that need. Some advances were made because of that relationship, for example the adaptation of a machine to produce a platelet concentrate as well as plasma and the development of a machine for intra operative cell salvage.

47. Haemonetics did fund some of my travel to expert meetings in other countries. There were apheresis symposiums at which I would be asked to attend to give a lecture and the manufacturers would pay for my travel and accommodation, but I would not be paid a fee for attending. I also recall, for example, giving a lecture to the staff at the Haemonetics factory about the importance of quality control and that if the integrity of the harness was compromised in any way e.g. a pinhole leak then the whole donation would have to be discarded.

48. Once I became National Director, I immediately ceased any association with any company so that I could remain entirely impartial.

i. the number of donations collected each year (you may find NHBT0027512 of assistance).

49. NHBT0027512 shows that the number of donations collected in 1988/89 amounted to 24,607L of blood and plasma. The document demonstrates

that the targets increased year on year so that by 1992/93 the target was 38,000L.

Section 3: Blood collection at the YRTC

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

50. When I joined as a senior registrar in 1971, I remember that the YRTC was still collecting blood in bottles. The centre had a huge steriliser and reused the bottles, so it was a very economical way of collecting the blood.

51. A second consultant was brought in by Dr Derrick Tovey (who was Director of the YRTC from 1966 to 1988), called Dr Rajah, primarily in order to begin the collection of components and he introduced the use of integral plastic packs so that we could make platelets.

52. I think Yorkshire was one of the last centres to phase out glass bottles for blood collection. I joined the service as a senior registrar during this change over process from bottles to plastic packs, enabling a better provision of blood components for patients and more recovered plasma for BPL.

53. I introduced voluntary donor automated plasmapheresis machines for the collection of plasma.

54. I recall that one of the only disagreements that I had with Dr Gunson was when we had a dispute over manual plasmapheresis collection compared to automated plasmapheresis collection. I recall that Dr Gunson felt that the manual method of removing whole blood and then centrifuging it, replacing the red cells and separating off the plasma was a more cost effective and efficient way to obtain plasma; whereas I was an advocate for automated plasmapheresis because of the much shorter donor time

(around 30 minutes) and the safety aspects. During a manual collection the blood had to be separated from the donor for centrifugation and separation of the plasma prior to reinfusing the red cells back into the donor whereas with automated apheresis the system was closed. Because of this disagreement I asked for my name to be disassociated from a working party recommendation that manual plasmapheresis was the preferred option for plasma collection.

55. At the YRTC we used automated plasmapheresis for the collection of plasma and I also devised a system where we could collect platelets at the same time as the plasma. This was a particularly cost effective system for collecting 2 components producing 0.5L plasma and the equivalent of 4-6 units of platelet concentrate (1 adult dose).

56. With respect to cryoprecipitate, we used to manufacture this using dry ice and ethanol. This is by a process of snap freezing at -70*C; when dry ice and ethanol are mixed the cryoprecipitate can then be separated from the plasma by thawing at 4*C overnight. This would leave a concentrate rich in Factor VIII. Later we had blast freezers to do this. The plasma would be frozen and thawed overnight and then the cryoprecipitate separated, which could then be frozen and stored for two years.

9. Did the YRTC have targets for the amount of plasma that had to be collected by the centre? If so, who set these targets and what were they? If not, why not? What was the purpose of the targets?

57. Yes, we had targets.

58. I am not certain whether it was Dr Harold Gunson, the National Director or BPL or a combination of Dr Gunson and the Director of BPL who set the targets.

59. There was a national target that was presumably apportioned between the regions.

10. Was the funding of the YRTC linked to meeting those targets? Please provide details.

60. By the time I was director of the YRTC the blood service had been devolved so the question of funding was how much we were paid for our products.

61. We had to make ends meet. Ironically, the more plasma we produced the more out of pocket we were, because there was a shortfall on unit price for apheresis plasma.

62. There was no funding whatsoever for research. Money had to be found from elsewhere in the budget if any work on research was to be undertaken, or self-funded in some way.

63. I recall at the time that I was doing research on the quality of plasma and on the machines we used, that it was fortunate that I had the Hospital chemical pathology laboratory next door to the YRTC and we could collaborate on a lot of the research and investigations, but my RHA did not have any research funding I could apply for and this had to come out of my budget. This was the position both before and after devolution.

64. Once the NBA came into existence there was a central funding pot.

65. Funding was tangentially linked to meeting targets because it was based on the amount of plasma that was produced.

11. What were the consequences if the targets were not met?

66. We would get less factor VIII concentrate and HAS back from our plasma for our local population so we would receive less, pro rata, if the targets were not met.

67. We only got back proportionately what we provided to BPL, so if we missed our target we got less back.

68. The target was based on the Factor VIII required nationally and then apportioned between the different regions. Therefore, our target didn't necessarily equate to the demands of our local population.

12. Were there any benefits to YRTC if the targets were exceeded?

69. The benefit was that the more plasma you gave to BPL the more factor VIII concentrate and HAS you would get back.

13. What impact did the setting of targets for the collection of plasma have on decision-making at the YRTC?

70. I promoted automated plasmapheresis collection. The first centre opened in Bradford in 1982 and about 2 years later a second centre was opened in the centre of Leeds and a 3rd centre continued to be maintained at the transfusion centre so that we had three apheresis centres operating at one point. This was to achieve maximum plasma collection.

71. The impact of targets would influence how I directed and spent the budget.

72. I cannot recall exactly how we managed large scale capital expenditure, for example buying and replacing equipment and securing premises.

14. What if any steps did the YRTC take to publicise itself to potential donor populations in order to increase donations? How successful were these steps? You may find NHBT0000077_103 of assistance.

73. We did a lot of publicity campaigns and local media campaigns.

74. When a mobile team went around the region they would advertise with posters. Blood donation was not by appointment, so our mobile teams had to make their presence known in the area in order to secure donors.

75. Publicity was therefore at a local and regional level and we made a lot of our own publicity material. I appeared on the radio, for example, in order

to ask for donors. I don't recall much by way of nationally coordinated publicity campaigns until the National Directorate was set up, when television adverts were then used.

76. At the YRTC we had a department to deal with donor recruitment and publicity. The donor services manager was responsible for donor recruitment and we had a publicity department which, for example, produced leaflets for plasmapheresis, plateletpheresis and whole blood donation.

15. To what extent did the YRTC collect blood from prisons, borstals and similar institutions? Please set out the number of institutions from which blood was collected and the frequency of sessions. In particular:

a. When did this practice cease?

77. I cannot recall precisely when blood collection from prisons ceased. I remember that when I was a senior registrar, I attended a session at Wakefield Prison. That would have been at some point between 1971 and 1976. I cannot recall any prison collections after I became a consultant, which was in 1976.

78. I recall opening a plasmapheresis centre in 1982 and I do not think at that time we would have allowed people to donate who had a prison history because of the association of institutionalisation increasing the incidence of Hepatitis B and non A non B hepatitis through close contact and IV drug abuse. That leads me to believe that we were certainly not collecting blood from prisons by 1982.

b. What role, if any, did you have in this practice?

79. Only that I remember that when I was a senior registrar, I attended a session at Wakefield Prison.

c. What were the relative costs of collecting blood from prisons as compared to collecting blood at YRTC?

80. The costs were comparable with collecting blood at the YRTC and from our other centres, it was no more economic to collect blood from prisons as far as I understand.

d. Were prisoners in England and Wales provided with any form of incentive to donate blood? If so, what?

81. There was no incentive for prisoners nor for the YRTC as far as I understand.

16. In September 1983, Dr Ewa Brookes of the SNBTS surveyed English and Welsh Regional Transfusion Directors ("RTDs") to ascertain which RTCs continued to collect blood from prisons. Dr Brookes' notes from the survey suggest that the YRTC was one of two RTCs that did not indicate that prison sessions would be discontinued. Dr Brookes wrote that the YRTC's Director, Dr Derrick Tovey, was "different," suggesting that his approach differed to that of other RTDs (NHBT0008628_001). As far as you can recall, what was Dr Tovey's position on the discontinuation of prison sessions? Did you agree with his position?

82. I do not recall having a conversation with Dr Tovey about when and why YRTC ceased prison donor sessions. I have been told by my advisers of, but have not seen, the minutes of 27 September 1983 meeting of The UK Working Party on Transfusion-Associated Hepatitis which reflect the decision of the group that "prisons should be considered in the context of a 'high-risk' population in terms of several transfusion-transmitted infections and as such should be avoided as a donor source". I can find no record of any national decision of when a recommendation was made that prison sessions should stop.

17. Please describe the way in which donations were collected at the YRTC during your time there. In particular:

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

83. At mobile sessions there was a team leader, a sessional medical officer and, depending on the population of the area, one donor carer per donor bed in a mobile session.

84. The team leader would organise the session with a donor carer on reception when the donors came in and another donor carer would do the finger-prick haemoglobin check. There would then be a six-bed set up with a donor carer by each bed.

85. My recollection is that there were ten people per team plus the team leader.

86. When I started, all of the venipuncturists were either part time GPs or our own sessional medical officers.

b. Where did these sessions take place?

87. Sessions took place in whatever premises we could rent that were suitable in the region, for example church halls.

c. How frequently could a person donate blood? You may find NHBT0003804 and NHBT0000191_144 of assistance.

88. When I first started, donors were called every six months. This changed over time when we changed it to men being able to donate every three months and women every four months. I think this was eventually regularised to four months for both men and women.

89. In plasmapheresis, because the red cells were returned to the body, people could donate more often, the minimum interval being once every two weeks.

90. The frequency is based on how long it takes the body to replace the volume of red cells that you lose from donation. In a man this can be

done in approximately three months and in women slightly longer. In people who are iron deficient it can be dangerous to donate blood too frequently or at all. When taking plasma all that you have to replace is the fluid and the protein that is lost from the donation, and this can be done within two weeks.

91. Plasma donors were routinely called once every three months, but we could cater for donors who wanted to donate more frequently.

d. How were blood donors recruited?

92. In various ways, for example:- by local and regional publicity campaigns, local radio, recruitment posters, advertising ahead in and around the next session venue, insertion of recruitment leaflets into the council electoral roll mail out.

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

93. To encourage more ethnic minority donors, particularly in the Bradford area, communication channels were opened up with local community leaders to demonstrate the need for and value of voluntary blood donation.

18. Did the YRTC meet its donation collection targets during your tenure? If not, why not? What was done to improve blood collection? What more could or should have been done? What were the barriers?

94. Yes, as far as I can recall, the YRTC met its targets during my tenure.

95. There were seasonal variations, for example during bank holidays and festive periods when we might run short and during those times, I would usually resort to the media to do an appeal for blood donors.

19. In a meeting on 10 April 1991, you stated that it was costing the YRTC more money than it received to produce plasma (NHBT0000077_056). Can you explain why this was? Did this change over time? Please give details.

96. I have in the main dealt with this above. In essence it was costing the YRTC more to produce the apheresis plasma than we were getting back from BPL. This was roughly a deficit of £15 per litre.

Section 4: Production of cryoprecipitate / fresh frozen plasma

20. Did the YRTC produce fresh frozen plasma ("FFP") and/or cryoprecipitate? If not, where was this produced for the YRTC region and what were the arrangements in place?

97. Yes, the YRTC did produce fresh frozen plasma and cryoprecipitate. This was produced within our own blood components laboratory.

21. If the YRTC did produce these two products please describe:

a. where this took place;

98. This took place within our blood components laboratory at the YRTC.

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

99. The capacity increased because we moved into a new building with a much larger and better equipped blood products laboratory.

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

100. A small proportion of the total amount of plasma recovered was processed to make cryoprecipitate / fresh frozen plasma which was kept locally to provide to regional hospitals. The vast majority of the remainder went to BPL for processing.

101. Initially, we used to make five litre pools of plasma for BPL, but with the introduction of the triple pack and the wedge pack, this meant that we no longer pooled plasma but instead froze individual packs into what can be likened to freezing ice lollies in order to meet BPL requirements so that they could use guillotines to cut off the end and squeeze out the contents of the pack for processing in larger pools at BPL.

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

102. With relative ease, but that would have meant that we would not have been able to provide the plasma to Elstree, so we would be effectively between a rock and a hard place. We did what we were asked to do which was provide as much of our recovered plasma and apheresis plasma to BPL as we could, so that they could make Factor VIII. We were always able to meet the demand for cryoprecipitate from the Haemophilia centres in our region.

103. If we had increased manufacture of cryoprecipitate this would have reduced the amount of plasma being sent for the manufacture of Factor VIII.

104. So, in answer to the question, if we did not have the requirement to provide plasma for the manufacture of Factor VIII, then it would have been relatively easy to increase the manufacture of FFP or cryoprecipitate, but that was not possible whilst we had a quota for the provision of plasma to BPL. Providing we had the blast freezer and refrigeration capacity it would have been possible to switch completely to cryoprecipitate provision of FVIII but this was never asked of us by the Haemophilia Directors who were prescribers of FVIII.

105. In order to make cryoprecipitate you need to snap freeze the plasma and then allow it to thaw overnight, then remove the surface plasma leaving the precipitate behind which is rich in FVIII; this is then frozen hence the term cryoprecipitate. So, the process is a little more complicated and,

whilst it could have been done, it would have required a total shift in how we used our labour force. We probably would have required more staff because the processes are a little more labour intensive and potentially more equipment in terms of blast freezers and refrigerators. In short, it could have been done, but would have required some restructuring, some capital outlay and re-staffing of the laboratory and it would most certainly have reduced the amount of plasma we sent to BPL for fractionation.

22. Please describe the arrangements for supplying FFP and/or cryoprecipitate to hospitals and haemophilia centres within the region covered by the YRTC.

106. All our dealings with the hospital haemophilia centres were through the blood banks; so the hospital blood banks would put the request in for the amount of FFP / cryoprecipitate the hospital required and we had a dispatch department at the YRTC who would send the products directly to them.

107. It was usually a haematologist who was in charge of the blood bank and a Haemophilia Director in charge of the haemophilia centre.

108. We delivered directly to the hospital blood banks and to nobody else. We did not have any dealings with imported blood products.

Section 5: Arrangements for obtaining and allocating blood products at YRTC

23. Please describe the arrangements in place in the Yorkshire 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") and (b) imported factor concentrates and/or other blood products ("imported blood products"). In particular:

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

109. We did not handle any imported factor concentrates or other blood products at the YRTC. We only dealt with BPL and NBS products.

110. There were three main haemophilia centres in my region. There was the haemophilia centre at the Leeds General Infirmary, one at St James', Leeds and one at Bradford.

111. The region also had a Haemophilia Director at Hull and all the individual hospitals would have had somebody in charge of their blood banks, but haemophiliac patients would have been referred to one of the big centres mentioned above.

112. We also had some links with Scarborough Haemophilia Centre because at the time Scarborough was a popular holiday destination and haemophilia patients who were on holiday required support from that centre.

b. Please outline the respective responsibilities of the YRTC, BPL/PFC, the relevant Regional Health Authority ("RHA"), and haemophilia centre directors, and how these responsibilities changed over time. You may be assisted by NHBT0017193, particularly what is said at point 5.

113. Document NHBT0017193 refers to BPL reagents not Factor VIII concentrates and is irrelevant in this context. The primary responsibility of the YRTC was the provision of source material to BPL whilst also promoting the appropriate use of whole blood i.e. reduction in use and increasing the proportion of red cell concentrates used by the hospitals in the region so the maximum amount of plasma could be recovered for BPL.

114. Initially we were accountable to the Regional Health Authority, then to the national directorate but still accountable to the region until finally in 1994 we became accountable to the National Blood Authority.

115. PFC is the Plasma Fractionation Centre and relates to the Scottish National Blood Service. It had nothing to do with the NBA or the YRTC.

24. Please explain whether any forums were established between the YRTC, BPL/PFC, the relevant 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? You may find PARA0000008 of assistance.

116. PARA0000008 relates to notes of a meeting at BTS on 4 December 1984 discussing heat treated FVIII and says that no decision can be taken until after a meeting with the Reference Centre Directors and Dr Lane has been held the next week when it is hoped that there will be a statement of policy on heat treatment (HT) and supplies; it discusses shortfalls and whether non-HT NHS is safer that HT commercial FVIII.

117. BPL ran the big fractionation centre in Elstree. I had a very close relationship with Jim Smith who ran the smaller experimental fractionation centre based in Oxford, I believe.

118. I did a lot of small pool trials to work out the quality of the sources of plasma in order to demonstrate the difference between recovered plasma and apheresis plasma and on a small scale it did show that it was of a better quality. I presume that this is what PFC is referring to in this question. It was a small experimental fractionation centre with which I had strong links.

119. I recall attending meetings at BPL with Richard Lane and Harold Gunson, so I presume there must have been a liaison group that I was involved with and I believe that we met more than once a year, but I cannot be more precise.

120. I also recall that I was invited to the regional haemophilia centre director meetings which I would estimate took place about once every year.

25. 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)?

121. At the YRTC we did not have any arrangement for imported blood products. We distributed NHS blood products received back from BPL pro rata for the amount of plasma submitted; and later when cross-charging came in, according to population requirements. I cannot comment on what other regions did.

26. Did you, or anyone else at the YRTC, contract directly with any pharmaceutical company involved in the manufacture and/or importation and/or sale of imported blood products? 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 when determining whether to contract with one pharmaceutical company over another. You may find NHBT0000077_056 of assistance.

122. No. I had a relationship with some of the apheresis companies, as I have described above, but no pharmaceutical companies involved in the manufacture or importation / supply / sale of blood products.

123. When the blood service was nationalised and the NBA was created, I had some dealing with the companies who provided testing kits for transfusion transmitted infections such as Abbot, but mostly delegated to my scientific expert, Dr Peter Flanagan, who was involved with the central purchasing of testing kits. We did try to have more than one supplier if possible and if the kits were of equal sensitivity and specificity.

27. What was the impact on the YRTC of shortfalls in NHS product coming from BPL? How frequently did this occur? You may find NHBT0000534_003 of assistance.

124. There was a persistent shortage of Factor VIII. I usually got all of the human albumin solution I needed, and I got the anti-D that was required.

125. So the impact was that there was insufficient source plasma to produce the amount of FVIII concentrate required.

126. The problem I had as the director of the YRTC was the inability of BPL to produce sufficient Factor VIII, hence we did not get the best relationship we could have with the haemophilia directors and hospital blood banks because there was a shortfall; the impact on the YRTC was simply that we did not have enough Factor VIII concentrate. This is what I am trying to say in my letter NHBT0000534_003. The haemophilia directors were left with no alternative but to buy commercial product because BPL was not producing enough NHS product.

28. Was the YRTC 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?

127. No, the YRTC was not responsible for any of those decisions.

29. If haemophilia centre directors were responsible for these decisions, did the YRTC have any influence over their product choices? You may find the correspondence in BPLL0005770 of assistance.

128. This correspondence between myself and Richard Lane indicates that after a meeting I had in Dec 1990 with the Yorkshire Haemophiliac Directors to determine the predicted requirements for 1991/1992 there were 13 new "virgin" haemophiliacs requiring special treatment. I therefore put in a plea for these patients to be included in any clinical trial of 8SM, the new BPL purified F VIII product prepared from NBTS plasma to be available from March 1991, such that 8SM would become the treatment of choice in the Yorkshire region rather than pasteurised monoclate.

129. Richard Lane responded that I should encourage my Haemophilia Directors to write to him ASAP setting out their requirements for establishing previously untreated patients on 8SM, which I no doubt did.

30. What influence did pharmaceutical companies have in the way the imported blood products they supplied to the UK were used? For example, can you recall whether pharmaceutical companies provided advice on the use of the products?

130. I had absolutely no association with the pharmaceutical companies that produced blood products such as Factor VIII.

Section 6: Knowledge of risk of hepatitis and HIV while at YRTC

HIV/AIDS

31. During your time as a clinician in transfusion medicine and at the YRTC, 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?

131. I think it is important to point out that during my time as a practising physician my speciality was in paediatric haematology and, in particular, the development of the paediatric oncology unit and the bone marrow transplant unit. We were the first hospital outside London to set up a regional bone marrow transplant unit, so I was involved in the development of blood components and obtaining them by apheresis and the therapeutic use of cell-separator machines and the collection of anti-D, platelets and plasma from a paediatric, haematology and oncology perspective. I was a transfusion medicine specialist and aware of transfusion transmitted infections but was not an expert.

132. With the discovery of HIV and AIDS I had to get involved with the virology side of blood, but I wish to make clear from the outset that I am not a virologist and not an expert in that field.

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

133. The first time I became aware that HIV might be a transfusion transmissible infection was when I attended an advanced symposium on apheresis in the USA in 1982. This is when I heard that some haemophiliacs had developed HIV and this is the first time I think I was in aware of the possibility of HIV being transmitted by blood or blood components.

134. By 1983 more of the risk factors for HIV were becoming clear to me, particularly in the gay community.

135. By 1 September 1983 we developed nationally, through Dr Harold Gunson, a HIV leaflet to be read by all donors. I can't recall how it was distributed, but I believe that with every call to a donor centre a leaflet was included, but there was no specific means of ensuring that every donor read it.

136. So there was a developing way in which we handled donors in terms of known risk factors and groups up until the introduction of testing in 1985.

137. By that point in time, I was aware of a high association of morbidity and mortality with HIV.

138. Most of my knowledge regarding blood borne viruses and transfusion transmitted infections was from attending meetings and symposiums and discussion with my peers.

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

139. Before we introduced testing, we had to work out how we were going to deal with any donors who tested positive. There was a national training scheme at St Mary's Hospital in London and it was felt that only senior

members of staff should be involved in informing positive donors. We sent Alison Townley, our associate specialist, who was trained in HIV counselling.

140. There were rules in place regarding the confidentiality of donors under which we could not contact their GP or partners if they tested positive for HIV / AIDS, without their authority. Donor confidentiality was paramount and we needed their consent. Given that the impact of the disease was so disastrous at that time, donors were also at risk of losing their life insurance and mortgage if reported to be positive and therefore confidentiality around HIV / AIDS was very different from other infections that we had dealt with in the past.

141. From memory, we did not have very many donors who tested positive, but one in particular sticks in my mind and he was a bisexual male which created issues because initially he didn't want his partner to be informed, who happened to be a nurse working in the health service. That created a very difficult situation for us. We had to persuade him that his contacts really needed to be informed that he had tested positive.

142. We had a transmission of HIV from a donor in Liverpool and each component made from his blood infected the recipients. That involved a liver transplant recipient and a kidney transplant recipient. He was a bisexual man who had donated during the window period before there was a detectable level of antibodies for the virus. This transmission occurred in 1996 and I recall having to make a big announcement about the infection because it was the first transmission of HIV that had occurred since we had introduced testing and before the tests had narrowed the window period down. That was a donor who knew he was at risk and should have self-excluded.

Hepatitis

34. What was your knowledge and understanding of hepatitis (including hepatitis B and NANB hepatitis/hepatitis C) and in particular of the risks of

transmission from blood and blood products during your time at the YRTC? How did your knowledge and understanding develop over time?

143. When I was a senior registrar in 1971, testing for hepatitis B (or the Australian antigen as we called it then) had already been introduced. Prior to that, hepatitis B had been known as serum hepatitis and it was recognised that it was transfusion transmissible.

144. When I joined the YRTC we had already started testing for hepatitis B.

145. Hepatitis A is an infectious hepatitis, causing an acute infection, which means that those with hepatitis A are unlikely to donate and it is not really regarded as a risk in transfusion medicine because of the history of acute jaundice and acute illness which means we can screen it out with relative ease. Once the host has recovered from the virus there is minimal risk of transmission.

146. At the time I started at the YRTC we were aware of hepatitis that could not be explained by hepatitis A or hepatitis B and this was labelled non A non B hepatitis (NANB) and because there was no test for this, all we could do was exclude all donors who had a history of jaundice. This was the only means that we really had to exclude non A non B hepatitis from the blood supply because we did not properly understand the epidemiology and risk factors at that time.

147. At the YRTC we had our own system of identifying post transfusion jaundice called the *J filing system*, by which, if we received a notification of a post transfusion jaundice, we would do a look back on the donation. One problem we faced is that post transfusion jaundice can happen a long time after the virus is contracted post transfusion and therefore the clinicians did not always realise that it was related to the transfusion and so did not notify the blood service.

148. Most of the discussions about hepatitis were in a forum that I was not involved in.

149. It was in 1989 that Dr Harold Gunson set up the Advisory Committee on Transfusion Transmitted Infections, which was the first time we were taking advice nationally with experts such as Richard Tedder, Phillip Mortimer and John Barbara, who were expert virologists in the field of hepatitis, and who made the recommendations that were relayed to Harold about how we should handle things. I was not party to most of these discussions until I was appointed director of the YRTC in 1988. I was never on the ACTTD committee. Advice from the committee meetings would be cascaded down to the RTDs.

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

150. I recognised my lack of expertise in this particular field, but also recognised its importance and therefore appointed a new consultant, Dr Peter Flanagan, to use his specialist expertise in transfusion medicine and microbiology and transfusion transmitted disease at the YRTC. Peter Flanagan eventually became the medical director of the National Blood Service in New Zealand. I can't recall exactly when I appointed him but believe it was around 1990.

151. Dr Flanagan was very good and he was my Northern Zone Clinical Director.

152. From memory, Dr Peter Flanagan left for New Zealand in around about 1997.

153. At the YRTC we always followed the guidance which came out from Dr Harold Gunson. The exclusion questionnaires that we used to exclude HIV were mostly transferrable to hepatitis (for example, previous IV drug use) and this therefore reduced high risk donors for hepatitis as well.

36. 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?

154. I understood from when I started clinical practice that hepatitis B was a serious condition associated with liver disease and cirrhosis with poor prognostic outcomes.

155. I have vivid memories of using a cell-separator in a famous TV presenter who was in acute liver failure from acquired hepatitis B and was to undergo liver transplant and so I had to exchange his plasma to remove the toxins. I was therefore well aware in the 1970s that hepatitis B was life threatening.

156. Hepatitis A was an acute illness and once the patient had got over it then they no longer carried the virus. There was therefore not much risk of transmission since patients tend to be too ill during the early acute stage to be a blood donor. Hepatitis A is a nasty acute condition which causes inflammation of the liver and jaundice, but once the patient has recovered from the virus there is not usually any long term sequelae or a high incidence of mortality and morbidity. Hepatitis A does not have an association with hepatocellular carcinoma.

157. When I entered the transfusion service in 1971 it was thought that non A non B Hepatitis was relatively mild and often a subclinical infection, without the knowledge that it could carry on as chronic hepatitis.

158. By the time I was a consultant in 1976, non A non B hepatitis was still thought to be just a mild hepatitis not associated with persistent and long lasting infection.

159. I can't pinpoint exactly when I became aware that non A non B Hepatitis was a more serious condition than had been appreciated originally, and I believe that this was a more gradual appreciation over time.

160. I was not aware, for example, of the work that Eric Preston was doing with haemophilia patients in the 1980s. Nor was I aware of the publications and textbooks that Dame Sheila Sherlock was producing on diseases of the liver. This was not in the remit of my specialty. I suspect that it was

between 1986 and 1988 that I became aware that non A non B Hepatitis could have serious consequences. This is why there were discussions about using surrogate testing around this time.

161. I was certainly aware before hepatitis C was isolated that non A non B hepatitis was associated with significant consequences and my appreciation was mainly through discussion with my colleagues, for example at the British Blood Transfusion Society meetings, the Society of Haematology, the Association of American Blood Banks and the International Society of Blood Transfusion. It was through those meetings that I listened to leaders in their field present on the developing state of knowledge of non A non B hepatitis and had an opportunity to talk to these people and my medical peers afterwards, which led to a greater understanding and development of my knowledge around the area.

162. I remember in 1988 / 1989 when the agent responsible for hepatitis C was finally isolated that I was quite excited that we finally had something specific to test for, because prior to that point we only had non-specific surrogate testing.

163. It is very difficult, even with the benefit of hindsight, to pinpoint exactly when I knew what and, as I said above, it was very much a development of knowledge over time.

37. 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% (PRSE0002161). He further noted that "if one assumes that the 2.3 million donations in the UK 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.

164. The figure quoted in the question should read 22,500.

165. I am not certain whether I saw this paper at the time of its publication. I was not director until 1988 and was not aware of the discussions surrounding surrogate testing.

b. Were these figures regarding the prevalence of NANB post-transfusion hepatitis ever discussed by RTC directors? If yes, please describe the general response to these figures.

166. The figures quoted by Dr Gunson seem like an over estimation in my opinion. I am not sure if I had any opinion at the time but was subsequently aware that there were papers showing the actual prevalence of about 0.5-1%

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

167. There was no means of detecting the presence of hepatitis C in donors prior to screening tests becoming available (introduced in the UK in September 1991) and we had limited feedback from recipients of the virus due to the length of time this took to be picked up post transfusion, which meant that there was a lack of association clinically between the virus and blood transfusion initially.

168. My view had always been that surrogate testing, particularly ALT testing was far too non-specific to be of use for general donor screening purposes.

169. I was aware that London areas were likely to have a higher incidence of hepatitis C. YRTC was not part of the initial trials for testing of the first generation HCV screening kits.

General

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

170. With our increase in knowledge of the risk factors, our leaflet and advice to donors regarding high-risk activities gradually changed, for example, to include previous sexual relationships with anybody who had lived in Africa; so when we became aware of risk factors they were then incorporated in our questionnaire donor exclusion criteria.

171. The difficulty with hepatitis C was that we did not really know what the risk factors were. It subsequently became clear, due to the paper I read from Edinburgh where there was a very high incidence of HCV which was linked to drug abuse, that there was an association with hepatitis C and IV drug use, but as far as other risk factors were concerned, these were not well understood and the proportion of HCV from blood transfusion was comparably very low when considered against the number of overall cases in the population.

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

172. When Dr Harold Gunson created the National Directorate he was able to set up the Advisory Committee on Transfusion Transmitted Infections and involve experts like Richard Tedder, Philip Mortimer and John Barbara, so that way we had a national system of getting advice out to the RTCs. I do not recall anything specific to the YRTC, other than my appointment of Dr Peter Flanagan in an advisory capacity on viral infections and the introduction of new testing kits.

173. As far as decision-making and advice goes, advice was certainly given by Dr Harold Gunson, but the autonomy to accept the advice and make the

decision rested with the RTCs and in my case the YRTC. If money was required to implement these decisions, then this had to come from the regional health authority and be incorporated into our budget.

41. What if any role did the YRTC 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.

174. I had a standard lecture called the 'Hazards of Blood Transfusion' which I regularly gave to undergraduates and post graduate meetings, or wherever I was invited to talk: my agenda was a lecture on the hazards of blood transfusion, one of the most important messages being that infections could be transmitted through blood.

175. I used to use a maxim *'the safest transfusion is the one not given'* which would have been in the 1970s.

176. The YRTC had a senior registrar rotation in haematology and blood transfusion. There were usually four on rotation and we always had one with the Seacroft Centre, which is how I started with the YRTC.

177. The haemophilia doctors had greater knowledge as to the risks associated with blood products as they were witnessing it in their patients and monitoring them.

Section 7: Reduction of risk of infections

Donor selection

42. What donor screening processes were in place during your tenure at the YRTC, and how did these change over time?

178. We had a donor team and the team leader at each session together with the sessional medical officer. We had haemoglobin screening and the reception desk. We had a standard questionnaire of looking at donor

health and their past history to identify illnesses which might cause a problem for them or the recipients of blood, travel history to look for things like malaria, and we had a department of donor care with associate specialists who dealt with donor correspondence, queries and counselling.

179. So, there was screening at sessions which was basically a questioning of the donor. The physical assessment of the donors included blood pressure readings and pulse checking. We also checked their haemoglobin with a finger prick test using copper sulphate solution.

43. How were decisions made at the YRTC as to which donors were high risk and should be excluded from donating? What was your role in this process?

180. I would take advice from divisional and national meetings about what should and shouldn't be excluded. Until the A-Z list (a list containing all the conditions that might arise from donor characteristics in order to make a decision as to whether to bleed that donor) and JPAC started, there was some variation between RTCs, but this was discussed at divisional and national level.

181. With the advent of JPAC there was a national route for raising queries so the selection of donors could be standardised.

44. 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? You may find NHBT0020668, paragraph 20 of NHBT0018200, NHBT0016142, NHBT0052209_262, paragraph 3.5 of NHBT0070258, paragraph 3.1 of NHBT0097469_014, NHBT0071771, NHBT0096473_014, NHBT0097469_049 and paragraph 4.4 of NHBT0046958_002 of assistance.

182. I have read all the documents provided by the inquiry in relation to this question from 1986 to 1992 which deal with how we provided information to donors about HIV high risk activities and who should not donate.

183. NHBT0052209_262 is a letter from me to a donor in 1986 who objected to the HIV information leaflets at sessions dealing with high-risk activities. They deal with the issue of sexual activity with an African national and the contentious issue endorsed by EAGA of excluding any male donor who had had sex with another man since 1977 (in other words how we dealt with exclusion criteria as our knowledge of the epidemiology of HIV developed), with the definitive advice coming from the expert advisory group on AIDS chaired by Jeremy Metters, who ultimately decided on the content of the HIV leaflet

184. I don't recall whether we had a leaflet or not at the YRTC. The only nationally agreed and produced leaflet I recall is the leaflet relating to AIDS as mentioned above. Prior to that I cannot remember whether we had leaflets at sessions or whether we just relied on the information taken from interviewing each individual donor.

185. Part of the donor consent form (form 110) included information to the donor about what screening tests were carried out on their blood and that they would be informed of the results. Equally, there was an obligation on the donor to inform us if they developed an illness after donating blood.

Introduction of virally inactivated products

45. What role did you consider the YRTC had (or should have had) in pushing for factor concentrates to be virally inactivated in the late 1970s and early 1980s? In particular:

a. Was the need for safe products raised by you or anyone else at the YRTC with BPL and/or pharmaceutical companies (or anyone else) during this period? If not, why not?

186. The only thing that I am able to recall is that we had liaison meetings between the blood service and the CBLA at which issues like this would have been raised.

187. Once viral inactivation was mentioned it was recognised that this would have an impact on the amount of plasma that we would need to collect; any form of viral inactivation was likely to have an effect on the FVIII yield as FVIII is extremely heat sensitive hence if heat treatment was used the yield of FVIII would fall significantly.

188. I was therefore aware that there was a problem, but aside from raising this at the liaison meetings, the only action that was taken was about donor selection.

189. The driving force from the NBS was to make blood components as safe as they could be. BPL had accountability and responsibility for the final product. The RTCs were simply providing the raw materials to BPL to produce the components. I was concerned with the safety of the fresh blood and blood components that we were supplying. BPL set the standards of what source plasma they would accept and we had to comply with those requirements.

190. To make it clear, I did not have any contact with any pharmaceutical companies whatsoever in relation to blood products.

b. Please consider the minute of the meeting on 18 December 1981 at paragraph 3.2 (CBLA0003298). Why was the need to produce hepatitis free product considered to be an aim for the future, not for the present given what was known about hepatitis in 1981?

191. Jim Smith at PFC Oxford was working on ways and means to inactivate hepatitis viruses during fractionation. As Hep C had not been identified in 1981, he only had Hep B to work with and worked on the assumption that if Hep B could be inactivated then this would also work for other hepatitis viruses, including NANB.

192. Methods of viral inactivation usually led to a reduction in Factor VIII yields and with that the requirements for source plasma went up. That was the predicament we were in; every time a method was introduced to virally inactivate, then the amount of source plasma required went up, which is one of the reasons we did not achieve self-sufficiency, because there was a constant increase in the need for the amount of source plasma and moving goal posts for the raw material required.

Provision of diagnostic screening kits

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

193. This is an area I can't really remember. Dr Peter Flanagan at the YRTC in around 1989 made the arrangements for the provision of diagnostic kits on my behalf. He was the microbiological expert and was heavily involved in which kits were used and how reliable they were.

194. I don't recall any personal involvement with kit supplies or pharmaceutical companies.

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

195. I have very little recall, but my belief is that I did not contract directly with any pharmaceutical companies regarding the manufacture and importation of screening kits, and I left my microbiology expert, Dr Peter Flanagan, in charge of this aspect of the service. The letter referred to is from Dr Gunson to Ortho Diagnostics and refers to a demonstration –

possibly of HCV screening kit. I believe I would have referred this on to Dr Flanagan.

48. What were the key factors influencing choice of screening kit and/or pharmaceutical provider?

196. The main factors were specificity, sensitivity and reliability. Secondary to this would be the cost of the kits. My philosophy, and one I know my predecessor, Derrick Tovey, held was that we should not be dependent on one single supplier.

197. I cannot recall if contracts were negotiated on a national basis, but my belief is that they probably were.

49. 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?

198. I don't have much recall, but when a new machine is installed we have to rely on the manufacturer's instructions on how to use the machine and our technicians have to be educated on its use so, certainly, guidance and training would be required from the manufacturer on how to use and maintain the equipment. Once the machine is installed there would need to be a regular maintenance contract.

Introduction of HIV testing

50. When did the YRTC begin HIV screening?

199. The YRTC began screening, as was implemented nationally, on 14 October 1985.

200. On that date, all of the blood that we released, but also all of the FFP and cryoprecipitate that was in storage was also tested, so anything released on or after that date would have been screened for HIV.

201. This involved the back-testing of all stocks of FFP and cryoprecipitate in time for the start date.

51. Please describe the implementation of HIV screening at the YRTC. In particular:

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

202. The prime method for screening donors was through the AIDS leaflet. My recollection is that we put the leaflet in every call up letter and also had the leaflet available at donor sessions. The logic behind putting the leaflet in the call up letter was that they had time to read this and self-defer if necessary – that is to exclude themselves without attending the donor session.

203. Donors were asked at the session if they had read and understood the leaflet but were not asked direct questions above and beyond that.

204. As for the blood donations themselves, these were all HIV tested after the implementation of screening in October 1985. There was a very low incidence of HIV in the Yorkshire region, so this did not have a great impact on the YRTC.

205. The screening of the donations for HIV takes place on site using an auto analyser using the Elisa test. The process of screening takes under 24 hours.

206. Positive results would go for confirmatory testing. Any positive test was repeated to make sure that it remained positive and then sent to a reference laboratory for confirmatory testing. This was the case for any positive test we had, not just for HIV.

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

207. The introduction of HIV screening had very little impact on the YRTC because of the very low incidence of HIV in the Yorkshire region.

208. If a donation tested positive, then a letter went to the donor asking them to contact a medical officer. They were never told the results over the phone. An appointment was made for them to meet off-site and confidentiality and anonymity was adhered to at all times. We had a trained counsellor called Alison Townley who asked the donor for permission to take a confirmatory test and permission to inform contacts and the GP. There were very strict rules regarding third parties and we could not inform the GP or the donor's partner without the donor's explicit consent. This is an example of the process and logistical impact the introduction of HIV screening had on the YRTC.

209. I remember the first case that was brought to me by Alison regarding a bisexual man who really didn't want his partner to be informed of his positive HIV status and Alison managed to persuade him that his partner was at risk and therefore it was imperative that he informed her.

210. No additional staff were required for the introduction of HIV screening.

211. There was no additional cost because my budget came directly from the region.

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

212. As noted above in response to question 50, all blood from 14 October 1985 was screened for HIV and any blood or blood components that we had in storage were back-tested so that by the time of their release they had been subject to HIV screening.

213. To the best of my recollection when we did the back screening no positives were found.

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.

214. We sent a letter to the donor asking them to contact the medical officer and upheld confidentiality and anonymity. Alison Townley was our donor counsellor who would ask for permission before confirmatory testing and contacting the donor's contacts and GP. The lookback was performed on prior donations. From our lookback records we identified where the donations went. I don't recall ever having to inform BPL that they had had a positive donation from YRTC. We would have to go through the hospital blood bank to find out whether the donation had been transfused and if so to whom. Once we had passed the information on to the blood bank it was the blood bank's responsibility to trace where the donation had gone.

215. There were very strict rules about the notification of third parties so that the patient themselves would be referred to a specialist HIV clinic.

216. It was not the role of the transfusion centre to notify public health, as we were screening for HIV, not diagnosing a patient.

52. In a letter you wrote to Dr Gunson on 8 March 1993 (NHBT0016058), you stated that donors had been attending sessions with the YRTC in order to get a 'confidential' HIV test. How common was this? What were the reasons for this, in so far as you understood?

217. My recall is that in order to try and avoid this situation all HIV screening was simultaneously announced and arranged with PHLS with confidential testing provided by them. The tests were not performed by a GP because if they were it would be recorded in the medical records and this could affect things like life insurance, given that at the time there was no cure.

218. My concern was that blood donation was being perceived as a way to get tested without a record being made in the GP notes.

ALT testing

53. When did you begin the process of ALT testing at the YRTC? You may find the letter at NHBT0000188_158 of assistance.

219. There was an agreement between Dr Harold Gunson and Dr Richard Lane to test all apheresis plasma on 29 January 1990, as it was required for BPL's Intravenous immunoglobulin (IVIG) product licence.

220. The only reason that I introduced ALT testing at that time was for plasma which was going to be used by BPL to produce IVIG and as the method of producing IVIG was gentler than other virucidal processes ALT testing was required to fulfil BPL's EU product licence.

54. How was the ALT testing performed? You may find NHBT0000078_015 of assistance.

221. I used the biochemical laboratory at the Seacroft Hospital in Leeds where I held a joint post with the YRTC. I ran the haematology laboratory there.

55. What impact did ALT testing have on the YRTC? In particular:

a. What was the process for screening donors and/or blood donations? Were the issues you raised in your letter to Dr Gunson (NHBT0000189_028) addressed to your satisfaction?

222. NHBT0000189_028 refers to the issuing of platelet concentrates from platelet rich plasma collections if the ALT was found to be elevated. Because ALT was so non-specific, a donor was not deferred on a one-off elevated result. I recall a paper by Dr Harvey Alter from 1985 which

showed that the incidence of non A-non B in patients did not change in the three years post ALT testing compared to the two years prior to having had it. I was aware that ALT was incredibly non-specific.

223. As far as the process is concerned, this was undertaken by the biochemistry laboratory and I was not involved with this.

224. I can't recall whether the issues raised in the letter to Dr Gunson were ever addressed.

b. What impact did the introduction of ALT testing have on the YRTC?

225. Very little, because this was only undertaken for the plasmapheresis donors.

226. There were additional costs associated with the tests which we had to pay to the biochemistry laboratory at the Seacroft Hospital. There was not a significant number, so the cost was not substantial.

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

227. ALT testing was not being used as a standard screening test so blood, cryoprecipitate and FFP was released as usual, even if it had not been ALT tested.

228. To reiterate, the ALT testing was being used at BPL's request for their product licence – for a specific product - and was not used as a screening test.

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.

229. ALT is a very non-specific test and very variable and can be raised for reasons other than the hepatitis virus, for example, alcohol intake and obesity. A donor would therefore not be deferred on the basis of one raised ALT level.

230. The word 'positive' is quite unhelpful in relation to ALT because there is such a wide range. If ALT was raised significantly above the normal limit, then I would have referred the donor to a hepatologist. If it was just marginally raised, I probably would have ignored it on the first occasion because 90% of the time it tested within the normal range on repeat testing.

231. There is therefore no such thing as a positive ALT test. There is a range and if the results came back outside the range, then I would make a judgement call based on how far outside of the range the result was when deciding whether to take action, in making a referral or ignoring it.

232. I don't recall ever having to contact a donor to ask for their permission to refer to a hepatologist because of a significantly raised ALT level.

56. What were the circumstances in which you stopped ALT testing? You may find NHBT0000027_022 and NHBT0000189_060 of assistance.

233. BPL made a request for us to stop testing for ALT.

234. The documents the Inquiry have provided in relation to this question confirm that ALT testing was only commenced because of BPL's product licensing and was on a small scale for a small number of donors and did not really have any impact.

57. Was there a period before the implementation of HCV screening in late 1991 when ALT testing ceased at the YRTC? If so, did you have any concerns about this? Please set them out and the steps you took to address them.

235. I had no concerns about stopping ALT testing because I did not regard it as a particularly helpful test. The 1985 Dr Harvey Alter paper explains why ALT is not a particularly helpful test when trying to exclude nonA nonB Hepatitis.

Introduction of anti-HCV screening

58. In a letter dated 29 January 1991, you informed Dr Gunson that the YRTC would be able to commence anti-HCV testing from the "beginning of May", provided national financial arrangements were in place (NHBT0016205). Why did the YRTC not commence testing from the beginning of May?

236. The YRTC did not begin testing in May because we were a national organisation and I was informing Dr Harold Gunson when we would be able to start, but from what I can gather, the purpose of Dr Gunson's request was to establish when all of the regional centres would be able to start, so that we could have a uniform start date.

237. I did not start testing because I was behaving as a member of a national organisation.

238. In order to commence testing we required access to the kits and potentially a new auto analyser machine. I can't remember precisely whether a new auto analyser was required.

239. I agreed with Dr Harold Gunson in wanting a nationwide start date with recommended second-generation test kits, in relation to which the YRTC was part of the pilot for testing those kits.

240. It also needed an agreed standard protocol for dealing with positive donors and donations, so we started using second generation test kits in May 1991, as part of a trial process and working out what the protocols would be. So, whilst we were testing it was more on an evaluation basis than a live basis.

241. In some ways, it was a staggered start as more centres began to join in the second-generation testing. This carried on until the start date of September 1991.

242. The first-generation tests brought up as many false positives as true positives in people, so were not a helpful test in terms of screening for Hepatitis C.

243. Overall, the reason why I did not start testing on my own at the YRTC was because we were part of a national service and I followed the guidance issued by the Department of Health and Dr Harold Gunson. As it happened, I was able to begin testing earlier in fact, because I was part of the second-generation screening trial.

59. In a draft statement intended to form part of the *A and Others* litigation, you stated that the YRTC began screening for anti-HCV on 20 May 1991 as part of the "multi-centre trial assessing the second generation tests" (NHBT0000234_001). There is a note on the draft querying whether this date is correct. Please confirm:

a. the date on which the YRTC began testing as part of this trial;

244. The document provided in respect of this question NHSBT0000234_001 has the relevant part missing. I therefore can't confirm whether the date is correct but from this document It looks like we started screening on 20 May 1991

b. whether the trial incorporated all donations made at the YRTC and, if not, what proportion of donations were screened and how were these selected; and

245. As far as I can recall we included all donations.

c. whether arrangements were put in place for counselling of patients who tested positive under the trial (you may find NHBT0034922 and NHBT0033635 of assistance).

246. I assume this question is a reference to donors rather than patients.

247. I can't recall precisely, but my belief is that if we were testing and found a positive result then I would put in arrangements for counselling those donors to include referral to the GP for onward referral to the regional liver units.

248. In my draft statement for the case of A v NBA [NHSBT0000234_001], I note that in the run up to the introduction of HCV screening, we arranged for information and counselling from leading liver specialists in the region to be available for donors. With my agreement, Dr Flanagan wrote to consultant hepatologists and gastroenterologists and asked if they would be willing to see and counsel donors who were identified as HCV positive.

249. I further note that Dr Flanagan also wrote to the Regional Health Authority to clarify the position on funding for donor counselling. After national screening had commenced, Dr Flanagan wrote to Dr Gunson providing information on how we dealt with donor counselling and referral. He refers to standard letters that appear to have been in use.

60. Was the trial concluded before 1 September 1991? If so, did the YRTC continue to screen donations or did it revert to using unscreened donations?

250. My recollection is that once we started second generation screening in May 1991, we did not stop to await the national start date of screening in September 1991.

61. A week prior to the commencement of screening at the YRTC, Dr Gunson wrote a letter to you in which he stated that by agreeing to take part in the extended trial, you "helped to avert a very difficult situation" (NHBT0033630_001). Please explain the "difficult situation" referred to by Dr Gunson.

251. I presume this letter refers to Dr Huw Lloyd in the Newcastle RTC and his decision to commence testing earlier than the proposed national start date of September 1991.

252. This is a difficult situation with one centre acting out of sync with the other centres, some of whom had an inability to commence testing earlier than the proposed and agreed start date of September 1991.

253. In my draft statement in the case of A v NBA [NHSBT0000234_001] I note that it was highly improbable that the RHA would have allowed YRTC to act against national consensus and the advice of ACVSB and ACTTD.

62. 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). Did you agree or disagree with Dr Gunson's suggestion to delay testing to undertake this comparative evaluation? Please explain the basis for your answer.

254. I agreed that there should be a second round of evaluation to include all available kits.

255. I do agree with Dr Harold Gunson's suggestion that we needed to do a comparative evaluation and that we needed more than one reliable kit available to use and would be using different kits and different combinations to see which kits/combinations were most effective.

63. In response to Dr Gunson's letter, some RTC directors suggested a staggered start date for the implementation of testing (i.e. different start dates for different RTCs) while others supported a uniform start date. Which view did you take? Why?

256. I wanted an agreed start date, but in reality it was a staggered start date because of the second round evaluation of the test kits: some RTCs were already testing by the time the uniform start date of September 1991 arrived.

257. The reason I was in favour of a uniform start date was because there was a directive from the Department of Health and we were a national service. I was obedient in carrying out the recommendations from the Department of Health and the national director; but as set out in paragraph 33 of my draft statement in A v NBA, I believed that all patients in England were entitled to receive the same service.

64. 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 agree or disagree with Dr Lloyd? Please explain the view you had at the time.

258. Dr Lloyd began testing in April 1991. At the time I disagreed because I felt it was important that we acted as a national service and some centres were not ready to begin testing on that date. I felt that we should follow the advice of Dr Harold Gunson and the Department of Health.

b. Why did you express dismay at Dr Lloyd's decision at the meeting on 13 June 1991 of blood transfusion consultants (NHBT0071757)?

259. My expression of dismay was probably because we were failing to act as a national organisation and with fairness to all patients.

c. Have your views changed since then? If so, why? You may be assisted by (NHBT0000076_009) and (PRSE0001183).

260. I would not have wanted to start testing whilst there was uncertainty about the accuracy of the testing kits and I was sure that I could inform a donor correctly of their status.

261. I maintained that it is preferable to have a national start date and agreed position and, nowadays the situation would not happen because there is truly a national organisation with NHSBT, where all regions are in the same position and things are automatically introduced uniformly at the same time.

262. I can see with hindsight that some infections would have been prevented with earlier screening and of course I would want to have prevented these.

263. There must be some focus on the donors as well as on the potential recipients. Without donors there is no blood service. The actions of donors are entirely altruistic and not for their own benefit and there is an aspect of collateral damage when something like screening is introduced because it will have an impact on the donors to whom, as a service, we owe a duty of care. If we introduce something that is going to have an impact on them, we are their only champions and, for example, telling a donor that they are hepatitis or HIV positive when they are not because of a failure in the sensitivity and specificity of a test is highly damaging to that individual who is receiving no benefit whatsoever from donating their blood.

65. In response, the Department of Health wrote to senior government medical officers on 9 May 1991 notifying them of the Northern RTC's decision and providing them with a "line to take" if there was press interest in the matter (NHBT0000062_060). The Department of Health recommended advising the press and other interested parties that "the risk of [HCV] being contracted through blood transfusion...is remote" and that anti-HCV screening should only be implemented once "the screening kits had been adequately assessed." The Department of Health also recommended advising that HCV "is normally a mild infection (not like AIDS)." Did you see this document at the time or were you otherwise aware of the Department's position? If so, did you agree or disagree with these statements at the time? Please give reasons for your answers.

264. I believe I was made aware of this document through Dr Harold Gunson. The concern for the NBTS was the rate of false positives and equally false negatives.

265. The Department of Health document referring to the 'line to take' describes Hepatitis C as *'[a disease that] may run a symptomless course, but in some cases it can result in chronic liver damage which may ultimately be fatal. There is also a rare but serious acute form of illness'*. I agreed with this statement. My view has not changed.

266. This was a line to take. I was not compelled to take it and the full description in the document refers to the disease having links to chronic liver damage that may ultimately be fatal, which was known by 1991.

66. What impact did HCV testing have on the YRTC? In particular:

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

267. I am unclear whether this question relates to the screening of donors at the session or screening tests performed on their blood. It is worth saying that the exclusion criteria put in place for HIV had removed the vast majority of donors who were also at risk of hepatitis C. A lot of the screening that we did at the time, particularly around IV drug abuse would have screened out and excluded hepatitis C carrying donors. Other than that, there was not a great deal we knew of factors at that time which made individuals susceptible to hepatitis C. The HIV leaflet that we sent out to donors during call up, and also handed out at the sessions, excluded most of the known risk factors for both hepatitis C and HIV. There was no individual leaflet for hepatitis C, but reference to it was introduced later on into the AIDS leaflet. In addition, as I understand it, Factor VIII was heat treated from 1985, which effectively eliminated the risk from that source.

268. Hepatitis C is endemic in the community but there was less knowledge about how it is spread and only a very small percentage is caused by a blood transfusion.

269. The processes for screening the blood donations in themselves were undertaken in the microbiology lab at the YRTC.

b. What impact did the introduction of HCV screening have on the YRTC? You may find it helpful to consider the letter you wrote to Dr Gunson dated 23 December 1991 in which you stated that no additional funding was provided to support the introduction of anti-HCV testing in Yorkshire (NHBT0000193_095).

270. When a new test is introduced for blood donations then there is always a cost recovery associated with this. In the Yorkshire region budgets had already been devolved from the YRTC to the hospitals so we were able to recover costs by putting the cost of the HCV screening onto the unit price of the blood and blood products, so the region actually covered the cost. I was therefore able to implement the screening without too much difficulty in terms of cost recovery.

c. What happened to all the unscreened blood that had been collected prior to the HCV testing being implemented? You may find point 7 of NHBT0000066_031 of assistance.

271. If the test was negative on the confirmatory test then it could be released because it could be recorded as HCV not detected, i.e. suitable for use. This is what document NHBT0000066_31 is referring to. I think there has been a misinterpretation of what I am saying; I am not saying that the blood is unscreened. It was screened and although there was an initial reactive, it was negative on confirmatory testing so was screened and found to be safe for issue and release.

272. If a positive result was found on confirmatory testing, then blood and products made from that blood would be discarded.

273. Because the YRTC started testing in May 1991 by the time national screening of blood for HCV was introduced in September 1991 there were no stockpiles of unscreened blood for release.

274. So, in answer to the question by the time HCV screening was introduced in September 1991 there was no unscreened blood at the YRTC.

275. FFP and cryoprecipitate can be held for up to two years; although the shelf life is 2 years most of our stock would have been issued and used within 3 months. I do not believe that we had any that was unscreened by the time of introduction of screening in September 1991 because we had been screening since May 1991. I can't recall if we back-tested, as we had with the introduction of HIV screening. With stock rotation it was unlikely that we had anything in stock that was two years old.

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.

276. If a confirmatory test was positive the donor was notified. All products made from that blood were not released and would have been discarded. My recollection is that we notified the donor face to face and then referred them to their GP who would in turn refer them to their local liver unit.

277. As with HIV we upheld the utmost donor confidentiality and would not take steps to notify other parties without the donor's consent.

e. Please consider point 12 of NHBT0097469_014. Were you there suggesting that rather than telling a donor who is HBsAG and anti-HIV reactive of this, you would (to avoid the cost of counselling) continue to take their donations and dispose of them? If not, please explain what you were saying. What was your practice in those circumstances?

278. Document NHBT0097469_014 at point 12 is concerning the re-admittance of apheresis donors who are HBsAg and anti-HIV positive to the panels which I do not understand because anybody who had tested positive for these viruses would not have been re-entered, so my suspicion is that this is referring to previous false positives or to a new algorithm for re-entry?

279. I can be certain and make clear that there is no way that I would have carried on bleeding a donor and not told them of their HBsAg or HIV status as this would be unethical. In any event, I would not be bleeding those donors in the first place if they had returned positive results.

280. I don't understand this minute and it is unfortunate that this was not queried at the time, because I don't understand the context of what the minute is saying on the face of it, but I can say with certainty that people who were HIV positive were told, and I would not have bled these donors. They were never re-admitted to the panel.

Anti-HBc testing

67. On 17 June 1993, you wrote to Dr Harold Gunson with the recommendation that anti-HBc testing be introduced "as soon as is practically feasible" (NHBT0006078). Please explain how you came to form this view, including reference to any medical studies or other scientific information.

281. Having read the letter to Dr Harold Gunson, I had had a case of a possible post transfusion Hepatitis B that was HBsAg negative, but HBc positive and I don't recall it specifically, but my belief is that the HBV antigen test wasn't specific enough then to pick up a recent HBV infection. This is the background to why I wanted to start using anti-HBc testing.

282. I note that I say in the letter that we would be able to fund it out of revenue savings and that we would be unlikely to get extra funds from the region. I also referred to it being 'another hot one' for Dr Gunson, which suggests I did not expect it to be straight forward.

68. On 8 October 1993, Dr Gunson informed you by letter that a decision had been made by the Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation not to introduce HBV testing (NHBT0006053_001). Were you able to implement the testing in light of Dr Gunson's letter? If not, why not?

283. I presume the question intends to refer to anti HBc testing. The letter refers to a decision not to introduce anti-core testing for HBV, rather than not introducing HBV testing. We were still testing for the surface antigen for HBV – HBsAg.

284. In light of MSBT expert advice, I did not introduce anti-HBc testing in addition because of the frequency of false positives and because there was no satisfactory gold standard and there was debate at the time relating to the presence of anti HBs, as that was thought to mean the donor was unlikely to be infective.

285. Overall, regarding anti HBc testing, I was prompted by the particular case that I had, but then was advised by the experts at the MSBT, and took their advice, that it would not be a good idea to introduce anti HBc general testing.

Increasing cryoprecipitate production

69. Please explain what consideration the YRTC 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.

286. I don't recall there being a big increase in demand, but I was aware of the requirement for all 'virgin' haemophiliacs (i.e. those newly diagnosed haemophiliacs or those who had had no previous treatment) to be treated with cryoprecipitate. I cannot remember the date of this advice, but I believe this was around June 1983.

287. What I did was to make sure that the cryoprecipitate that they received was from a second time donor so that the donor would have been tested twice before products were released. As far as I can recall there was not a great increase in demand, but nevertheless we made preparations to supply it if requested.

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

288. Production of cryoprecipitate would have been increased in response to regional demand from the haemophilia directors and I don't recall there being any difficulty in the YRTC's ability to meet this demand.

289. Essentially, the YRTC was able to produce the cryoprecipitate that it was requested to do. If there had been a request to switch everybody to cryoprecipitate then we would have done our best to meet this demand, but there would have been an impact on plasma for other NHS plasma products and it would have taken time to switch over production of capacity to meet the demands for cryoprecipitate. If we had to switch totally to cryoprecipitate then there would have been no source plasma for NHS BPL Factor VIII production, as all of our resources would have gone to producing cryoprecipitate.

General

71. Please describe all other steps or actions taken at the YRTC 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.

290. I was director from 1988 to 1994. The YRTC was already testing for HBV prior to my tenure and this testing commenced in 1972. We started testing for HIV in 1985. We began anti-HCV testing as a pilot in May 1991 and officially in September 1991. The YRTC had been testing for Syphilis for as long as I can remember, and certainly before I started there. We prepared cryoprecipitate from repeat donors and tried to supply platelet concentrates, again from single repeat donors using apheresis. We updated donor selection criteria as advised by Dr Gunson and SACTTI (and following the Red Book Guidelines).

291. In other words, the YRTC did all the things we were advised to do and kept updated.

72. 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?

292. No. I never felt as director that I was constrained by cost, time or staffing, or anything else for that matter with regard to blood safety. If Harold Gunson, or through him the ACVSB or MSBT or SACTTI, advised a particular safety measure then I was able to implement this without constraint.

293. I have to say that the Yorkshire RHA was particularly good with funding and I never felt constrained by my budget. I had a business manager who assisted with budgets. Sometimes I would be involved in writing an application for funding, for example, if it was for something new, but otherwise my business manager (Tony Heywood) would take charge of this aspect of the YRTC. That would happen without my knowledge or support.

294. I was guided by experts on what would be wise to introduce to ensure the safety of blood and blood products and recommendations came through Dr Harold Gunson or the transfusion transmitted infection committee, but I did not take individual action off my own bat. I was constrained in the sense that if Dr Gunson and the safety committee did not advise something then it would be difficult for me to persuade my region that it was the right thing to do, for example, with anti-HBc testing. Ultimately, I took the advice of the experts on these issues.

73. How did the desire for consensus across the RTCs impact efforts to achieve blood safety at a local level?

295. I suppose in some ways the service operated at the rate of the slowest. The difficulty we had was that if some centres introduced a measure first then there was an inconsistent approach and no consensus across a national service, so some people would be potentially at an advantage

by virtue of the region they were in against others, and if there is not a consistent approach then it allows those centres which are slower for whatever reason to act out of line with those centres who are quicker. Essentially, by introducing things on a consistent basis we were seeking to avoid a postcode lottery and ensure equality for all users of the service. Dr Harold Gunson could only recommend, he could not enforce, nor did he have any power over budgets and my understanding is that the main constraint when introducing new measures was the costs associated. Some regions struggled with this more, but this was not an issue, as explained above, for the YRTC.

296. This is a problem that is not faced with a truly national service. At the time we were doing the best that we could with what was available to us.

297. There was a variation in preparedness and readiness for the introduction of anti-HCV testing and that did have an impact, but equally the difficulties in determining the sensitivity and specificity of the available screening tests also had an impact. The need for secure confirmatory testing and systems to counsel the donors was essential, so it was not just a case of not being prepared and ready enough, there were issues around the tests themselves as to why we did not start earlier.

74. To what extent were you and other RTDs reliant on the decisions of other bodies (advisory committees, directorates, NBTS, DoH) to achieve blood safety? Who or what was responsible for defining what constituted safe blood? What happened if your own opinion conflicted with the decision or advice of that person or body?

298. We were reliant on the advice of other bodies, such as advisory committees. The question refers to the NBTS but at the time we were not a national blood service; we were a disparate group of RTCs operating on a feudal basis. When I started, the National Directorate was in existence and we had the divisional set up and I was very reliant on experts in particular fields and, specifically, transfusion microbiology.

299. Dr Harold Gunson and the advisory committees such as the ACVSB were responsible for defining what constituted safe blood with the backing of the Secretary of State. This was then exercised through Dr Harold Gunson who had influence on the rest of the transfusion service, but could only advise and not enforce.

300. If opinions conflicted, then these were settled through debate and input from the appropriate experts. If you disagreed, you took it up with the appropriate authority rather than going on to do your own thing in my belief. If there was a significant disagreement, I could ask for my name to be removed from the report / advice, but I would still abide by national policy.

301. I was very much reliant on advice from my local expert on microbiological safety for blood and input and output of SACTTI, public health, university virologists and the ACVSB, but would not introduce a new screening test unless approved by SACTTI and the ACVSB following expert debate and scientific data including exploration of the impact of introduction on donors and recipients. If my opinion ever differed this was resolved through scientific debate and evidence-based studies.

75. 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.

302. I do not agree with the concept of 'maximum benefit at minimal cost'. This is not how the blood service worked. I understand how Professor

Contreras has expressed this in her letter, but I do not agree that this is how we approached the safety of blood.

303. It was not a case of minimal cost. We had to do a cost benefit analysis when something new was to be introduced, but the concept of maximum benefit at minimal cost is not how I would express this.

304. If a new test was required then it was introduced in the most cost effective manner possible, for example through national purchasing and contracts for cost of kits etc. More important was the balance of risk on donors and recipients and that was dependent on the sensitivity and specificity of tests and means of confirmatory testing.

305. When product liability legislation was introduced, I felt a huge sense of relief because if there was a fault with the product then those recipients would no longer have to prove clinical negligence and would receive compensation even though there was no fault of our own.

306. There was a shift around the time of vCJD when the concept of the 'precautionary principle' was introduced. At that stage we were doing enormous things at great cost which we had not done before.

307. I recall during a TV interview in which I had to talk about the introduction of white cell filters to try to remove the protein that was responsible for the transmission for vCJD and it was felt that it might be concentrated mainly in the white cells, but we could not really prove that. Nevertheless, to introduce filtration it cost £20 per filter across 3,000,000 blood components, which drastically increased the price of blood and blood products, but we did it anyway so the real shift in the way we behaved was when we were dealing with something like vCJD.

308. The precautionary principle came into the language through the public's perception of risk, which developed and changed over time.

309. I recall our Chief Medical Officer, Dr Ken Calman, having to announce the first ten cases of vCJD around 1995 and at that point the public's

perception of risk was a lot different from during the 1980s when cases of AIDS were announced. We didn't know whether vCJD was transmissible by blood, but we had to act on the basis that it was, which led to the UK ceasing the use of home recovered plasma.

76.If you do agree

a. When, in your view, was this shift made?

310. The concept of the precautionary principle came into our language in around 1995 when vCJD was announced.

b. Who was responsible for the original policy and who for the change in policy?

311. The Chief Medical Officer, Dr Ken Calman.

c. What caused the change to occur?

312. The catalyst was vCJD in around 1995.

d. What is your opinion of the merits of cost-benefit approach to blood safety as against the latter approach?

313. There is always a cost benefit approach in healthcare and sadly nothing in healthcare is the best it could possibly be as every treatment carries a risk, even with all the funding in the world and as there is never enough money for every possible treatment, inevitably choices have to be made.

e. Was the introduction of anti-HCV testing affected by this prior approach? What about other transfusion transmitted infections?

314. No, it was not. The introduction of anti-HCV screening was mainly affected by the problems with the test kits rather than financial factors.

In the case of HCV, we had been battling with nonA nonB Hepatitis for a long time so the arrival of a screening kit meant there was no debate about whether this should be introduced, but rather making sure that we had the right test kits and all the measures in place necessary to begin screening. You have to carefully consider the impact on the donor and the recipient of introducing anything and what, if any, collateral damage may be caused by the introduction of testing, which must be dealt with.

Section 8: Services for donors

77. In the draft statement intended for the *A and Others* litigation, you stated that you had "always held a strong view that the [Blood Transfusion Service] has clear obligations to its blood donors", that you "favoured counselling of donors being undertaken by RTC staff" and that you made various efforts to ensure that funding and procedures were in place in your region for the counselling of infected donors (NHBT0000234_001). As to this:

a. What counselling was offered to donors prior to (i) ALT testing, (ii) HIV testing (iii) HCV testing and (iv) HBV testing taking place? Please describe the process.

315. i) ALT Testing – this was only ever done at the request of BPL for their blood licence with a view to supply of a particular product into Europe (they didn't ever actually supply it as far as I am aware). I never had a case of ALT testing where I had to do anything about this because on repeat testing it was within normal range.

316. ii) HIV – We had a properly set up system with a whole department dedicated to donor care with four associate specialists who dealt with all the donor correspondence and communication with any donor who was positive and followed the guidelines very closely, in that they were interviewed off site following being given a letter to contact the donor

service team at their regional transfusion centre. The term 'counselling' is however, not strictly correct, as we were acting more in an advisory capacity, telling the donor what was wrong and then referring them on to a third party at the STD clinic in the case of HIV. I was very keen that the first contact was from us because we had done the test and we had to tell them it was positive and advise them what to do next. Dr Alison Townley and Libby Williams, Beryl Scott and Susan McNichol were my associate specialists in donor care.

317. iii) HCV – this was the same set up as for HIV testing and counselling, except that rather than referral being made to the STD clinic, referral was made to the regional hepatology department. I recall that Dr Peter Flanagan and myself did a lot of work with the hepatologists in the region to make sure that they would accept hepatitis C positive donors and that we could refer them onwards.

318. iv) HBV –We did have one case identified through a post transfusion patient with jaundice and the implicated donor was anti-HBc positive but HBV negative so this donor would have been counselled and referred on to a hepatologist. Once HBV screening had been introduced these cases were very rare.

b. What counselling and psychological services were available for donors who tested positive for hepatitis or HIV? Were such services delivered by YRTC or were referrals to other agencies made? Please describe the process. You may find NHBT0019492 and NHBT0009664 of assistance in answering this question.

319. We did not provide any psychological services at the YRTC. As I said above, counselling is not the correct term in the sense that the word is commonly now used. We were acting in an advisory capacity. There was no long term or ongoing therapeutic relationship as we would understand counselling to mean today.

320. We delivered the initial advice but then referred the donors to specialist agencies who were experts in that particular field and who were able to offer a true therapeutic counselling service for conditions such as HIV and hepatitis.

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

321. We do not have direct contact with recipients.

322. If a positive test was picked up, then all products were withdrawn and no recipients received the products.

323. With HIV, for example, there was a look back and if previous positive donations were picked up then we had to locate when they were given and where they were sent and inform the hospital blood bank. The hospital blood bank would then trace the blood / blood products through their records to inform and notify the prescribing clinician, so we did not really have direct contact with the recipient.

324. We were very reliant on the chiefs of the blood banks and local haematologists in following up and locating the clinician responsible for giving the products.

325. Hepatitis C was slightly different as there was a more established process where the blood service consultants ended up having a much greater involvement in informing recipients when their consultants / GPs declined or failed to assist. I have described this process in detail in my earlier statement in response to the lookback Rule 9 request.

d. Was this sufficient in your view? If not, why not?

326. The insufficiency would have been the ability of the blood bank to trace which patient actually received the blood, which was the downfall of the

process discovered when we started the HCV lookback. Hospital records were the main insufficiency when it came to locating recipients of blood and blood products.

Section 9: Information handling by and information sharing between RTCs

78. Please describe the record keeping system in place for blood donations and blood donors at the time of your directorship of the YRTC. In particular, please explain what records were kept, in what form, where and who had access to them.

327. We had a whole department for donor records at the YRTC. We held card records called 101 cards which, I believe, were used universally across all RTCs. I remember vividly that these cards were coloured depending on blood group. They were kept in a huge rolodex and were kept locked away in the records department.

328. When I took over as director, we introduced computerisation which was a major challenge because all the records had to be transferred onto the computer system and we had to employ extra staff to do this. The computer system we used was the Welsh Consortium which my business manager, Tony Heywood, masterminded. At the beginning we were hopeful that all the RTCs would join this consortium, but in the end it was just Cardiff, Cambridge and Yorkshire with the other RTCs introducing their own IT systems.

329. I became director in 1988 and appointed Tony Heywood as business director in 1989. I believe it was around 1990 when we became computerised at the YRTC.

330. Those paper records which were transposed onto a computer were then, I believe, archived. I don't believe any records were destroyed.

331. We had an administrator in charge of the records who would deal with call up to sessions. In terms of looking at the details in the records that would be the donor care department and the associate specialists. Any of the consultants could have access to the records if necessary.

332. At the donor sessions, I believe that the 101 cards went to the sessions and then came back to the donor centre with the blood. The cards were stamped with a number for each donation that the donor gave.

333. When the transfer to a computer took place, we had an algorithm for lapsed donors who had not donated for, say, five years plus and they were not transferred onto the computer system.

334. The 101 cards contained the donor's name, date of birth, address and blood group.

335. Any correspondence or complaint from a donor would go to the donor care department with the donor 101 card and a letter attached and we always obtained the donor's permission before contacting a third party such as a GP.

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

336. I do not believe that the records were ever destroyed. Once the paper 101 cards were transferred over to a computer, I believe the old cards were archived.

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

337. As far as I recall, records were never destroyed. I would have followed any healthcare guidelines about the standards and timescale for record keeping.

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

338. I believe the 101 card was standard across all RTCs. How this was stored and accessed probably varied.

82. Do you consider that the record keeping measures in place at the YRTC were adequate to prevent donors who were suspected of carrying blood-borne infections from continuing to give blood donations at the YRTC and at other centres? Please give your reasons.

339. Donors either were or were not carriers of blood borne infections. We did not 'suspect' donors. We questioned and tested them and if they were excluded or on testing shown to be carriers of blood borne infections then they were taken off the donation register, and any donations were not used. If we suspected a donor of having a problem, then they were either refused for having not passed the health screening process or a donation was taken and was tested and if shown to be positive the donation was not used, and that donor was resigned from the donor database.

340. If a donor having been excluded from one centre decided to try and donate at another centre, they would be faced with the same screening and testing and be picked up independently by that centre.

341. Because the service relies on altruism, there would be no financial or other incentive for a donor who had been excluded or removed from a panel in going to donate at another centre.

83. In a memo dated January 1991 from Dr Contreras to Dr Barbara and Dr Brennan, reference is made to a proposal for an "anti-HCV database" (NHBT0000052_016). Please answer the following questions regarding this database:

a. Were you aware of this proposal for a database? If so, how did you become aware of it?

342. I don't believe that I was aware of this proposal. I do not have a background in transfusion microbiology and did not get involved in these things until I became national director. If anybody in my centre had been involved it would have been Dr Peter Flanagan, but I do not recall him mentioning it.

b. Who proposed the creation of the database?

343. The document referred to suggests Phillip Mortimer proposed the database

c. What was the intended purpose of the database? How was this to be achieved?

344. I believe it was to establish the incidence of hepatitis C positive donors and what the rate of positivity was and how that evolved after the commencement of testing.

d. What data were RTCs expected to contribute to it? Were all RTCs expected to contribute data to it?

345. I presume that it was to pass on the data of any positive case we had, but this was an assumption because I was not involved in the proposal.

e. Were you involved in the proposal for the database? Can you recall how the proposal was received by other RTC directors? What did you think of it?

346. No, I do not believe I was and I cannot recall how it was received by other RTCs.

347. In document NHBT0000052_016 Dr Contreras suggested that it could be run from Colindale by Dr Barbara or by PHLS.

f. Was the database ever created? If no, why not?

348. I do not know. The only database I was involved in was set up with joint involvement with PHLS for recipients who were HCV positive and assumed to be 'virgin' recipients (i.e cases with a known start date of infection) of blood or blood products and that was established for very particular reasons to look at the natural history and progression of hepatitis C.

349. I believe every centre kept a record of how many cases of hepatitis C they had.

g. If yes, who was responsible for overseeing the database?

350. I do not know but believe that this would have been Dr Harold Gunson.

h. As far as you are aware, does the database still exist?

351. When we began national computerisation in around 1997 using PULSE the data was readily accessible nationally on the computer system.

352. I was involved in the HCV look back database, which is still in existence.

353. I have discussed, in my response to the look back Rule 9, my work in relation to the lookback database and establishment of the register.

84. 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 this database? If so, please answer the following questions regarding this database, as far as you are able:

a. Please describe the J donor system

b. The use of the word "re-introduce" implies that the J donor system was operational from an earlier date until its operation ceased. When was the J donor system first introduced, and why did it stop operating?

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

d. What was the intended purpose of the J donor system? How was this to be achieved?

e. What data were RTCs expected to contribute to it? Were all RTCs expected to contribute to it?

f. Were you involved in the proposal for the re-introduction of the database? Do you recall how the proposal was received by other RTC directors? What did you think of it?

g. What was the purpose of the database and what information was it intended to collect?

h. Was the J donor system widely used after the "re-introduction"? If not, why not?

i. If yes, who was responsible for overseeing the database?

j. As far as you are aware, does the database still exist?

354. My response below covers all the subsections to this question.

355. This was an internal memorandum unique to the Manchester RTC. At the YRTC we had our own system likened to this called the 'J file' which was originally a system whereby if you were notified by a clinician in the region that someone had developed what they suspected was post transfusion jaundice then that information went into the J file and, where possible, you would try to identify all the donors who had provided a donation which that recipient had received.

356. There would have been some sort of algorithm whereby if that donor re-appeared to donate and was flagged up as a J file donor, they would have had more extensive testing than the standard screening.

357. Because post transfusion jaundice doesn't happen immediately after the transfusion, it was rather uncommon for clinicians to make the link.

358. My reading of NHSBT0005388 is that this is an internal memorandum as to how the Manchester RTC is going to deal with computerisation with J file [donor] cases.

359. To my knowledge we never stopped using our J system, but with the introduction of computerisation this required a new method of dealing with it. It was not a case of re-introducing it, but simply adjusting the computer system to deal with it.

85. In addition to the database(s) mentioned above, did the YRTC 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 YRTC used to share this information, if any.

360. We did not formally notify other centres about any positive donors we had, we resigned them from the panel. Until there was a national computer database, that particular donor would only appear in that centre's records.

361. However, any donor that posed a risk would have to go through the same screening processes at each centre. It would therefore require a donor to be not honest and deliberately malicious when answering the exclusion questionnaire and pre-screening questions, having already been excluded from one centre in order to give a donation at another centre, and assuming that there was no screening test in place to objectively test the blood, which does not rely on information obtained from the donor.

362. The reason the service is so keen on voluntary as opposed to paid donation is because there is no incentive not to tell the truth. We were reliant to some extent on the honesty of donors, and this has proved a

robust method of maintaining the safety of nationally recovered blood. This is all part of an altruistic voluntary blood donor system.

363. To answer the question, we did not routinely share information unless we knew a donor was moving to a particular area then we would transfer their records to the local RTC; and we were reliant on our screening processes to defer that donor if they went to another centre.

86. In his statement to the court 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? If not, what if any steps did you take to address this?

364. Yes, I agree with the view expressed by Dr Harold Gunson that there was no central organisation to ensure that all RTCs operated in a uniform manner.

365. With respect to the sharing of information between centres, I refer back to my response to question 82 and 85. What I would add is that if there were blood shortages at one centre, I might send some of our blood, for example, to Sheffield, or we might obtain some from another centre and then if it subsequently came to light that there was a problem with one of the donations we shared, then I would always inform that centre.

87. Please describe the process (if any) of obtaining the consent of donors for:

a. The sharing of their information with third parties. Did this change over time? If so, please give details.

366. As far as I recall, it is the case that we did not share information about donors with any third party without their express consent. That includes

the donor's GP, and the GP name and address was not usually contained on the donor 101 card so we would need to obtain this information directly from the donor with their agreement.

367. This even applied to police enquiries, because often I would get police enquiries on the off chance that I would give them the blood group of several donors so they could exclude them for whatever reason. I refused to do that unless the donor consented.

368. Donor confidentiality was paramount (and I believe still is today) in allowing the donor to have faith in the blood donation system. Our donor base is precious, so we do not share the information with anybody.

b. Testing for HIV and hepatitis. You may find NHBT0007423_004 of assistance.

369. The document referred to in this question, highlights difficulties where there is a language barrier, and an interpreter is required. It is not possible to rely on the answers given where an interpreter is involved because there is a higher chance that a donor will lie or withhold information due to having to speak to a third party to translate the information. We have a similar position with people who are deaf. Given the questions we were asking there would be a deterrent to a particular person telling the truth if they were having to give that information via a third party.

370. We had to make sure that we got direct consent from the donor and not through a third party.

371. The process of testing for HIV and hepatitis is explained to the donors verbally at the session, that this testing will be done and that they will be informed of the results and when they sign the donor consent form, they are consenting to having this testing performed on their blood and acknowledge that they will receive the result from the centre.

Section 10: Meetings of various committees

Meetings of Regional Transfusion Centre Directors

88. The Inquiry understands that you attended the final meeting between the Directors of RTCs which occurred in January 1989 (NHBT0018188). What do you consider to have been the purpose(s) of those meetings?

372. By the time of that meeting the National Management Committee had already been established by Dr Harold Gunson in December 1988. A general agreement that the RTD meetings would be dissolved was reached because Dr Harold Gunson's structure would take over in terms of communication and direction.

373. With 14 RTDs meeting, it was not the best forum for discussing policy and strategy because there were too many people with too many different opinions to get anything resolved at the meetings.

374. The RTC meetings were dissolved by agreement to be replaced by Dr Gunson's National Management Committee to organise a better way of proceeding.

375. It was decided that we would have a regional directors' meeting once a year on a scientific topic and I can tell from the minutes that those meetings did take place and topics were picked up such as medical audits.

376. The purpose of the RTD meetings was to provide a forum for the Department of Health to control what the RTCs did, and for consistency, and to share information and allow debate. Dr Harold Gunson was the Department of Health Advisor and the meetings were the Department of Health input into the policy of the transfusion services. It was a forum where we could put forward ideas and suggestions but there was no real

way of getting the consensus, given the number of people and conflicting opinions involved.

89. Please explain, as far as you are able, the decision-making remit of the group. Were the RTC directors empowered to make collective decisions that affected the policies and procedures of all RTCs? If yes, please describe the decision-making process and how decisions were disseminated.

377. We had no executive decision-making powers at the RTD meetings. Decision-making was only possible with the approval of the Department of Health and the Regional Health Authorities. Decisions were disseminated by the transfusion directors to their region.

378. Decisions could not be made on policy - for example the commencement of testing - without the approval of the Department of Health. The Department of Health would direct the Regional Health Authority which would then be fed down to the Regional Transfusion Centre.

90. Do you consider that these meetings were conducive to fulfilling the purpose(s) for which they were established?

379. My view is that there were too many different opinions and they were not conducive to easy decision-making; decisions could not be made without Department of Health endorsement and RHA approval.

380. Each RTC operated independently and was accountable to its RHA and reliant on the RHA for budget. This led to a variety of practices between the regions.

91. What was your understanding of why the meetings were abolished?

381. The meetings were abolished because a National Management Committee was set up.

382. After the dissolution of the RTD meetings we had divisional meetings which meant that all the medical staff could attend the divisional meeting with one representative from the division and the chair of the meeting being the chair of the National Management Committee.

92. Did meetings between RTC Directors continue after this date in a different forum? If so, please give details.

383. Yes, they did carry on in the form of an annual scientific symposium. This annual symposium got taken over by the actions of the British Blood Transfusion Society which held an annual scientific meeting which covered everything.

384. The meetings also continued in the form of the divisional meetings where all of the RTDs met. This in my opinion was a better forum as there were fewer people which was conducive to positive debate and in my opinion a good forum for discussions. I believe that the divisional meetings were more efficient and more effective than the RTD meetings which they replaced.

93. If the meetings were not replaced with another forum, please advise, as far as you are able, why that was the case and what impact that had on the YRTC.

385. This new forum which replaced the old one with the National Directorate and the divisional structure was much more efficient and effective with much better dissemination of information regarding policy etc.

386. The meetings were replaced by the National Management Committee and divisional meetings as described above.

Meetings of the Northern Division of Blood Transfusion Service Consultants

94. Please describe the remit of this group. The Inquiry holds meeting minutes of this group between 1989 and 1993, which are provided for your assistance: SBTS0000096_052, SBTS0000096_076, SBTS0000097_008, NHBT0070258, SBTS0000097_022, NHBT0070264, NHBT0071759, NHBT0071757, NHBT0097471_051, NHBT0097471_023, NHBT0097469_049, NHBT0097468_024, NHBT0097466_006, NHBT0016142, NHBT0071593_001, NHBT0015638.

387. The remit was to provide the forum for discussion about policies, issues, questions, what needed to be done at a northern level. The chair of that group would then take the questions and issues raised by the Northern Division to the National Management Committee.

388. It was a two-way process because we would have the agenda and discussions which had been going on at the National Management Committee and we could raise questions or concerns about whatever was going on there.

389. We discussed medical policy but also things like budget devolution and how the regions would deal with that.

390. When the meeting of the Northern Division Blood Transfusion Service consultants began the Chairman was Douglas Lee.

391. The meetings encouraged the use of national working parties for matters such as donor recruitment and donor retention, research and publicity campaigns.

392. Any advice that came from the ACVSB was disseminated at these meetings, for example how to handle post-transfusion jaundice.

393. I have considered the minutes and note that the group discussed things like length of time to keep key medical records, which was agreed at 30 years.

394. I note from the minutes that Dr Harold Gunson had a meeting with the haemophilia directors at which not everybody supported the use of Factor 8Y which in the end turned out to be one of the safest products ever produced. There was discussion about the beginning of the prophylactic treatment for haemophiliacs which increased the use of Factor VIII and that is important because the increase in the use of Factor VIII and the heat treatment to remove HIV virus meant that our targets for plasma kept going beyond the level we could reach.

395. I have set out below a summary of the minutes in order to give the Inquiry an idea of the kind and range of issues discussed.

396. In the minutes from **20 April 1990** [SBTS0000097_022] the Department of Health was reported as unwilling to limit clinical freedom of haemophilia clinicians to prescribe the Factor VIII preparation of their choice.

397. In the minutes of **13 December 1990** [NHBT0070264], I became the new chair of the divisional meeting and there was discussion about budget devolution and that on devolution Yorkshire managed to retain a specialist budget for the services we provided. That is important for the reference work we did but also for the therapeutic apheresis service which benefited all hospitals in the region; so we had a separate specialist service budget in addition to what we charged for blood and blood products.

398. At the YRTC we used to treat region-wide Guillaume Barre Syndrome with plasma exchange and chronic leukaemia with high white cell counts with leukapheresis and removed anti-D from pregnant women by plasma

exchange in order to try to save their babies and for treatments of that kind we had to take our cell separator machine to the hospital ITU units.

399. The annual RTD meeting proposed for 1991 was to do with medical audit.

400. In the minutes of **21 February 1991** [NHBT0071759] there was regional medical officer support requested for the setting up of Hospital Transfusion Committees and the minutes show there was opposition from hospitals. This is important because the only way you can follow through what is happening to the recipients of blood is through the Hospital Transfusion Committees. Also, in the 21 February 1991 minutes there is the algorithm for HCV testing and confirmatory testing and the malaria area algorithm.

401. In the minutes of **13 June 1991** [NHBT0071757], we first became aware of the discussion about setting up a National Blood Authority and there are some references to the Department of Health being opposed to this. Concerns were expressed about the CBLA managing BPL separately from the NBTS such that RTC's requirements might be taken into account.

402. In the minutes for **17 October 1991** [NHBT0097471_023] concerns were expressed about the Ernst and Young proposals for the National Blood Authority and how this would operate.

403. In the minutes of **22 August 1991** [NHBT0097471_051] there was discussion and opposition from the RTCs regarding the proposals for a National Blood Authority. Concern was being expressed about the possible conflict of interest between the NBTS and CBLA.

404. In the meeting on **9 January 1992** [NHBT0097469_049] it was reported that the new AIDS leaflet including the Africa exclusion had been agreed by EAGA.

405. In the minutes **26 March 1992** [NHBT0097468_024], it is noted that I resigned as Chairman of the group because the workload was too much now that I had a young family. I had noted from this meeting that the SNBTS had a national register of donor deferrals. England and Wales did not have a register of donor deferrals, but by comparison, Scotland by population is roughly the size of Birmingham so on a different scale. In addition, Scotland had always been a national unified service not 14/15 feudal style RTCs.

406. At the next meeting of **18 June 1992** [NHBT0097466_006], it is recorded that the final analysis of the HCV trial was awaited which had been done at five centres. All consultants were required to participate in CME, a continuing medical education system. The concern of blood donation being used as a means of a screening test for people to establish HIV status was also discussed.

407. In the minutes for **27 August 1992** [NHBT0016142], Douglas Lee re-took the position of Chairman and the meeting deals with donor selection criteria, the new AIDS leaflet, the British Bone Marrow and Donor Panel and the question of bone-banking and whether this should be implemented or not; we discussed anti-D and albumin supply and anti-HBs collection for BPL.

408. In the minutes of **19 November 1992** [NHBT0071593_001] we cover the abuse of the NBTS as a national HIV testing service and we recommend that the CMO writes to all Doctors not to recommend it but the minutes record that 'CMO activity unlikely unless documentary evidence available'. I recall a local paper in Sheffield which was free, advertising that the easiest way to obtain a confidential HIV test was through blood donation. At the same meeting there was discussion of doing medical audits and producing a donor charter and trying to persuade each centre not to produce its own charter as the NMC had already produced standard recommendations.

409. In the minutes of **11 February 1993** [NHBT0015638] the issue about abuse of the service for HIV testing is raised again and it is recorded that all regional consultants and GPs were sent a letter with the new AIDS leaflet to try to stop other doctors from recommending the NBTS as a HIV testing means. Records storage and donor selection were discussed again as well as blood transportation policies. Because the NBA was about to come into existence there was discussion at this meeting about how the divisional set up would continue and how important it was because of the medical audit and medical advisory machinery and the need for much greater coordination between centres.

95. How frequently did this group meet?

410. The group met five times per year which was in sync with the National Management Committee meeting. At first, they were post NMC meeting then it was decided we would have them in advance.

96. Please describe the relationship between the divisional meetings of BTS consultants and the meetings of the National Directorate.

411. It was a two-way feedback system with the agenda and minutes being shared between us.

97. In your opinion, did the divisional meetings of BTS consultants provide a suitable alternative to the meetings of RTC directors following their cancellation?

412. Yes, I believe they did. They informed all medical staff and provided a forum for constructive discussions and feedback both ways to and from the National Management Committee and for example led to the setting up of a National Management Information System and medical audit. All aspects of the NBTS were discussed and it provided a forum for liaison with BPL.

National Directorate of NBTS

98. In his witness statement for the *A V Others* litigation, Dr Gunson outlined 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). As to this:

a. Did you have a role on this committee, if so, what was it?

413. When I was chair of the Northern Division, I was a member of the NMC.

b. How effective in your view was the National Directorate in overseeing the work of the RTCs? The Inquiry has provided minutes of the meetings of this group which you attended for your assistance: NHBT0071870_002, NHBT0046958_002, NHBT0071715, NHBT0071860_002, NHBT0071804, NHBT0000191_144, NHBT0071673, NHBT0071771, NHBT0001877, NHBT0097469_014.

414. Because I was based in the north, I used to go to the Scottish meetings at the SNBTS and was part of the liaison committee with BPL.

415. The National Directorate had a powerful influence in attempting to coordinate, standardise and improve services. It also attempted to get a basic management information system going and was involved with national donor publicity for example arranging TV advertising and improving donor recruitment. So, in other words it had a powerful influence but could not impose recommendations. I therefore agree with what Dr Harold Gunson says in his statement about the National Directorate, although I would add that we all had a lot of respect for Dr Gunson and in that sense although the recommendations were only persuasive, and he did not have any executive powers I felt the recommendations were nevertheless powerful and respected through his powers of persuasion.

416. The inquiry has provided me with minutes of the National Directorate which I have considered and I set out below my summary of the important issues discussed at these meetings.

417. The minutes of **4 January 1990** [NHBT0071870_002] note that I was not a member at that point and Dr Lee was the Chair. It is noted that 20% of donations at that stage were from first time donors which made it difficult to provide products from repeat donors. The minutes note that the National Management Committee and the Provision of Donors Committee were set up together with the Research Coordinating Committee and there was emphasis on Hospital Transfusion Committees for improving hospital transfusion practices.

418. In the minutes of **5 July 1990** [NHBT0046958_002] I took over as chair of the Northern Division. Dr Bill Wagstaff set up the Medical Audit Committee and we got a medical officer responsible for medical audit in each centre. This was used to assemble patient outcome data. It is noted with respect to the management information system that not all centres were returning the data that was required in order to set this up. It was noted that there was inter-regional variation in the donor health questionnaire so the NMC set out to identify a set of core questions that every centre should use. The devolution of the RTCs budget was also discussed at this meeting.

419. In the minutes of **3 September 1990** [NHBT0071715] there is reference to the HCV screening trial with 10,000 donors tested in Glasgow, Colindale and Newcastle using the Ortho and Abbott screening kits.

420. In the minutes for **25 October 1990** [NHBT0071860_002] there was discussion about reducing the donor minimum age to 17 years and increasing to the maximum to 70 years because Scotland had reduced theirs, but we did not in the end because it required parental consent for a 17 year-old to donate. This would be to increase the donor pool. We did however agree to increase the donation age to 70 provided the donor was fit and well post-65. QUIN was also set up as a quality

management system to get quality assurance into whatever we did. It also referenced two-year retention of samples from donors to be kept for testing which was a recommendation made during this meeting.

421. In the minutes of **16 April 1991** [NHBT0071804] Hepatitis C screening is discussed, and it is noted that blood stocks for O negative were down. An important point to make here is that we knew what our own blood stocks were within our own transfusion centres but had no idea how much blood was out in the hospitals and in general that was up to five times more than we had in the central bank. So, one of the first things we did was set up a Blood Stocks Management Scheme. Hospitals were initially uncomfortable about sharing data to do with their blood stocks with us because they thought they would be penalised for overstocking of blood. Therefore, any concept that the blood service held all the stocks of blood is incorrect as most of it was out in the hospitals.

422. The minutes of the meeting on **20 June 1991** [NHBT0071673] deal with a discussion surrounding the format of the National Blood Authority and one of the proposals was for the NBA to be a contracting authority which contracted services from individual RTCs. During this meeting it is noted that guidelines were produced for the introduction of HCV testing and a leaflet produced for donors which described what we did with their blood, including what testing was undertaken on it. This is so donors were given information in writing about what tests were done on their blood post-donation. The meeting also marked the commencement of the Red Book as it is now known.

423. At the meeting on **2 September 1991** [NHBT0071771] the first round of medical audit was reported, and the AIDS leaflet was revised and released. The debate was whether the 1977 exclusion should be removed and replaced with a five-year exclusion, but it was ultimately decided to retain the 1977 exclusion. The African exclusion was retained as well.

424. The meeting of **30 September 1991** [NHBT0001877] involved:- the Chair of the lab scientists, the Chair of the regional donor organisers, the Chair of the business managers and Ron Wing who was Chair of CBLA. The meeting was concerned with the future reorganisation of the NBTS. Ron Wing made a presentation with the suggestion that he was going to be the Chair of the new National Blood Authority. At that meeting Ron Wing also mentioned that from January 1992 plasma products were defined as pharmaceutical products and would be nlicensed in Europe. The minutes record that the Department of Health agreed to consult on the formation of the National Blood Authority. Dr Diana Walford of the Department of Health had sent a letter to all Regional Transfusion Centres and asked them to consult with users over the proposed reorganisation.

425. The next meeting was **16 January 1992** [NHBT0097469_014] where there is a minute at item 12 on the re-admittance of apheresis donors who are HBsAg and anti-HIV positive to the panels. I really do not understand this minute because anybody who is positive for these viruses would not be re-admitted. It is possible that the minute is referring to indeterminate or incorrect results from old tests. In the same minutes there is reference to the monthly HIV and HCV reports from Dr V Rawlinson who was Dr Harold Gunson's scientific officer. It is noted that these reports must not be shared with commercial firms. This minute also contains the first record of a national agreement with Haemonetics involving a bulk discount for the apheresis harness orders.

NBTS/CBLA liaison committee

99. In January 1989, the Central Blood Laboratories Authority ("CBLA")/NBTS Liaison Committee was set up to coordinate issues between the two bodies, including in relation to the plasma supply. Please explain your involvement in the CBLA/NBTS Liaison Committee. The Inquiry has provided minutes of the meetings of this group which

you attended for your assistance: NHBT0017193, NHBT0000065_019, NHBT0000077_056, NHBT0000066_031.

426. My involvement in the committee was as part of the National Management Committee for the NBTS and I was the expert in apheresis. I have always been a strong supporter of self-sufficiency in plasma so Dr Harold Gunson asked me to be a member of this committee.

427. In the minutes provided to me I have noted that in those for the **26 September 1991** [NHBT0017193] meeting we discussed issues regarding barcoding of source plasma which was important for tracking back to individual donations that entered the plasma pools prepared at BPL. We discussed pricing policies for Factor VIII. The question of ALT tested plasma was raised. It is mentioned that plasma supply was on target to meet the Factor VIII demand. There was a quality assurance SOP (Standard Operating Procedure) for handling a contaminated plasma pool which is important because if it turns out that any plasma pool has been contaminated with an infectious marker then the pool has to be disposed of. It also came out at this meeting that the Regional Transfusion Centres had to be registered with the MCA and that we needed a special manufacturer's licence. Applications had to be in by April 1991.

428. The next meeting was **10 April 1991** [NHBT0000077_056]. The minutes recorded problems with Regional Transfusion Centres handling Factor VIII because some hospitals were requesting delivery straight to the pharmacy whereas we always delivered to blood banks. There is noted conflict between the RTC voluntarism and BPL commercialism which I recall was an ongoing cause of friction. My recollection is that Bernard Crowley, Chief Executive of BPL was at all these meetings and Richard Lane, Medical Director of BPL attended some of them, mostly when the meetings were on BPL's site at Elstree. The meeting

mentions that the annual plasma target for 1990/91 was being met. I commented that the plasma from Yorkshire was costing £15 per kilogram more than income from BPL because of the large proportion of apheresis plasma that I sent to BPL which included the cost of the harness and the running costs. This highlights that we were not getting fully funded for the plasma that we were producing.

429. In the meeting on **21 June 1991** [NHBT0000066_031] issues were raised with what to do when we got a hepatitis C positive screening test but a RIBA negative result so a repeat reactive which was not confirmed positive and the issue of whether or not to use that plasma. In this minute it was categorised as '*HCV not detected*' by PHLS, the suggestion therefore being that you could use the plasma. During this meeting the Plasma Fractionation Laboratory (PFL)in Oxford announced that it would close in 1992 and a recall procedure for Factor VIII was established.

100. What was the function and remit of this Committee? In particular:

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

430. CBLA reported to the Department of Health and to its Chairman Ron Wing and the NBTS reported to the Department of Health through Dr Harold Gunson.

431. The committee met quarterly.

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

432. CBLA was a special Health Authority and had more freedom to act independently and with executive authority. The NBTS could only function through influence. Dr Harold Gunson could only exert authority

by influence in contrast to CBLA which had executive authority. The RTCs were professionally obligated to the NBTS and Dr Harold Gunson but were managerially responsible to their Regional Health Authority.

433. CBLA could set plasma specifications and set required targets and contract directly with RTCs to source supply. Dr Gunson could only act in an advisory capacity but was able through this committee to ensure all RTC/hospital feedback was provided and negotiate agreements on RTC targets, plasma specifications and specific immunoglobulin needs.

c. **Was the Committee an effective point of discussion and resolution of issues between the two bodies? *Advisory Committee on the Virological Safety of Blood/Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation***

434. The committee was the only means of having an effective discussion and attempting to resolve issues between the two bodies.

435. The reports would go back to the National Management Committee (NMC). We all had a common goal but there was a conflict between BPL's aspirations to be a pharmaceutical company versus the RTC's aspirations to meet the need of all patients to provide fresh blood components from voluntary blood donors; so, there was one common goal but diverging goals from our respective starting points.

100. In April 1989, the Department of Health Advisory Committee on the Virological Safety of Blood ("ACVSB") was set up for the purposes of giving advice to the UK Health Ministers on major policy issues (see NHBT0000041_003). Please explain your involvement in the ACVSB, if any.

436. I note that the previous question and this question are both described as question 100.

437. I had no involvement with the ACVSB and relied on Dr Gunson to keep me and the other RTDs informed regarding what was discussed at these meetings and any recommended policy change. The minutes provided record, specifically, that the Chair reminded members that their advice on the subjects under discussion could be publicly sensitive and should not be discussed outside the committee unless specifically indicated.

438. The views of this committee were referred firstly to the Chief Medical Officer. The first meeting dealt primarily with human growth hormone and CJD and it was recommended at this meeting that all recipients of the human growth hormone should be traced and advised not to donate blood and the NBTS was to defer any donor in receipt of human growth hormone (of which there were not many).

101. The ACVSB was replaced by the Advisory Committee on the Microbiological Safety of Blood and Tissue ("MSBT") in 1993. What was the function and remit of this committee? In particular:

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

439. I became a member of the MSBT once I was made Medical Director and my first meeting was the third meeting of the MSBT. The Chair then was Jeremy Metters who was the Deputy CMO.

440. The MSBT chairman reported to the CMO. It met quarterly - sometimes more frequently.

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

441. The MSBT was only advisory but its recommendations to the CMO if approved by the Secretary of State would become mandatory.

442. I have reviewed the minutes provided by the Inquiry and set out below my summary of the important points to assist the Inquiry in understanding the range of issues discussed.

443. At the third meeting which was **29 September 1994** [PRSE0003670] there was discussion about HCV 1 and 2 and HIV 1 and 2 combination tests. The HCV lookback was discussed and the quarantine of clinical FFP. In that meeting it was decided that anti-HBc testing would not be introduced until we had more evidence. It was recognised that tissue banking was in need of standardisation and regularisation. HIV 0 was discussed but we could not test to see whether the kits for HIV 1 and 2 would work because France would not provide us with a local serum (the virus was uncommon but mostly prevalent in France and West Africa).

444. It was at this meeting that I first proposed the HCV lookback and my rationale behind this was the development of knowledge in association with better outcomes for earlier diagnosis and therefore earlier treatment, and that antiviral drugs had become available. This was the meeting at which I presented the SACTTI recommendation that we should begin HCV lookback.

445. It is recorded in an item in these minutes that in life and death situations for organ transplantation, transplant surgeons may ignore PCR HCV positivity.

446. The committee reported to the CMO and the CMO would take whatever recommendation was made to ministers for ministerial approval. The recommendations could not be implemented without ministerial approval.

447. The issue was raised as to whether, if BPL had any surplus of blood products once the Factor VIII needs were met for this country, they could supply the other products to Europe. They would have to ALT test

in order to have a product licence to supply the products to Europe. This had to go to ministers for approval and they did not approve it.

448. I believe the ACVSB met quarterly, sometimes more frequently.

449. At the meeting **15 December 1994** [PRSE0003635] I reported the findings of the sub-committee about the HCV lookback which was recommended and received committee approval. I have discussed this in detail in my statement in response to the amended lookback request dated 14 August 2020.

450. There was a note that heat treatment of Factor VIII introduced in 1985 killed HCV.

451. The CMO was present when we discussed the HCV lookback and the recommendation to do it and that the recommendation should go to the Secretary of State, with guidance on how to do it to follow. This is minuted as confidential advice to ministers i.e. not to go to the public until the Secretary of State had given the go-ahead.

452. The possibility of quarantining FFP for clinical use was first raised at this meeting and referred to SACTTI for consideration. This explains why, during interviews, after this meeting but prior to the ministers giving approval, I could not discuss the lookback.

453. The next meeting was **25 May 1995** [MHRA0023194] which marked the beginnings of SHOT (Serious Hazards of Transfusion). It started as a means of obtaining proper reporting for bacterial contamination incidents.

454. Ministers endorsed the decision not to introduce ALT testing.

455. There was discussion about revision of the blood donor leaflets for inclusion of all the viruses we tested for, not just HIV but also Hepatitis B and C and to try to include the issue of heterosexual activity in Sub-

Saharan Africa which caused issues with the Commission for Racial Equality.

456. Item 8 of those minutes covers vCJD and blood transfusion. The SACTTI proposal was that we should attempt a lookback programme on CJD patients to see whether they had donated or whether they were recipients and if they had donated. We were proposing to share the vCJD records because at that moment there was no evidence for transfusion transmission of vCJD via blood and blood products but the two databases were completely separate so we needed to share the database in order to establish a link between the vCJD and blood donations.

457. I presented at this meeting on quarantining of FFP and cryoprecipitate for 90 days pre-release for clinical use. This would be logistically difficult because of the increased storage requirements and would be costly and take 2 years to introduce. This identified a need for education in the use of clinical FFP and marked the beginnings of the Better Blood Transfusion initiative. A decision was made not to recommend quarantining or the introduction of viral inactivation of plasma in favour of guidelines on the appropriate use being brought to the attention of clinicians.

458. It is recorded that MSBT might be reluctant to introduce a test showing only a small margin of benefit for a disproportionately high cost if a mechanism existed to recompense recipients harmed as a result of not testing.

459. In the minutes of **13 October 1995** [SBTS0000516_001], I presented the proposals for SHOT and the joint post between the NBS and the PHLS, the object being to collate transfusion transmitted infections to devise an annual reporting system with feedback and to publicise it to start at the beginning of the next year, anonymised similar to other confidential reporting systems.

460. It is recorded that HIV 0 was covered by kits in use in the UK and we had determined this through a sample I had obtained from my peers in France.

461. In the minutes of **8 January 1996** [DHSC0020692_118] we discussed the bottlenecks caused by the HCV look back exercise which included the need for NBS staff to provide the counselling, because GPs were unwilling or unable to take on the role. The suggested resolution of this bottleneck was the approach to Medical Directors at various Trusts to emphasise the need for their consultant staff to assist with the production of records and the use of infection control nurses to assist the production of records. It was clear that the bottleneck with regard to medical records was at the hospital end and that the BTS consultants managed to do most of the counselling. We discussed during this meeting whether any delay in donor counselling and obtaining medical records was likely to cause detriment to the patients' health and we took advice from a hepatologist who confirmed that the delay of a matter of months was unlikely to be detrimental since damage to the liver from Hepatitis C occurs over 20 – 30 years, so that a matter of months would not make a material difference.

462. At this meeting we also discussed the risk of the Human Herpes virus (HHV) and how white cell filtration could deal with this.

463. This meeting also marked the beginning of SHOT and the reports of adverse events.

464. Our blood safety leaflet was commended by the MSBT and was for launch on 1 February 1996. This marked a change from the AIDS leaflet. The blood safety leaflet covered all the virology screening tests that we performed.

465. There was reference in these minutes to the appropriate use of FFP and this marks the beginning of the CMO's campaign for Better Blood Transfusion.

466. We discussed a new virus on the horizon called Hepatitis G, which actually turned out to be nothing of significance. There is no test available for HVG, but the epidemiology seemed to be similar to HVC.

467. We discussed the use of PAEDI packs which was a small pack containing one unit of blood from one donor, which we used in neonates who were having continuous samples of blood taken and would therefore require a constant transfusion; and in order to minimise the risk brought about by several transfusions we developed PAEDI packs so that we could ensure that they would only be exposed to one donor.

468. The next meeting was on **2 May 1996** [SBTS0000518] at which Hepatitis C lookback was on the agenda. At this meeting it was noted that there was a much higher proportion of negative recipients than we anticipated.

469. We again discussed a new Hepatitis virus called Hepatitis G at this meeting. We determined that screening was not likely to be needed because it made up only 0.3% of the known hepatitis cases and therefore had a very low prevalence. We discussed that viral inactivation of Hepatitis G should work since it had the same structural similarities to Hepatitis C, so any haemophilia patients who had Hepatitis G must have acquired this from products prior to 1985 when viral inactivation began.

470. The meeting covered virally inactivated FFP and the problem with this was that virally inactivated FFP was formed from a pool of around 200 donors and the pooling of the plasma increased the risk of cross contamination. Viral inactivation with detergent did not kill all the viruses and therefore there was a discussion about quarantining clinical FFP and how to make this safer.

471. At this meeting we discussed the relationship between CJD and blood transfusion. This was before we knew about the new variant CJD and at this stage we were looking at people who had developed CJD after they

had been given the human growth hormone. We discussed whether a look back study should be instigated because the CJD surveillance unit had identified 50 patients with CJD who had donated blood and the question was whether we should establish the fate of those donations.

472. The next meeting of MSBT was on **2 July 1996** [SBTS0000519]. At this meeting we discussed HTLV testing and the minutes of the SACTTI meeting, which recommended universal screening for two years in the first instance. It was commented that the NBS had been able to introduce universal screening within current resources and would need a six-month lead in period to introduce this screening and the NBS cost estimate was £3.8 million per annum, which would be recoverable from blood charges. The committee approved the introduction of the screening test and I proposed that we ought to do a lookback at this meeting, but there was a reluctance in the committee to do that. My view is that when a new screening test is introduced you really ought to do a lookback to track the fate of previous donations and identify recipients who may have acquired the virus through transfusion.

473. I presented my lookback proposal for CJD at this meeting.

474. The next meeting is the meeting of **18 October 1996** [DHSC0004018_090] where I presented a paper on the HCV lookback and an update on the results of this.

475. The next meeting is the meeting of the MSBT on **18 October 1996** [DHSC0004018_090] where HTLV was on the agenda and we discussed the duty of care owed to donors. I pushed for the introduction of HTLV testing and for donor lookback, but the committee decided that there ought not to be a look back because there was no effective treatment available. This was distinguished from the HCV look back because of the licensing of the antiviral drug Alpha Interferon as a form of treatment.

476. In the meeting of **25 March 1997** [NHBT0006016], it was remarked that in relation to the HCV lookback, the number of negative recipients was much higher than anticipated.

477. I raised a concern that there was a lack of information about the amount of blood being held in hospital blood banks and I quoted the 1984 Department of Health circular where it stated that all blood banks were supposed to provide information about donations and their fate on a monthly basis to the NBS. I raised a concern regarding the standards of record keeping within hospitals.

478. It is mentioned in these minutes that the Department of Health research department had agreed to fund the HCV registry, which to my knowledge is still active today.

479. The next meeting was on **8 July 1997** [NHBT0019394]. At this meeting we decided not to screen for the virus HGV which was determined not to be a form of Hepatitis. We discussed PCR testing for HCV as it was a requirement by 1998 for plasma pools to be PCR tested and the best option was to use mini-pools. I remarked during the meeting that this would be at the cost of approximately one additional pound (£) per unit of blood.

480. Regarding CJD and blood products, we decided to exclude donors who had had neurosurgical procedures requiring a dura mater graft so that our exclusion criteria were in line with the European community.

481. We discussed the first case since 1985 where there had been a donor transmission of HIV who had donated during the period of sero-conversion, i.e. during the window period where the screening test did not pick up the virus. This individual was a practising homosexual who was using the NBS as a means of confidential HIV testing by donating blood and we decided to begin asking donors directly about lifestyle factors rather than simply asking whether they had read the blood donation leaflets.

482. The next meeting was on **27 October 1997** [SBTS0000522] at which again the HCV lookback was on the agenda and it was noted that the HCV registry had been funded and started. We discussed CJD and a French firm which had banned the importation of human albumin from BPL due to the risk of CJD. I noted that a question had been asked of me by the Haemophilia Society whether any implicated donations had been used in the manufacture of factor VIII or IX, therefore carrying the risk of CJD and whether these would be withdrawn. At that stage a lookback was not being performed to identify recipients.

483. I raised at this meeting the difficulty of introducing leukodepletion whilst reorganising the NBS and the introduction of NAT testing for HCV which was a lot to take on at once. The question of autologous transfusion was raised and it was noted that this could be valuable if arrangements were properly targeted and managed, but the process was expensive. One of the issues with autologous transfusion is that you had to have a date for the surgery taking place and the surgery had to take place on that day, otherwise the autologous blood would have expired and be wasted.

484. At the meeting of **26 February 1998** [SBTS0000523] HCV lookback was still on the agenda, and it was noted that no more cases had been registered.

485. We discussed informing patients who received new variant CJD blood or blood products but the advice and opinion of a range of ethical committees was that recipients need not be informed, with the exception of an individual clinician decision or in the event of a recall of an implicated product.

486. We discussed the NBA position statement that a permanent record must be kept in the patient notes where blood or blood products were given. During HCV look back we identified that there wasn't always a record of what donation had been given.

487. We discussed the implication of proposed preventative measures by deferring donors who had been previously transfused because of any risk they would pose to the blood supply and we estimated that we might lose between 15 and 17% of donors if we used that as a deferral criterion. It was felt that we could not maintain a safe blood supply if we introduced that as a deferral criterion. My comment was that the NBA was only just meeting supply at that time and any reduction in donors would produce a shortage.

488. We noted that the Secretary of State had decided that all patients under 16 and new patients should only receive recombinant factor VIII and it was proposed that BPL should only use imported non-UK plasma for fractionation.

489. The next meeting was on **4 June 1998** [DHSC0004026_033] at which it was noted that the HCV lookback had gone as far as it could, and we had support for NAT testing from the blood services. Ministers re-looked at the proposal to introduce HTLV-1 tests. A progress report was given on the new variant CJD.

490. It was announced that blood products would not be sourced from UK plasma, which was an extremely difficult decision and hard for blood donors as we had to explain to them that their plasma would be destroyed. All the plasmapheresis centres were converted to platelet collection centres.

491. The first SHOT report was produced in 1998 and came up with several useful recommendations, including the setting up of transfusion committees in hospitals.

492. The CMO introduced his better usage of blood initiative aimed towards reducing the usage of blood and improving patient care.

493. The next MSBT meeting was on **21 October 1998** [DHSC0004026_032] at which it is stated that by October 1999 we anticipated 100%

leukodepletion of platelets. Ministers decided that HTLV-1 should not be introduced based on current evidence.

494. It is noted by this point that BPL was only manufacturing from non-UK sourced plasma (this included PFC).

495. In relation to NAT testing, it was noted that the UK was behind Germany, who was ahead of the rest of Europe, but by April 2000 all red cells and platelets would be NAT tested.

496. The deferral of previously transfused donors was again discussed. Canada proposed that any donor who had lived in the UK since 1980 be deferred.

497. It is noted that we had a £25 million budget for CJD research. The national blood user group chaired by Ted Gordon Smith was noted to have been set up. Ted Gordon Smith was the deputy president of the Royal College of Pathologists and also a haematologist and he chaired this group which was like a national transfusion committee.

c. 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. The Inquiry has provided minutes of the meetings of this group that you attended for your assistance: NHBT0000041_003, PRSE0003670; PRSE0003635, MHRA0023194, SBTS0000516_001, SBTS0000517, SBTS0000518, SBTS0000519, NHBT0006005, NHBT0006016, NHBT0019394, SBTS0000522, SBTS0000523, DHSC0004026_033, DHSC0004026_032.

498. As far as I am aware the ministers generally did take the advice of the MSBT; the difficulty faced was getting any recommendations put forward to be approved by the Chair Jeremy Metters but once endorsed by the Chair then it was rare that ministers disagreed with those recommendations.

102. Please explain the relationship between the MSBT and the NBTS, including but not limited to:

a. whether the MSBT made decisions that NLBTC/NBTS was required to implement;

499. Yes, provided ministerial approval was obtained.

b. how frequently the MSBT met;

500. I believe this was quarterly as a minimum.

c. whether, and how frequently, you provided feedback to NBTS on the recommendations made by the MSBT.

501. I was a member of SACTTI as was Terry Snape who was a member of the MSBT (Terry Snape was the Quality Manager for BPL). We both provided feedback to SACTTI and I provided feedback to the NBA executive. I presumed Terry Snape would have informed BPL.

Standing Advisory Committee on Transfusion Transmitted Infections

103. Also 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 these committees.

502. The document quoted in this question is my letter to Jeremy Metters explaining the remit of the ACTTD and SACTTI.

503. Dr Harold Gunson chaired the ACTTD and this was set up by him to provide expert professional advice for the transfusion services. He set this up in 1988 as advisor for the Department of Health. Much like myself, because Dr Gunson did not have any specialist virological knowledge, he needed an expert group to help advise him on virally transmitted diseases.

504. In 1993, when the NBA was set up, Dr Gunson used the UKBTS / NIBSC (National Institute of Biological Standards and Controls) as the liaison organisation to formalise a structure to provide expert professional advice to the NBA and the SNBTS. This was to regularise standard input across all the National Blood Transfusion services so that we could work together to provide professional advisory machinery. As part of this structure, what was originally the ACTTD became the SACTTI. The principal difference was that it was providing advice to all of the national blood transfusion services, not just the NBA.

505. With regard to the extent of my involvement in these committees, once I was the Medical Director of the NBA, I sat on both the UK BTS and the NIBSC liaison committee. I also attended all the SACTTI meetings as did John Cash from the SNBTS.

506. Prior to 1990 I was not involved with SACTTI and sat on the National Management Committee with Dr Harold Gunson. I was not involved with SACTTI prior to becoming the Medical Director. The same applied to the MSBT.

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

507. As set out in DHSC0006906_013, this Standing Advisory Committee on Transfusion Transmitted Infections was an expert advisory group which formed part of the Committee structure reporting to the executive committee of the UKBTS/NIBSC Liaison Group chaired by Dr W Wagstaff.

508. The remit of the committee was to advise the UKBTS/NIBSC on all matters concerned with the possible transmission of infection by transfusion of blood and blood products. It was to commission, conduct and coordinate trials of new technology involved in the screening of donors for transfusion transmissible agents. Each standing advisory committee was accountable to the executive committee at the UKBTS/NI BSC liaison group which was chaired by Dr Wagstaff. Both the NBA and SNBTS directors were on this committee and any action was directed from this executive committee.

509. SACTTI was the expert professional advisory group for UK transfusion services and their respective medical directors, whereas the MBST was the expert advisory group advising ministers on policy.

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

510. The SACTTI reported to the Chair of the UK BTS/NIBSC liaison committee, which included both Medical Directors from Scotland and England. The minutes were sent to both Medical Directors.

511. Any proposal from the SACTTI went from myself to the MSBT and I believe Scotland had similar arrangements. I was given the remit to present the SACTTI recommendations to the MSBT.

512. I believe SACTTI met quarterly, but they had special topic meetings in between.

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

513. SACTTI was purely advisory. It did, however, have key roles within the blood service and could influence the operational ways of doing things. For example, the technical subcommittee of SACTTI was involved in the evaluation of any new microbiological test kits.

c. You note in a letter to Dr Jeremy Metters that "an attempt to formalise links" between SACTTI and MSBT "could potentially compromise their respective remits" (DHSC0006906_013), but did the Department of Health ever take advice from SACTTI?

514. Any recommendations from the SACTTI were presented by me to the MSBT. For example, a recommendation to perform an HCV lookback exercise.

515. There were some occasions when SACTTI was asked to provide recommendations by the MSBT to the Department of Health. All these came via me.

516. There were occasions when the SACTTI was asked by the MSBT to provide recommendations and advice. I can recall one example involving fresh frozen plasma.

517. In other words, it was a professional advisory mechanism that the Medical Director at the NBA and the Medical Director at the SNBTS used to provide advice on blood transfusion issues to the MSBT. Originally, Dr Harold Gunson set it up with himself as chair to provide him with expert professional advice, but when the NBA formed, he felt it necessary to formalise the structure under the auspices of the UKBTS and NIBSC liaison committee to produce a standardised set of practices throughout the UK.

d. How did SACTTI's remit differ from its predecessor ACTTD? The Inquiry has provided minutes of the meetings of this group which you attended for your assistance: NHBT0010970, NHBT0000088_009, NHBT0017284, NHBT0009458_002, NHBT0000088_013, NHBT0005590, JPAC0000109_025, NHBT0010921, NHBT0001142_077, NHBT0000088_017, NHBT0000088_020, NHBT0000088_021, NHBT0000088_022, NHBT0000088_023, NHBT0004601_001, NHBT0000088_025, NHBT0000088_030, JPAC0000089_020, NHBT0002623_001, NHBT0002594, NHBT0017175, SBTS0000413_008,

NHBT0003420, JPAC0000029_158, JPAC0000081_032, NHBT0001954_001, NHBT0002575, JPAC0000084_002, JPAC0000029_079, JPAC0000114_012, JPAC0000117_008, JPAC0000118_009, JPAC0000117_003, DHSC0011031, JPAC0000061_023, JPAC0000065_033

518. The Inquiry has provided me with various (in excess of thirty) sets of minutes from the SACTTI's meetings which I have read. I draw some important points from these as below in order to demonstrate the range of topics and issues discussed.

519. At the SACTTI meeting of **3 March 1995** [NHBT0017284], a special meeting was held on the virological safety of plasma (clinical FFP). Kate Soldan had been appointed in a joint NBS / PHLS role so that she could collect all the data and analyse it and perform epidemiological risk studies. The SHOT reporting system had been set up. For a reason I am unaware of, Dr Harold Gunson was at this meeting even though he had retired by this point.

520. We discussed the increased risk of pooled plasma and three-month quarantined apheresis plasma from repeat donors.

521. The next meeting was **31 January 1996** [NHBT0009458_002] at which we discussed residual risk from sero-negative HCV / HBV donations, in other words what was the sero-conversion rate in the donor panel.

522. Next is the meeting on **19 October 1994** [NHBT0010970], which was my first meeting as a member of SACTTI and as Medical Director of the NBA and I gave feedback on the HCV lookback proposal.

523. There was an agreement for two types of SACTTI meetings which were the quarterly meetings, but also specific topic meetings which could take place as and when these specific topics arose. Relevant experts could be invited to assist in the discussion.

524. At the meeting of **13 February 1995** [NHBT0000088_009] I reported on the new post of Kate Soldan which the NBA funded. We discussed a report from the NIH of the United States written in January 1995 in which there was a consensus statement that anti-HBC played no role as a surrogate test for nonA-nonB Hepatitis subsequent to the introduction of HCV screening.

525. A kit evaluation group was established by SACTTI to evaluate new testing kits that came on the market rather than simply relying on the manufacturer data.

526. The next meeting was **31 January 1996** [NHBT0009458_002] at which we discussed the residual risk from sero-negative HCV and HBV donations based on the seroconversion rate in the donor panel. We discussed HIV 0 and what kits had the ability to detect HIV 0 and that we could not simply rely on the manufacturer's data but getting access to an HIV 0 serum was proving difficult.

527. A question of declaration of interest came up at this meeting, which is important because if anybody at that meeting had a vested interest in a company or manufacturer for whom we were discussing a testing kit they had to declare that interest. This was introduced when Dr Peter Flanagan took up the chairmanship of SACTTI to ensure that no member present at any meeting had a conflict of interest in the topics under discussion.

528. At this meeting the MSBT was asking for professional advice from SACTTI on HTLV antibody testing. SACTTI prepared a special one-day meeting so that they could advise the MSBT.

529. The next meeting was **16 April 1996** [NHBT0000088_013] at which we had an update on the anti-HBC study and the HCV look back exercise and there was agreement to the formation of a standing advisory committee on tissue banking because there was a great deal of tissue

banking taking place within the transfusion service and this needed regulation and proper standards.

530. The revisions by SACTTI of the Red Book were submitted to Dr Bill Wagstaff, who was the Chair of the Red Book liaison committee.

531. The last meeting is **14 May 1996** [NHBT0005590] which was a special meeting regarding HTLV at which there was a recommendation for universal screening for two years.

105. How frequently did SACTTI meet?

532. As a minimum SACTTI met quarterly, but there were sub meetings in between these quarterly meetings to discuss specific topics such as FFP, HTLV and other issues.

106. Please explain the relationship between the SACTTI and the YRTC/NBTS, including but not limited to:

a. whether SACTTI made decisions that the YRTC/NBTS was required to implement; and

533. The original SACTTI was set up by Dr Harold Gunson as an advisory committee when he was National Director. His recommendations would come to me as Director of the YRTC and recommendations which he made, I would try and follow. This was, of course, dependent on funding from my RHA.

534. When we became the NBA, the organisation became much more powerful and I was able to instruct transfusion centres to undertake particular procedures as recommended by the MSBT.

535. No new screening test would be introduced unless it had been approved by the MSBT and sanctioned by the Secretary of State. HTLV is a good

example because we recommended its use, but it did not obtain ministerial approval, so we were unable to start screening.

536. SACTTI made recommendations to the executive committee of the NBA and if those were approved then the NBS was required to implement those recommendations. It was a two-way process because all the individuals within the organisation would have known the contents of the discussion and what plans were being made.

537. SACTTI made recommendations which went to Dr Harold Gunson and then Dr Gunson as the National Director would then make a recommendation that we should do something. The problem we faced was that if the Regional Health Authority was not prepared to fund the recommendation, then it was difficult to implement it, so SACTTI did not make decisions, they made recommendations, which Harold picked up and cascaded down to us through the organisation to implement; providing we could get funding from our Regional Health Authority.

b. whether, and how frequently, you provided feedback on the recommendations made by the SACTTI. Please explain, to the best of your knowledge, the relationship between the SACTTI and other RTCs.

538. By this point we had become a national organisation so there was a free flow of information of what discussions were going on and RTCs weren't separate entities but rather part of the national service. We were all part of the same organisation.

539. SACTTI was set up by Dr Harold Gunson as a means to understand and minimise transfusion transmitted infections and any recommendations he made would come through the National Management Committee to each RTC to be implemented providing funding was granted by the Regional Health Authority.

107. What was the impact of there being so many committees in place at around the same time? Was there overlap between them? If so, how did this impact on their effectiveness?

540. Initially the committees were to advise Dr Gunson because he did not have specific expertise in the virological safety of blood and transfusion transmissible infections, but when we became the NBA, we needed a mechanism to ensure that Scotland and all the other national blood transfusion services were working to the same standards throughout the country. As far as I can tell, there was no overlap between the respective remits of the committees.

541. The legacy of these committees, which is the Red Book, is still in existence today and provides the standards by which the blood service is measured and other important initiatives such as SHOT and JPAC stemmed from these committees.

542. The committees were not overlapping, and each had specific functions and so did not impact upon each other's effectiveness.

Section 11: Funding and cross - accounting

108. The Inquiry understands that a system of cross-accounting for blood and blood products was established across the blood transfusion service ("BTS"). When was this implemented? Please explain how this system of cross-accounting worked. What impact did its introduction have on the YRTC?

543. As far as I can tell from the documents that are available to me it was implemented in April 1991. The Yorkshire Regional Health Authority devolved the YRTC's total budget and apportioned it to the individual hospitals, who then had to buy blood and blood components back from the YRTC. This meant that we had to come up with a unit price for whole blood, FFP, cryoprecipitate and platelets.

544. The RHA kept a central budget for specific services, particularly in relation to the management and treatment of rare disorders because we would get sporadic requests throughout the region and could not expect one hospital to pay for this. One example would be the regional apheresis service that the YRTC provided, but there were other specialist services like tissue-typing and HLA-typing that remained centrally funded.

545. Cross-accounting is simply a mechanism whereby we were prohibited from making a profit from the service we provided. As far as donors and health service users are concerned, blood is free. There was some difficulty in us getting the message across that there was a cost element to the obtaining, testing, processing, and distribution of blood.

546. I am not certain why cross-accounting was introduced, but I assume that it was part of the government's policy when introducing the internal market.

547. BPL was slightly different and, initially, the amount of plasma we produced we would get back in 'kind' from BPL, for example in the form of human albumin solution. This worked well for the YRTC because we produced a lot of plasma and got back all the human albumin solution that we required for the region. When a national pricing system for plasma was set up by BPL, the YRTC struggled because this did not cover the cost of the apheresis plasma which we supplied.

548. I can't recall how we negotiated contracts with the individual hospitals, but I assume that we had to have an annual contract based upon the history of supply and requirements.

549. Cross-accounting did not affect our ability to produce safe blood and, if anything, it increased our flexibility because, where necessary, we could increase the prices per unit of whole blood: for example, if we needed to introduce a new test at additional expense such as HCV screening.

550. I think a positive outcome of this was that our users understood what it cost and what was required to produce each unit of safe blood and that this was not free, albeit voluntarily donated. I think that the value of blood, therefore, became more appreciated by the users because they understood the cost attached to it which, in my opinion, was a beneficial effect of cross-charging. The difficulty we had, as I said above, was explaining to donors that the processing of their 'free gift' of blood came at a price and that was quite a difficult PR exercise.

551. My opinion is that once users understood the cost attached to the blood it helped to promote better and safer use of blood.

109. It was noted in a minute of the NBTS/CBLA liaison committee, that all RTCs were due to devolve their budgets from 1 April 1991 (NHBT0000065_019). Can you elaborate on this change, the reasons for introducing it and its intended effects? What effect, if any, did this change have on the ability of the RTCs to provide safe blood? What effect, if any, did this change have on the subsequent introduction of anti-HCV testing?

552. As I have said above, I think the devolution of budgets and cross accounting had a positive impact on the safer use of blood because it made users understand the costs associated with blood collection and processing and helped promote more appropriate and safer blood use.

553. One PR challenge we faced was rationalising with donors that whilst they were altruistically donating their blood this still came at a cost due to, for example, the testing, production and distribution costs associated with this.

554. The effect this had on the subsequent introduction of anti-HCV screening was variable across the country. It did not have any effect on the YRTC because we were able to charge for it on top of the unit price of blood, so funding was not an issue, but for some of the other RTCs it was an issue because finding funding was not as straight forward.

555. The introduction of anti-HCV testing was not centrally funded, although I believe there was a national procurement exercise in order to obtain the best possible price for the testing kits.

Section 12: Reform of the BTS in the 1990s

110. In 1990, in a letter to Dr Gunson, you expressed your concerns over the proposal to move from a local to a nationally managed BTS, saying that many of the proposed benefits could be achieved "without advancing to a strict organisation that is managerially controlled from the Centre" (NHBT0001871). What were the benefits that you had in mind? What were your concerns about central control? In particular, what was your view about:

556. In my letter to Dr Gunson of 11 July 1990 (NHBT0001871) I express reservations on central rather than local control and my attitude at this stage was that because we had a good working system in Yorkshire then 'if it wasn't broke, why try to fix it'.

557. In the national directorate meeting of **5 July 1990,** I attended as the new chair of the northern division. We discussed devolution of the budget and the notes record that the vast majority were in favour of national management.

558. Overall, I was unhappy with the plan and the reason for this is that they were going to use CBLA as the management authority to manage BPL and the NBTS and I felt there were conflicting interests. BPL was striving to be a pharmaceutical production company working in a commercial environment, whereas the NBTS was based on an altruistic voluntary blood donation system working in a *not for profit* environment and I felt that the emphasis focused too much on the BPL side and the NBTS were just being viewed as a plasma supplier.

a. the prospect of market forces being expanded within the BTS;

559. I was more in favour of the national management because this would cut out competition and promote more cooperation between centres. If the service was being driven by BPL, then it would be more commercially focused, losing sight of the donor voluntarism upon which the service was based, which I was not in agreement with.

b. the merits of national coordination over national management; and

560. My response to this question is the same as set out above in response to 110a.

c. the use of persuasion over compulsion when managing the BTS? You may find NHBT0046958_002 and NHBT0001089 of assistance.

561. I could not see the advantage of the use of persuasion over compulsion when managing the BTS as Dr Harold Gunson had clearly demonstrated during his term as National Director of NBTS that although he was able to achieve much by persuasion alone because of the respect within which he was held, he could have achieved many more improvements had he been given the executive power to do so.

111. In 1991 you wrote to all RTDs arguing in favour of a set of amendments to the DoH reorganisation proposals (NHBT0001882). What was the response to these proposals:

562. In my proposal I was setting out certain provisos that if we were going to be centrally managed then we needed to make sure suitable arrangements were in place. For example, concern about other services such as apheresis, tissue typing, and haematology and these services were not fully appreciated by the CBLA and BPL. I wanted to bring out

that we were not just a plasma producer but that we had other specialist services as part of our remit. I raised again the issue of BPL being a pharmaceutical company, whereas the NBTS was part of the gift relationship and depended on the altruism of its donor population.

563. The meeting in Birmingham on **25 October 1991** was led by me. We reached agreement to amend the proposal for the DoH's reorganisation in terms of the national management and, in particular not CBLA taking over the NBTS. I think the proposals in hindsight were a little bit crass, but what it was bringing out was that the transfusion service was providing services to the region and the patients therein.

564. It ended up as a deputation, which consisted of me, Jean- Pierre Allain, who was the Cambridge Director, and Marcela Contreras, who was the director of the North London Blood Transfusion Centre, and we represented the RTDs. We took our proposals and petition to the Deputy CMO, Diana Walford, to try to explain to her the difference between CBLA and BPL and the National Blood Service and how this arrangement had to be very carefully and centrally managed.

565. The upshot of the meeting was that Ron Wing, who was the chair of CBLA, and was expecting to take over and become the chair of the NBA, did not get the job and it ended up with the blood service becoming a special health authority with the appointment of a new chairman, Sir Colin Walker and a new chief Executive, Mr John Adey, with Harold Gunson remaining in post as the national Medical Director.

a. from the remaining RTCs;

566. My recollection is that the remaining RTCs were very supportive and at the meeting in Birmingham in October 1991 as far as I can recall all RTDs were present and were in full agreement with the proposals that we came up with. It resulted in a deputisation with us speaking to the Deputy CMO, Diana Walford, to present our proposals to her. My

recollection is that I made that deputisation along with Jean-Pierre Allain and Marcela Contreras.

b. from Dr Gunson and other senior BTS figures; and

567. My recollection is that Dr Gunson understood our concerns about the CBLA appearing to manage the National Blood Service, which I felt was an inappropriate relationship because of the competing interests of a pharmaceutical company versus an altruistic service.

c. the Department of Health.

568. My recollection is that we had an empathetic hearing with reassurance that the issues we had raised would be investigated with the net effect being that we were set up as a special health authority which would manage both BPL and the National Blood Service, which was ultimately the desired outcome and which I believe was always Dr Harold Gunson's desired outcome.

112. In the proposal, you write that "above all, patients must receive cost effective treatment with safe and efficacious products." You also stress the importance of achieving self-sufficiency. In what ways, if any, did you and other RTDs envisage that the reorganisation would help achieve these aims?

569. Through national management it was possible to set a national direction within the service and introduce quality assurance, audit; to set and raise standards throughout the NBS and remove variations in practice so that all donors would be treated in the same way and all recipients would receive the same standard of blood and blood components and we would be able to maintain a continuity of supply to all patients (for example, shortfall in one region covered by surplus in another region).

570. It gave us national purchasing power, for example for microbiology test kits and blood bags, etc, which would make us more cost effective and allowed a national pricing structure to be developed eliminating price differences between the regions. It also allowed us to share resources and eliminate unnecessary duplication.

571. It allowed for research and development, central funding and peer review projects. It allowed us to define areas of greatest need and an overall more effective use of resources.

572. On the question of self-sufficiency, it allowed centres with the capability to increase supply and maximise recovered plasma by increasing the use of red cell concentrate and maximise plasmapheresis plasma by increasing donor panels where feasible. This was all part of the Bain consultation strategy.

113. Please could you describe the restructure of the BTS that followed these consultations. In particular:

a. What were its aims?

573. The aim was to provide sufficient and safe blood and blood products and supplies in the most cost-effective manner to treat all patients in England and North Wales, i.e. all of the regions covered by the NBS, and that aim never changed, but the way of achieving this was in need of improvement.

b. Did these aims differ from those set out by you in your proposed amendment?

574. No, these aims never changed, just the way of achieving the aims was improved.

c. How did the reorganisation alter the management structure of the BTS? How did it alter the functioning of the RTCs?

575. A key factor was the NBA being part of a special health authority which meant that the RHA's devolved their budgets and responsibilities to the NBA, which, in turn, meant that there was central management with centralised budget control. The management structure, therefore, had to change to meet the requirements of a centrally managed large organisation.

576. At this point the NBA employed a management consultant called Bain Consultancy to assist in this reorganisation. All regional transfusion directors were involved with this consultation. I have to say that this was the best consultancy firm I have ever come across. What they managed to achieve was to include everybody in the collection of data and analysis of data and feed it back to us, making us recognise the areas that we needed to change. It was therefore a huge data collecting exercise where all the NBS activities were covered.

577. I recall that I went to Washington with one of the Bain consultants and our director of IT to review the American Red Cross technology and their move to computerisation. The consultation brought out areas of duplication and areas of variation so the organisation evolved from individual RTC management to central NBS management and the first step was to move to zones.

578. The only problem with this was that we ended up with three very powerful sub-organisations making up the whole organisation, so we had to move from this to management along more functional lines. This was a gradual evolution over time where we had clinical directors across the three zones (divisions) and operational directors who were responsible for the laboratories and component production, together with finance directors and personnel directors. Each of the zones had this

functional arrangement but we had to evolve to make sure that this was one unit and not disseminated through the three zones.

579. Because of the zonal structure we did begin to get into differences in zonal practices which we had to overcome as some RTCs had a specialism, not just within the region but nationally, for example the tissue and bone bank in Liverpool and the apheresis services became a nationally organised system with people in charge of this.

d. What is your view on the changes made to the management of the BTS? In particular, did it achieve improvements in the ability of the BTS to deliver "cost effective treatment with safe and efficacious products" in a self-sufficient manner?

580. My view is that the change did achieve improvements in the ability of the NBS to deliver cost effective treatment with safe and efficacious products in a self-sufficient manner. For example, PULSE which was the national IT system, was implemented and this meant that we achieved standardisation of procedures and processes and practices with elimination of variation in standards, and that was accomplished by involving all the key personnel in designing it.

581. Another example is that we came up with the Better Blood Transfusion initiative and SHOT. We also began to reduce the inappropriate use of blood, which is relevant to self-sufficiency. We promoted the use of concentrated red cells over whole blood. If clinicians used whole blood as opposed to concentrated red cells the plasma could not be recovered and there are not many indications where a patient would require whole blood, so this drove a change in practice by persuading clinicians to use concentrated red cells, which meant that we could recover much more plasma. You can obtain about 250mls of plasma from a whole blood pack so it would require four donations to make one litre of plasma. Even if we did 100% of plasma collection from red cells, we would still not achieve enough plasma from whole blood collection, so you either

over collected and wasted the red cells or you introduced plasmapheresis programmes. We therefore reduced inappropriate use, which meant an increase in patient safety nationally. We also set up joint hospital transfusion posts which improved transfusion medicine practice within the hospitals.

e. What differences, if any, were there between the reorganisation of the service and the proposals that you made in 1991?

582. The main difference in the actual reorganisation and my 1991 proposals was the decision made by the DoH to set up a special health authority to manage the NBTS and BPL. The RHAs devolved their responsibilities and budget to the National Blood Authority (NBA) so all RTC operations and services and contracts were managed centrally with service delivery from the regional transfusion centres. With the RHAs taken out of the equation this meant that the NBA was able to set national prices, organise national contracts for test kits, blood packs etc. This enabled the NBA to promote higher standards and uniformity of transfusion practices, blood products and services nationally particularly once management evolved along functional lines.

f. If there were differences between the actual reorganisation and the reorganisation proposed by you and other RTDs, to what extent, if any, did these differences impact on the ability of the BTS to deliver on the above aims?

583. The actual reorganisation that took place enabled the NBS to be better able to deliver the aims of my original proposal which is why I applied for and took up the post of National Medical Director of the NBA.

Section 13: Look back programmes while at the YRTC

114. Please outline your involvement in the BTS's efforts to institute "look back" programmes in relation to HIV and HCV. Please confirm whether you were involved in a look back process relating to any other infection during your time at YRTC. If so, please provide an overview of the relevant programmes and detail your involvement.

584. As set out in my Rule 9 Look back response, the term look back was coined in relation to HIV, but the process which it described was not new, having been discussed for example in 1970 summarising early experience with the then new test for the hepatitis associated antigen (HAA), later named Hepatitis B Surface Antigen (HBsAg), when a positive result was obtained in a donor's blood and an attempt was made in the case of previous – or regular - donors to trace the fate of previous donations and the recipients of those donations.

585. This procedure was a targeted lookback which commences with a laboratory test indicating possible infection in a donor with a transfusion-transmissible agent and a history of previous donations. The donor is apparently asymptomatic, so that they would not have been deferred – the term used for being removed from the donor list - from donating. Any blood, blood components or products derived from an infected donor still in stock can be identified; blood banks and hospitals can be advised and material they hold quarantined.

586. It is important to explain that an infectious agent may be present in recipients of transfusion before the resultant disease becomes manifest and before the disease is known to be transmitted by transfusion. This means that it is impossible to screen it out of the blood supply or test for it in advance; this was the case with the hepatitis viruses; post-transfusion jaundice was identified and discussed in the 1940s, but knowledge developed over decades of the various types of hepatitis, including Hepatitis C which was long described only as non-A, non-B hepatitis (NANB). The same was true of HIV, but knowledge of that developed far more quickly.

587. I can't think of any occasion where a transfusion transmitted infection occurred during my time at the YRTC which required a lookback, other than HIV and HCV.

588. Very occasionally we had to do a reverse lookback at a 'J file' case where a recipient later developed Hepatitis B. We then put the donors in the 'J file' and those donors would be flagged and retested at the next attendance for donation. That is the only other quasi lookback which I can think of. There were very few of these from my recollection.

115. Did you consider there was an ethical obligation to inform patients who may have received transfusions from infected donations? If not, why not?

589. We did not have direct access to the patients. I did consider that there was an ethical obligation to inform donors and patients who may have received transfusions from infected donations, but it was the duty of the clinician who was treating the patient and not the NBS to do the informing. The treating clinician had to consider the individual patient's circumstances before doing so. Our duty as a blood service to the donors was more straight forward as we were responsible for all aspects of donor care.

590. In other words, yes, I do believe there was an ethical obligation to inform patients but that had to be exercised from us through the clinician responsible for the care of that particular patient and it was then up to them to determine that patient's circumstances as to whether it would be right or not to inform them. For example, in a patient who was terminally ill and dying from a completely unrelated illness with a very short life expectancy, it would be up to the clinician overseeing the treatment whether to inform that patient of a potentially infected donation which has absolutely no bearing or impact upon their condition and prognosis. I do believe that there are some circumstances where it would be ethically correct not to inform the patient, which could be more damaging

to their health and wellbeing, but that would be a decision to be taken by the clinician overseeing that patient's treatment and care.

116. To what extent could an RTC implement its own local look back programme? Did the YRTC do this? If so please give details. If not, why not?

591. Each RTC could and did implement its own HIV and HCV lookback including the YRTC. On rare occasions the quasi lookback would extend to Hepatitis B virus.

592. The ease of implementing the lookback depended on the state of the paper records held by the centre and the degree of computerisation and the response of hospital blood banks.

HIV look back

117. Were you involved in setting up any national or local HIV look back programmes during your time at the YRTC? If so, please describe this process and your role in it and how it was funded?

593. I was not involved nationally in any HIV lookback programme, other than sending the YRTC donor care specialist (Alison Townley) to a specialist training scheme on counselling any donors who were HIV positive and providing support so that the national guidelines could be followed; for example, how to contact the donor and where to do the interview so anonymity and confidentiality was maintained.

118. Were you involved in implementing an HIV look back programme during your time at the YRTC? Please give details.

594. I was only involved locally by providing consultant advice, support and direction to the donor care clinician undertaking HIV lookback.

HCV look back

119. Were you involved in setting up any HCV look back programmes during your time at the YRTC? If so, please describe this process and your role in it.

595. I was not involved in the setting up of HCV lookback locally at the YRTC because at the time that this was instituted, I was no longer the Director of YRTC and the role was taken on by Dr Peter Flanagan as, by that point from 1994 onwards, I was the National Director of the National Blood Authority and was based in Watford and not in Yorkshire.

120. Were you involved in implementing any HCV look back programmes during your time at the YRTC? If so:

a. Please describe what this involved.

596. I refer to my response to question 119 above. No, I was not involved in implementing any HCV lookback while I was at the YRTC, but was involved in introducing HCV testing. Dr Peter Flanagan was the consultant lead in this.

b. How was any additional work funded? You may find NHBT0071804 of assistance.

597. With respect to document NHBT0071804 which the inquiry has provided to me dated 1 February 1991, regarding an NMC meeting with Dr Harold Gunson as the chairman, the document refers to the RHA's budget devolution and possible difficulties in locating funding for the introduction of HCV testing and is not related to the HCV lookback so, in my opinion, this document is not relevant.

598. Additional funding for HCV lookback was dealt with elsewhere and negotiated centrally with the Department of Health.

121. In 1994 the Standing Advisory Committee on Transfusion Transmitted Infections compared the approach taken by the BTS to HIV as against HCV. They noted that in 1991 a "look-back programme was not recommended" (PRSE0001236). Were you aware of this recommendation against adopting a look back programme? To your knowledge, who was responsible for this recommendation not to have a look back?

599. To my knowledge, and from reading the document PRSE0001236 provided, I believe that it was the experts sitting on the MSBT panel who recommended not to have a lookback.

600. I think I was aware of this document through Dr Harold Gunson, but I was not sure why the lookback programme was not recommended. I later realised this was an MSBT recommendation to the Department of Health but, prior to my own membership commencing in 1994, I would not have seen the minutes where the MSBT experts recommended not to do a lookback as the minutes were confidential and not shared outside the MSBT membership.

122. The group also note that the key reasons for rejecting a look back programme included the following:

a. "doubts about the long-term effects of hepatitis C infection";

b. "the lack of an effective therapy for individuals so infected"; and

c. "secondary transmission … appears to occur rarely" in contrast to HIV. Did you agree with this view? Please give details.

601. The key reasons for rejecting the lookback were perceived as reasonable at the time.

602. My view then and now is that despite these reasons the recipient had the right to know.

603. Developing knowledge revealed that the long term complications of Hepatitis C were more serious than first thought with the potential development of cirrhosis and, in a few, hepatocellular cancer and also secondary transmission, although not common, was a possibility, particularly from pregnant mother to unborn child and sexual transmission (although rare) could occur, so not telling people, was denying them the opportunity to adjust their lifestyle to improve outcomes, for example, alcohol intake.

Section 14: Anti-D immunoglobulin

123. On 25 April 1994, you received a letter from Dr Lorna Williamson informing you that Irish anti-D had been used by transfusion centres (NHBT0017278_001; NHBT0017278_002). Please explain:

a. what role the YRTC and the NBTS (in so far as you are aware) had in supplying anti-D to hospitals; and

604. The document I have been provided with, NHBT0017278_001 is a copy of a handwritten file note which was my personal note regarding a conversation with Dr Terry Walsh, who was the Medical Director of the Irish Blood Transfusion Service, and it was about HCV positivity in preparations of intravenous anti-D, particularly the 10,000 IU doses, which is a very high dose and transmission of HCV from the Irish IV anti-D. I can't recall this conversation or why I was asked to write to Dr Lorna Williamson because in 1994 it appears that there was one case in North East Thames and three cases in Cambridge, so I am not certain why I was asked to follow this up, although I did know Terry Walsh personally having met him on a transfusion course in Finland many years prior to this. I believe Dr Walsh was involved in a court case in Ireland to do with a failure to screen out HCV from anti-D immunoglobulin donors and he was to be prosecuted but actually died before the court hearing.

605. Given the date of the letter and the fact that Dr Lorna Williamson is congratulating me in the letter I believe that I must have been given the job as Medical Director of the NBA but not yet appointed and at the time Dr Harold Gunson was still the medical director and I assume had asked me to follow this up.

606. Presumably Cambridge and North London were involved because it was the policy of the Eastern Division that in the presence of a large feto-maternal haemorrhage from an RH positive infant to an RHD negative woman of child-bearing age, then you needed two huge doses and clearly in Cambridge and North London they used this intravenous Irish product. I am not certain what the biggest dose BPL produced was but I think it was around 500 IU and I can't recall whether BPL actually produced an IV preparation so I think it was circumstances peculiar to Cambridge and North London.

607. I do recall a scandal and inquiry about the Irish anti-D immunoglobulin, but I do not know much more than this, other than viral inactivation was not effective in the intravenous preparation of the anti-D immunoglobulin but seemed to be effective in the intramuscular preparation.

608. I don't believe the YRTC ever used the Irish anti-D immunoglobulin.

609. From my discussion with Terry Walsh, I noted that some Irish batches from 1992 – 1993 showed HCV PCR positivity, which was seemingly not withdrawn from use.

610. The YRTC did supply BPL anti-D immunoglobulin to hospitals and held some large dose vials in case of emergencies, such as massive feto-maternal haemorrhage, but I cannot remember whether the doses were prepared as intramuscular or intravenous doses. I think these were intramuscular, on the whole.

b. whether all anti-D was supplied through the NBTS or whether to your knowledge there were other sources of anti-D.

611. In the YRTC region I believe that all anti-D use came from BPL and, whilst there were some commercial supplies available, I don't think any were used. I say this because the previous director, Dr Derrick Tovey, was an expert in anti-D immunoglobulin and set up a big programme of collecting from donors who had donated their plasma, and that is a programme that I inherited from him and carried on when I took over as director of the YRTC. I believe that Dr Tovey was keen that any anti-D we used in the Yorkshire region came from English Donors.

124. What can you recall about the anti-D trial? You may find NHBT0070258 and NHBT0016142 of assistance.

612. The trial which is being referenced here is using prophylactic anti-D during pregnancy and the first trial of this that was ever performed was actually done by Dr Derrick Tovey in the Yorkshire Region because he was an expert in this field and had a good relationship with the obstetrics and gynaecology consultants. I believe he published a trial using one dose at 28 weeks in prima gravida Rh negative women to prevent their sensitisation, so they could have at least one live child, and used historical controls. Basically, all the women using the trial were given a dose, which was effective.

613. The trial which Douglas Lee is talking about, used two doses, which I believe were bigger doses than the dose that Dr Derrick Tovey used, given at 28 weeks and 32 weeks, and then one dose at delivery. This was one additional dose than used in the Derrick Tovey trial. From my reading of the paper, it appears that there was a control arm of a number of women who were not given the dose, just the post-delivery one, and there is an ethical question about whether that is appropriate given Dr Tovey's trial had shown that the pre-delivery doses were effective.

614. This is all from my memory and recall about the trial. I believe that there are papers that have been published by Dr Tovey but I do not have these.

615. If these trials were put into practice it would require a huge collection of anti-D plasma.

616. I believe that current practice is that every Rh negative prima gravida mother with an Rh positive partner is offered anti- RhD prophylaxis and they receive two injections during pregnancy and at delivery.

Section 15: Your role as Medical Director of the National Blood Authority

125. Please outline the roles, functions and responsibilities you had at the National Blood Authority during your period as Medical Director.

617. It was an executive position reporting directly to the chief executive officer of the NBA with professional accountability to the CMO and the principal objective was to ensure the NBS clinical advice and support was of the highest quality to meet the services' requirement.

618. I refer to a copy of my CV for my principal responsibilities.

126. Please describe the following in respect of the NBA during your period as Director:

a. its structure, staffing and hierarchy;

619. We had the Chief Executive Officer, the Finance Director and the Medical Director who were executive members of the National Blood Authority, which meant that we actually sat on the Board.

620. The NBS executive team when I joined it consisted of the CEO, finance director, myself, human resources, PR and IT, which is all we had in the

beginning. This was a very small executive team. The NBA board had a chairman who I presume was appointed by the Department of Health and three executive members and our non-executive chairman. I think we had six non-executive members. We had a secretary to the board and I had my own PA.

621. Initially, all the Regional Transfusion Directors were part of an executive committee.

622. When we became the NBA, we started with all of the RTDs around the table and we undertook the Bain Consultancy exercise, which involved the whole of the service, the outcome of which was that the individual RTC structure was dissolved and a zonal structure was put in place as an interim way forward: this over time evolved into a working functional structure with human resources, finance, operations, donor services, public relations and IT. Now the service is managed on a national basis rather than zonal.

b. its remit;

623. The remit was, and I believe still is; the provision of sufficient safe blood and blood products and related specialist services in the most cost effective manner to treat all of the patients in England and North Wales.

c. its aims and objectives;

624. I set out above in my answer to question 126(b) the provision of sufficient safe blood and blood products and related specialist services in the most cost-effective manner to treat all of the patients in England and North Wales, which I believe is the same to this day.

d. how it was funded;

625. The service was funded through blood and blood product pricing with access to the central department DoH funding for the NHS R&D and

some capital expenditure. This was all without making a profit. Capital funding and R&D funding came centrally from the Department of Health.

e. how decisions were made; and

626. Decisions were made in the executive committee but had to be approved by the NBA board. The NBA executives were accountable to the NBA board, who in turn were accountable to the Department of Health and through them to the Secretary of State for Health.

f. to whom the NBA was answerable.

627. To the Department of Health and the Minister of Health. There was a senior Department of Health advisor appointed to oversee our work. I had professional accountability to the Chief Medical Officer. I also had the clinical responsibilities of donor and patient welfare. When I was appointed Medical Director, I did keep my consultant status because that meant I would get respect from my peers and, at the same time, allowed me to have a professional line of accountability, which was very important to me.

127. What was the relationship between the DoH and the NBA? Please consider NHBT0009473 and NHBT0008473 and explain why the DOH was advising the NBA on 'the line to take'?

628. If statements or decisions that the NBA made could impact on the Secretary of State or DoH policy, then there had to be an agreement as to how to handle this. Document NHBT0009473 of 29 November 2000 is in relation to leukodepletion from 31 October 1999 which includes a briefing and 'line to take' regarding the banning in certain countries of anyone who lived in the UK for six or more months between 1980 and 1996 when BSE was endemic in British cattle from giving blood due to the risk of contracting variant CJD from eating contaminated beef. This clearly had an impact on foreign policy and our relations with other

countries, whilst needing to reassure our own population that we had no other recourse but to use our own blood donors. The balance was quite tricky because we had foreign countries banning people who had lived in the UK from donating blood, but those same donors were still donating blood for use in our population and where decisions impact upon foreign policy and / or health policy then we had to agree a 'line to take', I think partly in the interests of consistency.

128. What role did the NBA have in counselling patients infected by treatment with blood and blood products? You may find DHSC0003538_003 of assistance on this issue.

629. It was not the NBA's role to counsel patients.

630. In circumstances where others refused, we took on this role but, primarily, our responsibility was to counsel donors; recipients of blood and blood products would be receiving these from a clinician, whose patient they were. As I have explained before, it was the responsibility of the clinician with care of the patient to undertake counselling and refer him/her onwards to specialists as appropriate.

631. The document DHSC03538_003 which has been provided to me is a letter from Dr Pat Hewitt to me and my comment is that this is about counselling donors and not patients during the HCV lookback and that it is not the role of the NBA to counsel recipients upon receipt of infected blood. Our role was to identify them through our, and hospital records and it was the role of the clinician with care of the patient to inform and counsel that patient. NBA consultants took this role on when GPs and the patient's clinicians declined to do it and I believe in Dr Pat Hewitt's case she did far more than really should have been expected.

Autologous transfusions

129. Please explain what consideration, during your tenure, the BTS gave to the use of autologous transfusions as an alternative to allogeneic transfusions and the risks they posed.

632. Autologous transfusion is a pre-deposited blood donation, which is the patient donating their own blood two to three weeks prior to surgery and was offered as a service during the 1990s because the guidelines for autologous transfusions were written in around 1993.

633. Whilst this was a service that was offered, the issues of concern were;

a) The planned date of surgery could change in the health service and, if the operation wasn't completed within that timescale of three to four weeks, then the blood would be deemed out of date and wasted.

b) It was difficult to maintain the patient's haemoglobin pre-operatively. If a patient donated two to three units in a two to three-week period pre-operation, then they would lose approximately 1gm of haemoglobin each time they donated, so to have a patient with a normal haemoglobin at the time of surgery it meant, almost inevitably, that that patient would need to be transfused; whereas in many cases of surgery he/she would not have needed to be transfused otherwise, which is always safer.

634. Document NHBT0002286 is my letter to a donor who was concerned because he was disallowed from pre-depositing his blood and he was concerned about vCJD and had been a longstanding donor. In my letter I pointed out the issues and problems with pre-deposited blood donations, which was the much greater likelihood of transfusion being required during surgery because of the patient's haemoglobin levels and, often, the surgery could have progressed without the need or risk of transfusion, be it autologous or allogeneic, but for the pre-deposit (which was itself creating the need for the transfusion).

130. In January 2005, you wrote that "current expert opinion... has raised serious doubts with regard to the safety and efficacy of autologous blood donation" and "whether the benefits outweigh the harms" (NHBT0002286). Please explain the factors that led to autologous transfusion not being considered a viable alternative to allogeneic transfusions.

635. Expert opinion concluded that any benefit derived from autologous transfusion was outweighed by the risks because of the haemoglobin maintenance, blood being outdated because of the operation being rescheduled, and all of the other attendant risks of transfusion, which are set out in SHOT.

636. There is much greater benefit from using the red cell salvage machines which were a safer method of autologous transfusion. I had a good knowledge of these because they were similar to the machines that I used for plasmapheresis, so that during the operation the blood was salvaged by suction into the machine, spun and washed and then re-transfused into the patient meaning that cell-salvage took place on the spot and the blood was never actually separated from the patient, with no risk of transfusing the wrong blood or any risk of introducing new infections.

637. The Appropriate Blood Use Group had a surgeon, anaesthetist, transfusion committee personnel and an expert on cell-salvage to encourage the use of this during surgery.

638. The difficulty with cell-salvage was that it required a technician on standby in theatre ready to set up and operate the machine in theatre.

Safety of the blood supply during your time in the NBA

131. Was the NBA informed of any incidents in which patients were infected with HCV from blood or blood products after 1 September 1991 (i.e. after

the introduction of HCV screening)? If yes, please provide details and of how the NBA responded.

639. I am not aware of any incidences and if there were it would be recorded in Kate Soldan's update and they would have been handled as we did with HCV positive donors and recipients in the look back exercise.

640. HCV takes a long time to develop so when it develops in a recipient, often the link between the transfusion and the hepatitis is not made given the time period which has elapsed in between. Efforts were made so that any cases notified to the PHLS were in turn notified to us so that we could make the link.

Quarantining of FFP and cryoprecipitate

132. What was the NBA's policy on the use of FFP and cryoprecipitate, including the need for quarantining it? See, for example, PRSE0003670, NHBT0009371, NHBT0015504_001 and NHBT0008013_001.

641. The policy was that we continued to use single donor FFP and cryoprecipitate and we carried on with this despite all the things we went through. Quarantining was discussed after the SACTTI meeting which recommended a period of quarantine for clinical FFP and cryoprecipitate, which would require storage for five to seven months, which was the donation interval time. There is a note from me to John Cash in February 1995 [NHBT0009371] discussing the issues raised about the logistical feasibility and that some centres would find the quarantining impossible.

642. SACTTI canvassed full membership to consider alternative means of quarantining FFP and cryoprecipitate and, from there on, there is a rather long saga realising that the SACTTI meeting recommending quarantine of cryoprecipitate and FFP was not a full membership

meeting and there was much disquiet expressed later about quarantining not being a logistical feasible possibility.

643. In the interim, the NBS executive response to the quarantine proposition was to issue a directive to all RTCs on **8 September 1994** not to henceforth issue any clinical FFP from first time donors and to investigate the logistics of quarantining FFP and the timescale required.

644. So as an interim safety measure the directive went out only to issue FFP if it was from a repeat donor (this included FFP and cryoprecipitate).

645. In **1994** the agenda for SACTTI was to consider a national policy for the safety of FFP for clinical use and the options were:

a) From repeat donors only (the residual risk in single FFP of infection was very low – as collated and reported by Kate Soldan - See e.g. the discussion at item 12 in the SACTTI minutes for 1 July 1996 – document [JPAC0000109_025]).

b) Virus inactivation using Octapharma plasma solvent detergent which was made from pooled (probably paid) donor plasma. BPL did attempt to license the process to make it from UK plasma but failed because Octapharma would not agree the licence.

c) Pasteurisation – but I don't think this ever materialised.

646. Methylene blue ultraviolet light – but concern was expressed about the effects of toxicity from Methylene blue, particularly in neonates.

647. On **3 March 1995 (NHBT0017284)** there was a special SACTTI meeting on FFP which noted an increased risk in pooled FFP and that clinicians were not happy with the safety of solvent detergent (SD) FFP.

648. At the MSBT meeting of **8 January 1996 (DHSC0020692_118)** it was noted that it would be logistically difficult to quarantine FFP due to limited storage facilities and would take two years to introduce at great cost. In terms of viral inactivation, it was noted that there was a manufacturing step required and a licence needed. It was decided against quarantining and viral inactivation in favour of guidelines on appropriate use of FFP, brought to the attention of clinicians via the BTS and the CMO update.

649. A speciality meeting with clinicians was proposed by SACTTI in July 1996 and I believe there was a strong feeling amongst the hepatologists that they did not want to use the solvent detergent method and were much happier with the single use method, which was far less expensive.

650. At the MSBT meeting on **2 May 1996 (SBTS0000518)** no decision was made regarding the quarantining of FFP versus viral inactivation. The MBST meeting on **2 July 1996 (SBTS0000519)** looked at a PHLS / NBA study on the risk of post transfusion transmission of HIV, Hepatitis B and Hepatitis C, and that meeting was left with BPL to explore whether they could license the process of viral inactivation so that the clinical FFP and cryoprecipitate could be m ade from UK plasma.

651. In the MSBT meeting of **18 November 1996 (NHBT0006005)** no particular decision was reached and in the meeting of **25 March 1997 (NHBT0006016)** there was discussion regarding pros and cons of pooled SD plasma and single unit UK FFP. The MSBT advised that the NBS should make preparations to provide SD product from UK plasma once BPL had obtained a licence so that clinicians had a choice of products available to meet clinical needs.

652. In the MSBT meeting of **8 July 1997 (NHBT0019394)** it was noted that we had had the first case of HIV transmission via blood transfusion since 1985, which is significant because this meeting was 12 years after the introduction of screening. It was recorded that the donor donated during

the window phase and prior to us introducing antigen testing for HIV, and donors henceforth were to be asked directly about lifestyle risk factors rather than just asking if they had read the AIDS leaflet. This particular donor should have self-excluded based on the criteria and was using the service as a confidential way to test for HIV.

653. In the minutes of the SACTTI meeting of **9 July 1997 (NHBT0000088_017)** it was decided that an 'accredited' donor for FFP must be a current donor who has been tested within six to 24 months prior to the donation.

654. On **9 July 1997** there was a solvent detergent FFP hospital information leaflet ready and approved. The problem with solvent detergent was that it did not kill all the viruses. It killed the main envelope viruses, but not the other viruses, or indeed any viruses we did not know about. So, it was a balance of risk as to whether we took the extremely low risk of single unit plasma, the risk of having a pooled product, or the toxicity effects of Methylene blue.

655. At the meeting of MSBT on **26 February 1998 (DHSC0020709_063)**, NAT testing and leukodepletion took priority over the production of virally inactivated plasma until the risk assessment in relation to leukodepletion was available.

656. At the SACTTI meeting of **19 May 1998 (NHBT0000088_022)** the introduction of Methylene blue treated FFP was postponed by the NBA and the NBS was to implement Methylene blue in parallel with leukodepletion. I believe that Lorna Williamson was attempting to deal with the Methylene blue and Octapharma means of viral inactivation and trying to perform trials.

657. At the SACTTI meeting of **29 September 1998 (NHBT0000088_023),** MSBT accepted that the concept of Methylene blue FFP should be pursued as an alternative to pooled SD FFP.

HCV look back

133. At the meeting of the Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation on 29 September 1994, you raised the issue of whether there should be an HCV look back (PRSE0003670). This was discussed at a later meeting of the Standing Advisory Committee on Transfusion Transmitted Infections ("SACTTI") in October 1994 (NHBT0010970). Please set out what you recall about how the HCV look back programme came about.

658. I refer the inquiry to my response to the amended Rule 9 request on lookback dated 14 August 2020, particularly question 10 of that response.

659. The MSBT meeting on **29 September 1994 (PRSE0003670)** was the first of these meetings that I attended after my appointment as medical director and followed the ad hoc SACTTI meeting on 5 August 1994 (NHBT0057381_004) when I decided that I had to recommend a look back. This was the first thing I wanted to do when I took up the post as medical director of the NBA in April 1994.

134. On 3 November 1994, you attended a meeting of the MSBT to consider the HCV look back programme. At the meeting, it was suggested that there was a "duty of care" towards the recipients of infected blood (NHBT0005791). What was meant by this, and how did it operate in practice?

660. I refer the inquiry to my response to the rule 9 lookback request dated 14 August 2020 and in particular my response to question 1 of that Rule 9 statement.

661. The MSBT meeting in **November 1994** (NHBT0005791) dealt with duty of care towards recipients in some detail, as set out in my response to questions 1 and 10 of my lookback request.

662. We always regarded ourselves as having a duty of care to donors and recipients and the only issue was how it was exercised.

135. In relation to the establishment of the HCV look back programme, please explain:

a. when and by whom the recommendation to commence the programme was made;

663. The MSBT made the recommendation to the Minister of Health and it was then announced as a public programme by the CMO Ken Calman on **10 January 1995** when he made the statement in Parliament. Jeremy Metters dealt with all the post announcement publications.

664. In short, SACTTI recommended it, the MSBT endorsed it after discussion and it was then taken to the Minister of Health who agreed with the policy and the announcement by the CMO followed. (See for example NHBT0002764_001) Letter from the Chief Medical Officer of the Department of Health Dr Kenneth C Calman, re: Hepatitis C and Blood Transfusion Look Back dated 3 April 1995).

b. the purpose for which the programme was established;

665. To identify, counsel, test and treat the recipients of infected blood products.

c. the start date of the programme;

666. The start date of the programme was 3 April 1995.

d. how and by whom the programme was to be conducted;

667. The programme was to be conducted by the blood services and we had to run it reporting back to the MSBT.

668. The PHLS and laboratories had to be brought in and information was provided to the hospitals because they had to trace the recipients of infected blood and blood products and they, or the GPs were given a choice of whether to advise the recipients and, failing that, it fell upon the blood service to do so.

e. who was ultimately responsible for the programme;

669. I was responsible on behalf of the blood services as the Medical Director and was accountable to the Minister of Health who had overall responsibility.

670. I did everything I could from my position as Medical Director, but I could not control, for example, the hospitals and clinicians who were treating or had treated the recipients.

f. how the success of, or any problems with, the programme were to be measured, identified and resolved;

671. When practical issues arose some of these could be overcome operationally by agreement between me and the zonal directors and the hospitals, but others had to be escalated to the Deputy CMO, Dr Jeremy Metters.

672. Measuring success was difficult because we were not in charge of the blood banks and required cooperation from a chain of services and individuals before the information could reach the recipient.

673. The success of the programme also depended upon the cooperation of the recipients who were called in to attend for testing and counselling.

674. One example of the difficulties we faced was the obtaining of hospital records, which caused us a great deal of difficulty and delay. We tried to get a letter from the CMO to enforce compliance from those hospitals who were not complying with our requests for records.

675. When we identified problems as we went along, we tried to find ways to resolve them and improve the programme, so it was fluid in that respect. For example, we improved the counselling processes by auditing for consistency and identifying best practice.

g. the source of funding for the programme and what level of control, if any, the funding body exercised over the running of the programme; and

676. There was no funding body to speak of. I recall that we were assured through the Department of Health that funding would be made available and our Finance Director, Barry Savery, made arrangements with the Department of Health to ensure particular funding for the cost of the PCR confirmatory testing, and a system for paying the PHLS for all of the tests that they did. Where extra staff were required, we had to fund it within our own resources.

677. Again, I refer to my lookback Rule 9 response and in particular my response to question 15.

h. any other relevant details including your own involvement.

678. This was the first thing I wanted to do when I came into office notwithstanding that it would be of limited success and that it was introduced four years after the commencement of screening. I nevertheless felt that it was important to do because a small but significant number of people would be traced, offered testing, counselling and (a small proportion) treatment. The work that flowed from the lookback in terms of the HCV database and the HCV register and other safety initiatives such as Better Blood Transfusion,

Appropriate Blood Use and SHOT were also very valuable for the overall safety and improvement of the blood service.

136. Please describe the scope of the programme. In particular:

a. whether the programme encompassed all regions of the UK;

679. Yes, it did, although as Medical Director I was only in control of the England and North Wales part of the UK.

b. whether the look back included testing of stored samples (you may find DHSC0003595_040 of assistance);

680. I understand that Dr Patricia Hewitt has addressed this in her response to the Rule 9 lookback and I refer to her response and agree with that entirely.

c. the approach taken to cases where repeat donors, with a pre-September 1991 donation history, subsequently received an anti-HCV positive test result following a donation;

681. If such a donor appeared again after 1991 and they were HCV positive, then they fell within the lookback criteria and we would look back at their previous donations. Wherever there was a positive anti-HCV donor with a donation history we traced that back.

d. the approach taken to cases where repeat donors, with a pre-September 1991 donation history, subsequently received an anti-HCV indeterminate test result following a donation;

682. Indeterminate test results would go through the confirmatory testing processes and if the result was found to be positive then we would do a lookback.

683. The lookback was extended to indeterminate donors from **March/ April 1996**, but with very few people identified. I have described this in detail in my response to the lookback Rule 9 request.

e. the approach taken to cases where donors, with a pre-September 1991 donation history, ceased to donate on or before September 1991 and were therefore never personally tested for anti-HCV; and

684. We faced difficulties with contacting lapsed donors and this is dealt with by Dr Patricia Hewitt in her response to the lookback Rule 9 request. I refer to her response and agree with it entirely.

685. There were several reasons why lapsed donors may have stopped donating, for example if they had died, or moved, or ceased to donate for a medical or personal reason and it is very difficult for us as a service to know these reasons. Donors are volunteers, so there is the question of how far it is appropriate to chase the donors, in a system where we rely entirely upon their altruistic and *voluntary* donation, after they are unable or have chosen to no longer donate. We would be proactively tracking them down to ask these donors to return to be tested to see if they carry any infections, which may possibly have harmed others.

f. the approach taken to cases where repeat donors, with a pre-September 1991 donation history, subsequently received an anti-HCV positive test result not conducted in the course of blood donation (i.e. if they were tested for HCV during the course of some other treatment for which the NBA was not responsible). You may find NHBT0097156_004 of assistance.

686. The document which is quoted (NHBT0097156_004) is the transfusion transmission of HCV infection before the anti-HCV testing of blood donations in England. It is the result of the national HCV lookback programme and this is in transfusion volume 42, September 2002.

687. Provided we were notified of these pre-September 1991 donors who had received an anti-HCV positive test result not conducted in the course of blood donation, we would perform a look back on them, but this would require the clinicians or the donor themselves notifying us and we tried to track these through collaboration with the CDSC and PHLS.

688. We always tried to educate and remind clinicians to consider whenever there was a case of hepatitis, whether there had been a possible link to transfusion and if so to let us know so that we could try to trace the donor and then any other recipients (traceback, followed by lookback).

137. In a 1996 meeting, the issue of hospitals failing to provide information to the NBA to assist with the HCV lookback programme was raised (NHBT0009899_001). Please outline the problems experienced, how they affected the look back programme, whether information was ultimately accessible from the "poor performing" hospitals and what steps were taken to remedy the difficulty this situation presented. To what extent, if at all, were non-responsive, or slow-responding, hospitals responsible for a failure to trace donations through the look back exercise?

689. There is a document dated 22 February 1996 which is the minutes of a clinical directors meeting and item 7 on the agenda was the HCV update and what actions can be taken to improve the performance of poor performing hospitals.

690. We had to determine locally who were the poor performers and then give them a warning notice that they would be reported to the Department of Health if they did not comply.

691. I again refer to my Rule 9 lookback response and in particular my response to question 10.

692. In terms of the extent to which non-responsive or slowly responding hospitals were responsible for a failure to trace donations, I can say that it made the process more difficult and caused it to take longer than had

been anticipated, but it was always appreciated that it would not be easy because one of the problems with lookback is the difficulty in obtaining accurate and complete hospital records, either due to missing or incomplete records or the level of work needed to go through these and identify people.

693. I genuinely think that most people were trying to the best of their ability to assist with the lookback, but some faced more obstacles and handicaps than others due to the lack of personnel or where records were missing, for example.

694. I do not think there was any deliberate attempt not to comply, but sometimes the difficulties these hospitals faced were insurmountable.

138. On 25 November 1998, you responded to a letter relating to a recommendation in the US that all recipients of blood prior to 1992 should be tested for HCV. You stated that "I feel fairly confident that this will not cause us a problem" and proceeded to elaborate on the differences between the situation in the US and the UK (NHBT0036358). Please explain what you meant. In particular:

695. The situation in the USA is different from the UK. The document referred to by the inquiry (NHBT0036358) is a letter from me to Phillip Mortimer on 25 October 1998 with regard to the USA's decision that they had to offer testing to all transfusion recipients pre 1991 because it was impossible for them to do a lookback in 1998; they only kept records for seven years and were attempting to trace recipients 7 years after the introduction of testing, so the USA's situation was that they could not actually do a lookback and had no alternative but to test all pre-1991 donations.

a. Did you mean you were not in favour of testing the pre-1992 recipients of blood for HCV (or some similar grouping)?

696. No. Where GPs or clinicians or GPs felt it was necessary then patients were given the opportunity to have a test and I believe quite a lot of tests were done, but we did not recommend this as a policy because we did a more targeted and focused lookback, and even this did not lead to the identification of a large number of infected recipients.

697. It was a staged approach, starting with the most focused enquiry likely to identify people and then was extended to indeterminates, but beyond that it was a matter for the government as to whether to extend testing for all pre-1991 donations, and more widely to anyone in the community who may have undiagnosed HCV, a very small proportion of which was transfusion-transmitted.

b. If so, given that the look back programme was believed to have missed 30% of the issued components, why did you come to this view?

698. It was the government who ultimately reached this view. This is something that was not really discussed because there was a general consensus and if this had been something that had been thought to be worthwhile for the number of people who were identified then the huge nature of the exercise would have been justified, but the fact that it was never raised or discussed at that time suggests that it was not thought likely to have been a constructive exercise.

699. The risk of HCV by blood transfusion is very small compared to the risk of HCV in the community and if the government wanted to find everybody who had HCV but did not know about it, then that is a whole different question. This would raise the issue of why it would only be those who had been transfused who were prioritised as a public health imperative, since HCV is endemic in the community. Ultimately, this would be a government policy decision – whether to test everybody.

c. Has your view changed at any stage and, if so, why?

700. No, my view has not changed.

139. What was the process the NBA followed when a positive result came back? You may find NHBT0036685, NHBT0052419_004 and NHBT0052419_006 of assistance.

701. The process and protocol that the NBA followed when a positive result came back is set out in detail in my Rule 9 lookback response. I refer the Inquiry to this document rather than repeat it at length here.

Comments in the Panorama documentary January 1995

140. In the 1995 Panorama documentary, you stated that up until two to three years earlier you would not have wanted to be told that you had HCV as it would be harmful to your psychological well-being (NHBT0000236_020). Please explain why this was your view and what caused you to change your view. What did you do to inform those who had been so infected?

702. I recall this interview well. It lasted for around three hours and only small snippets of the interview were taken and scattered through the programme, so that what I said appeared disjointed and out of context. Having had the benefit of hindsight and seeing how Panorama pieced the interview together, I vowed not to do a recorded programme again, but only ever to be interviewed live.

703. To give some context, my interview and recording was done in December 1994 before the HCV lookback had been announced, although at the time I did know that it was going to happen, so I had to handle the interview extremely carefully. There was no way that I could pre-empt the ministerial announcement; I had signed the Official Secrets Act and so was bound by confidentiality. I was not given a 'line to take' by the government.

704. At the time, I was expressing the MSBT view in 1991 when they refused a look back because I was bound by confidentiality, but I was personally always an advocate for lookback and thought that this was what we should do. As I have said above, the first thing I did when I took the post as Medical Director was to make the case for lookback, which was approved.

705. Those who were infected were informed through the lookback programme, which commenced on 3 April 1995.

Response to risk from vCJD

141. Please describe:

a. the events that led to vCJD being recognised as a risk to the UK blood supply; and

b. how your knowledge of vCJD and the impact it could have on the safety of the blood supply developed over time.

706. In my answer to question 141(a) and (b), I have considered the various sets of minutes provided by the Inquiry which set out the developing understanding of vCJD and have summarised the important points below.

707. I remember that when I became Medical Director, I barely knew what Creutzfeldt-Jakob Disease (CJD) was and quite early on, after I had taken up the post, I received a phone call from the Department of Health in which I discovered the existence of a vCJD surveillance unit, which had been set up because of the human growth hormone and the development of CJD as a result of using human pituitary extract.

708. The first point I want to make is that there are various forms of CJD. There is:

a) Sporadic CJD

b) Iatrogenically induced CJD (which is the human growth hormone)

c) Familial CJD

d) Variant CJD (vCJD)

709. The sporadic, familial and human growth hormone types were quite rare.

710. The first MSBT minutes that mention CJD are the minutes of **2 May 1996 (SBTS0000518)** when there was a query as to a link between CJD and blood transfusion and whether a lookback should be instituted.

711. The first I knew about it was when the CJD surveillance unit identified 50 patients with CJD who had donated blood and the question was whether we should establish the fate of donations and identify the recipients, whether the recipient was still alive and if not what the cause of death was. This was in relation to CJD in general and not the new variant CJD.

712. At the same meeting there was an announcement of the new variant CJD by the CMO of 10 cases, one of whom was known to have been a donor and there was the potential link to BSE in cattle, but there was a lack of any information regarding transfusion transmissibility in other species.

713. The current evidence at that point was that Buffy Coats (the fraction of an anticoagulated blood sample that contains most of the white blood cells and platelets following centrifugation) played a role. So, the possibility of removing white cells from blood donation was discussed.

714. I did not know much about this until this **May 1996 (SBTS0000518)** meeting and the announcement by the CMO.

715. In the SACTTI minutes of **16 April 1996 (NHBT0000088_013)** when Dr Peter Flanagan was the chair, we discussed the implications of new variant CJD for UK transfusion services and I was to ask the MSBT to approve a lookback on recipient donations of variant CJD cases. At a special meeting on **9 April 1996 (DHSC0020783_088)**, representatives from SACTTI and the CJD surveillance unit noted that we needed to see information from the SEAC (on all forms of CJD (spongiform encephalopathy). SEAC is the Spongiform Encephalopathy Advisory Committee (SEAC) appointed by Ministers and sponsored jointly by the Department for Environment, Food and Rural Affairs (DEFRA), the Department of Health and the Food Standards Agency (FSA). So we first became aware and alerted to potential problems in **April 1996**. Then at the MSBT meeting **of 2 May 1996 (SBTS0000518)** I raised the issue of whether we should be doing a lookback.

716. On **1 July 1996** there was a SACTTI meeting held where the proposals for a CJD lookback were discussed and tracing donations from CJD patients to recipients **(JPAC0000109_025).** There was a meeting planned on **15 July 1996** with the chair of SEAC, who was Professor Patterson, with prepared questions and implications for blood transfusion **(NHBT0008231)**. It was the blood transfusion service who raised with the CJD experts the potential transmissibility by blood.

717. The common themes throughout these meetings were that there was a great deal of difficulty in breaking the confidentiality of the CJD Surveillance Unit because they were loathe to share names with anybody else and, of course, to do a lookback you had to first identify individuals and once individuals had been identified the questions come up as to whether you should or should not inform them of their exposure. There was and is no test in a living individual for vCJD. Around the same time the Data Protection Act came in, which put another layer of data protection and confidentiality upon patient information.

718. At the MSBT meeting of **18 October (DHSC0004018_090)** I reported the findings of SEAC and the implications on blood donations and

transfusions and that Buffy Coat extracts had transmitted infection during animal experiments. I reported that leukocyte removal from blood may reduce the risk.

719. At the next meeting of SACTTI on **9 July 1997 (NHBT0000088_017)** there was a CJD / DoH meeting looking at the need for research into blood transfusion and transmissible spongiform encephalopathies with experimental work needing to be defined.

720. The next meeting was of the MSBT on **27 October 1997 (SBTS0000522)** at which it was noted that a French firm was not renewing a contract for UK albumin with BPL, so in effect this was a French ban on human albumin solution from BPL prepared from UK plasma. We were to continue with the new variant CJD lookback without informing the recipient, as backed by the Lothian Ethics Committee which was the Committee local to the Edinburgh Surveillance Unit. We had received a question from the Haemophilia Society as to whether any of the implicated human albumin had been used in the manufacture of factor VIII or factor IX products and, if so, whether any such products would be withdrawn and patients told.

721. The DNV risk assessment was commissioned and there was a pending decision as to whether to leucodeplete blood or not and it was noted that there was no diagnostic or screening test and the only way to diagnose CJD was at post mortem. I believe that remains the case today.

722. At the meeting of **8 July 1997 (NHBT0019394),** we discussed the exclusion of donors who had had neurosurgical procedures likely to have had human dura mater grafts due to the risk of contamination with CJD. This was quite a difficult exclusion to achieve in terms of donor questioning, because donors who had had a neurosurgical procedure would not necessarily know whether they had had a dura mater graft. We therefore had to get input from neurosurgeons as to what neurosurgical procedures would be likely to use dura mater grafts and then include these procedures in the exclusion criteria.

723. There was a SACTTI meeting on **21 January 1998 (NHBT0000088_020)** at which we discussed the NBA position statement on vCJD in terms of what we knew at that time and what we were doing about it. There was a recall of UK human albumin solution used in 41 countries. The leukodepletion project was underway at this time. A discussion was had about whether, if food ie contaminated beef was removed as a source of the CJD then blood transfusion would be the only cause and modelling was done on that basis.

724. At the MSBT meeting of **26 February 1998 (DHSC0020709_063)** we discussed informing patients who had received new variant CJD donor blood or blood products and the ethical advice from a range of committees was that recipients need not be informed with the exceptions of individual clinicians who had the autonomy to make the decision about informing recipients or where there was a recall of an implicated product and the recipient had to be told why. There was an NBA position statement that there must be a permanent record kept in medical notes when a patient is transfused with blood or blood products because we found during the HCV lookback that this was not always done, despite it being a requirement.

725. We discussed the impact of introducing leukodepletion and calculated that it would be a cost of £82 million per annum with the NBA budget being a total of £152 million. Each leukodepletion filter cost around £20 and would need to be used on around 3 million components per annum, plus the additional cost of processing and staffing.

726. The next meeting was the SACTTI meeting of **12 March 1998 (NHBT0000088_021)** at which it was noted that no decision had yet been made about previously transfused donors and we were to discuss risk management strategies because the research results were at least two to three years away. Dr Flanagan pointed out that 48% of factor VIII used in the UK was commercially imported, as a result of clinician choice.

727. The next meeting was on **19 May 1998 [NHBT0000088_022]**, which was another SACTTI meeting, when it was noted that all members confirmed that the CJD cases were now notified and donations traced. The fate of fresh components was traced and identified recipients passed back to CJD SU.

728. It was noted that there were nine recipients of the CJD blood donations traced and one had died, and we discussed what steps were to be taken to ensure that any donations they might make would not enter the blood supply. There was an ethical discussion as to whether we could do this without notifying the recipient.

729. At the meeting of **4 June 1998 (DHSC0004026_033)**, which was an MSBT meeting, there was a progress report on new variant CJD with a focus on blood products, blood components and donations from previously transfused donors. Concern was expressed about blood supply if donor deferral was recommended. It was noted that it would reduce our donor panel by between 5 – 10% so there was a balance of risk between running out of blood and deferring donors who were of CJD risk. It was noted that if leukodepletion was to be advised by SEAC, it would take 15 months to implement. There would be no single start date and it would be introduced progressively, with completion by an agreed date, because of the technical difficulties involved and the different types of components that had to be dealt with. When we make components, it is in a closed system, but to achieve depletion a filter needs to be added into the system, so packs had to be made with the filter pre-attached to be able to link it into the system which of course increased the risk of bacterial contamination, so it was not a risk-free issue.

730. At the SACTTI meeting of **29 September 1998 (NHBT0000088_023)**, the Data Protection Act was raised again and the issue over donor and recipient confidentiality which caused a problem in terms of tracing recipients and access to their medical information was discussed.

731. The next meeting is the MBST meeting on **29 October 1998 (DHSC0004026_032)** at which I reported that by **January 1999** we would have 100% leukodepletion of platelets and by **October 1999** we would have 100% leukodepletion of everything. Platelets were significant because when you leukodeplete platelets you remove the Buffy Coat and these were the most implicated components, which is why they were tackled first. It was agreed that there should be no duplicate supply of UK plasma derived products, and only a non-UK sourced supply to avoid a mixed economy of supply; so all of the remaining supply had to be recalled and substituted with the non-UK sourced plasma products, including from patients' own personal fridges. There was an open recall of all UK derived plasma products.

732. We again discussed the deferral of previously transfused donors. It was noted that France and Canada, who were deferring previous UK residents and previously transfused donors, were having blood supply problems. New variant CJD research was given a £25 million budget. A study of haemophilia patients was proposed and a pre-clinical phased study was to be undertaken to look at tonsils and appendices removed during surgery.

733. At a SACTTI meeting on **25 November 1998** [NHBT0004601_001] anti-D and CJD risk was discussed and there was concern regarding the lack of availability of non-UK plasma specific immunoglobulins and in particular anti-D, which highlights the problem of other patient groups who were at risk aside from haemophilia patients as a result of this policy because all pregnant Rh negative mothers received anti-D. Again, the ethical issue about notifying recipients was discussed. The minutes note that an information sheet was created, although I don't have a copy of this. 31 new cases of variant CJD were reported, eight occurring in 1998. Non-English cases were not included (subsequently Scotland and Wales agreed to include their figures).

734. At the MSBT meeting of **28 October 1999 (NHBT0004333)** the Department of Health approved that blood from individuals who had received blood from donors who later developed variant CJD should not be allowed to enter the blood supply, but did not explain how we could achieve that.

735. The next time vCJD is mentioned is at an SACTTI meeting on **7 March 2000 (NHBT0002623_001)** at which it was noted that the Lothian Ethical Committee had removed ethical approval with regard to identifying the recipients of vCJD patient donations. This would have prevented us from stopping donations from these individuals entering the blood supply

736. At the meeting of **5 July 2000 (NHBT0002594)** it was noted that previously transfused donors were still being accepted.

737. At the meeting of **13 March 2001 (NHBT0017175)** the Department of Health's risk assessment team (the Economics, Statistics and Operational research team EOR (later ESOR)), were doing risk assessment on previously transfused donors.

738. At the meeting of **3 July 2001** there was an update on the CJD clinical incidents panel, at which it was noted that most plasma product recipients were not at risk.

739. At the meeting on **15 January 2002 (JPAC0000081_032)** there was discussion of the DNV risk assessment and new information regarding portioning of the prion, i.e. where does it go once blood is separated into components.

740. At the SACTTI meeting on **15 January 2003 (JPAC0000029_079)** it was noted that there were 26 cases of variant CJD in 2002; 20 cases in 2001 and 28 cases in 2000. From the tonsil experiment there was a suggestion that one in 8,000 were possibly infected.

741. At the meeting of SACTTI on **6 January 2004 (JPAC0000117_008)** it was noted that MSBT was likely to exclude donors who had been

previously transfused and I presume this was actually in force some time in 2004.

142. What steps were taken by you during your time at the NBA to protect the blood supply from the risk of vCJD? In particular, please advise whether you undertook:

742. The biggest step taken during my time at the NBA to protect the blood supply from vCJD was the use of leukodepletion.

a. screening tests;

743. As far as I am aware, and this is still true, there is no diagnostic test or screening test available for vCJD, other than making the diagnosis via brain biopsy at post mortem, so there were and are no screening tests available.

b. donor selection policies;

744. With regard to the familial CJD and iatrogenic CJD, we excluded family members of those who had had CJD with regard to familial; and with regard to the iatrogenic we excluded certain neurosurgical procedures where a dura mater graft had been used. Previously transfused donor exclusion came in around 2004.

c. methylene blue treatment;

745. This would have had no impact whatsoever on vCJD.

d. product recall; or

746. There was the issue of human albumin solution in other countries, but I am not aware of any product recalls in England because by the time we

discovered vCJD all the fresh components would have gone and I don't know whether we track and traced all the donations that went into plasma pools for factor VIII, etc. This was subsequently discovered to be the lowest risk for transmission.

e. importation of products from the USA or elsewhere.

747. From **14 April 1998** UK plasma was no longer used for fractionation.

143. To whom was the NBA, and yourself as its Medical Director, answerable in relation to vCJD and efforts made to ensure the safety of the blood supply? Please outline your interactions with these bodies, including reference to discussions, meeting groups and the power of any such body to influence policy decisions.

748. The NBA was accountable to the Department of Health and the Secretary of State.

749. I as Medical Director, was managerially accountable to the chief executive of the NBA but I was professionally accountable to the CMO or his representative and usually a deputy CMO.

750. In relation to my interaction with other bodies we had the MSBT, SACTTI, SEAC and the vCJD incidents panel.

751. The MSBT made the final decision but had to get ministerial approval before implementing those decisions. The MSBT theoretically represented all four UK territories.

144. In a letter to Dr Ailsa Wight dated 14 April 2000, you raised concerns over the "sensitive issue" of vCJD reporting procedures between the blood services (NHBT0004047_002). In July 2000, Dr Wight responded (NHBT0004046). She noted that "concerns have been expressed about the possibility of a case slipping through the net" if reporting procedures

are not properly followed. To what extent, if any, did the concerns set out by Dr Wight materialise? Did cases of vCJD "slip through the net" at any stage?

752. This letter was about the Welsh concern as to the sharing of CJD SU cases data with all transfusion services and the response indicated that there was very little likelihood of any case slipping through the net and the reporting system was left as it was as far as I can recall.

753. This was a case of trying to make sure that any donor who had been transfused from a person who later developed variant CJD could be kept out of the blood supply, so her concern was that if a named individual was not shared with all four services then there was a chance of it slipping through the net; but the response that we got from the CJD surveillance unit ruled that out because they had the full details of where the patient lived.

754. I am not aware that any cases slipped through the net.

vCJD look back

145. Please describe whether the NBA implemented a vCDJD look back exercise. In particular, please address the following:

a. how the decision to implement such an exercise come about;

755. It came about at the discussions with SEAC and we had to work out whether CJD was transmissible by blood or not.

b. the purpose for which the programme was established;

756. To determine whether there was a link between vCJD and blood transfusion.

c. whether the programme encompassed all regions of the UK

757. Yes it did.

d. the start date of the programme (you may find DHSC0038507_060 of assistance);

758. Post **March 2002** which is the date of the letter referred to in DHSC0038507_060 when the CJD lookback programme had clearly not formally started.

e. how and by whom the programme was to be conducted

759. It was commanded by the MSBT but run by Professor Robert Will.

f. who was ultimately responsible for the programme;

760. I believe either the MSBT or SEAC. I am not certain which, but it was one of these government departments.

g. how the success of, or any problems with, the programme were to be measured, identified and resolved;

761. It was funded by the committee on Transmissible Spongiform Encephalopathy (TSE) who I assume are monitoring its progress but I am not certain.

h. the source of funding for the programme and what level of control, if any, the funding body exercised over the running of the programme;

762. It was the TSE who I believe had a large budget because this was a high profile and nasty disease.

i. how the scope of the look back was defined;

763. Anyone who donated was followed up.

j. whether recipients of vCJD implicated blood or blood products were notified; and

764. On the one hand we had the public health interest of stopping vCJD entering the blood supply but on the other had the Data Protection Act and confidentiality issues and I don't know what the outcome was of the ethical committees and what decision was taken.

765. In relation to the flagging of donors point, there was a meeting with Department of Health officials in 2000 which I attended with the NBA Lawyer Steven Janisch and also Dr Patricia Hewitt. I had obtained legal advice about flagging and was told that it would be inappropriate to flag them as potential future donors and throw the blood away without telling the donors as it would negate the consent to destroy the blood without telling the donor. This was contrary to the ethical advice which had previously been given which is set out in my lookback Rule 9 response in relation to duty of care at question 1.

k. any other relevant details.

766. There is nothing else I want to add.

Section 16: Self-sufficiency

146. Please set out your responses to the following questions, both in relation to your views as an RTD and as Medical Director of the NBA:

a. What did you understand the term 'self-sufficiency' to mean? Did this change over time?

767. The term self-sufficiency to me meant providing enough safe blood and blood products to meet all of the patients' needs from voluntary donors in (as the service was then) England and North Wales. Scotland and Northern Ireland had their own services.

768. This understanding did not change over time, but the volume of plasma required always gradually increased and that was because of the development of home prophylactic therapy for haemophilia patients and as the methods to virally inactivate plasma reduced the yields of factor VIII. Factor VIII is very heat sensitive so if you heat treat plasma you reduce the yield of factor VIII. Whatever methods were used tended to reduce the yield and the amount of plasma required went up.

769. I have read somewhere that the original target was 450,000 tonnes per annum and by 1992 that had gone up to 550,000 tonnes (a tonne is 1,000 litres). A litre is about 4 donations – so this is a demand for 2.2 million donations (if acquired solely from whole blood but a proportion came from plasmapheresis where one donation yielded 0.5 L).

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

770. My view on the prospect of the UK achieving self-sufficiency was always positive but I recognised early on that it was not possible to achieve self-sufficiency by blood collection alone as insufficient plasma could be recovered from whole blood collection and if we met the patients' needs for red cells then we would not achieve enough plasma. We could deliberately over collect in the knowledge that the red cells collected were not going to be used and either wasted or discarded but that, to me, was inappropriate. As far as I could see a programme of plasmapheresis had to be introduced and we had already been using plasmapheresis for some purposes, so it was already an understood process.

771. One of the advantages of being in Yorkshire was that my predecessor, Dr Tovey had set up an active manual plasmapheresis programme which he used to collect anti-D. This programme had a lot of donors and he recruited many more. The other advantage I had was the fact that Yorkshire had been using a therapeutic Haemonetics machine (Model

30 Cell separator machine) which I used in 1980 to give one of the first ever plasma donations, and it occurred to me that I could actually get a donor programme going and collect plasma, and at the same time have the donors on my donor panel for white cell collections, and all of the other special components.

772. I could also convert Dr Tovey's established panel of anti-D donors onto apheresis machines. The programme started in a four-bed unit in the Seacroft Hospital. It was on the N Ward where I ran a pilot unit which resulted in the publication of a study into how we could achieve voluntary donor plasmapheresis to obtain sufficient plasma. This pilot was presented as a poster to an ISBT (International Society of Blood Transfusion) meeting in around 1980 or 1981.

773. I have since been involved in many of the standards of care and safety procedures for plasmapheresis and spent a lot of time collecting all the hazards in both the therapeutic and the donor sides to try to ensure it is safe. With the biochemist I worked with at Seacroft and Dr Jim Smith we formulated some anticoagulants so that there was less of a chance of the donor getting a citrate toxicity.

c. Broadly, what steps do you consider were required to achieve self-sufficiency in the UK? Were any of these steps taken?

774. The only other way to increase plasma was by an increased usage of concentrated red cells so the yield of recovered plasma would be maximised. This would require education in the use of concentrated red cells to clinicians rather than using whole blood. Clinicians were not keen on this because red cells are a lot stickier and they take longer to transfuse.

775. A bigger BPL was required because they did not have capacity to cope with the amount of recovered plasma even if we did scale up.

776. In summary there were two requirements for increasing plasma; one was increasing the use of concentrated red cells and the other was

increasing the scale of BPL, but even if we did those we would not achieve enough plasma without introducing a programme of plasmapheresis.

777. My pilot plasmapheresis unit at the YRTC Seacroft Hospital was the first example which could be followed and promulgated. I set it up in 1980 with four beds on the N Ward and then the first standalone unit opened in Bradford in 1982, which I am proud to say was the first voluntary donor plasmapheresis unit in Europe and probably in the world. I remember when I set this up that a television programme (I think Horizon) asked if they could come to film the unit which I agreed to. When I saw the documentary to my dismay, they had used the footage to imply that this was an American plasma parlour on Skid Row for paid donors, which was a gross misrepresentation and made me extremely angry.

778. In 1984 I opened a second plasmapheresis centre in the centre of Leeds on St Paul's Street as well as the one at Seacroft Hospital.

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

779. Yes, my views on self-sufficiency did accord with the views of my peers and the Blood Transfusion Services but we differed in some of our views of how to achieve it: for example, in Scotland they were able to over collect because they had a large donor panel but in England, we could not do that because we did not have a large enough donor panel so we had to introduce plasmapheresis and a new bigger BPL was needed. BPL was completed in 1987 and almost reached full capacity in 1989 but was not fully functional until 1991.

147. What did you do as Medical Director of the NBA to ensure the UK became self-sufficient in blood? How did the NBA perform, in this respect, while you were Medical Director?

780. During my time as Medical Director I did the following to ensure that the UK became self-sufficient in blood:

a) Improved donor retention and recruitment so that we had better national, regional and local campaigns and developed a new logo that is still used to this day, and a new strap line which is '***Do something amazing, give blood, save a life***'. Sir Colin Walker, who was the chairman, actually attended every donor team around the country to encourage them and show his presence and camaraderie. This took him about two years to visit every team in the country (around 200 teams) and the teams loved him.

b) The publicity events at the NBA were led by a professional PR team.

c) The Better Blood Transfusion initiative was set up by the CMO but followed through by the transfusion service with Ted Gordon Smith and the National Transfusion Committee. This was a campaign to use blood only when it was needed and on appropriate blood use, which led to quite a dramatic decrease in demand; so we had fewer blood shortages. The trouble was that if we reduced demand for red cells, we had to increase our plasma collection, so our plasmapheresis programmes had to increase and flourish. We recruited for plasmapheresis from our established blood donor panel in order to minimise the risks from recruiting new donors with infections.

d) I introduced the blood stocks management scheme, which was difficult to set up because the hospitals really didn't want to share what they held in their blood banks, but this did reduce the wastage of outdated blood in blood banks and encouraged the sharing of blood across the country; so there was less wastage and fewer shortages.

e) I maintained and increased the plasmapheresis programme and attempted to switch to collecting platelets and plasma at the same time by machines which collected PRP (platelet rich plasma). This meant that we obtained 500mls of plasma, plus the equivalent of two

or three units of platelet concentrate, which, in turn, meant the collection of plasma and platelets was more economic. When the decision was made to no longer use UK plasma, those plasmapheresis centres were converted to collect platelets only.

781. Huge efforts had to be made to increase our plasma production to provide for our haemophiliac population who conversely made up a very small proportion of the overall patient population for whom we had to provide services, such as life-saving treatments during surgery, obstetrics, accident and emergency departments and for the management of cancer and leukaemia patients to name but a few.

782. We always tried to use our resources in the fairest and most cost-effective manner to provide for the breadth of services required by all our user population.

Plasmapheresis

148. 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 the BTS gave to implementing plasmapheresis, including:

a. whether manual or machine plasmapheresis was preferred;

783. The document the inquiry is referring to (CBLA0001287) was the second meeting of the advisory committee of the National Blood Transfusion Service on **23 February 1981**. At that stage Dr Geoffrey Tovey (to be distinguished from Dr Derrick Tovey, the former Yorkshire Transfusion Director) was the consultant advisor to the DHSS and the Director of the Bristol RTC. A plasmapheresis working party was set up chaired by Dr Harold Gunson to consider what would be needed to meet plasma self-sufficiency targets.

784. In **1981**, as already described, I obtained four automated machines and I set up a pilot scheme where we considered everything from donor recruitment and safety to frequency of attending, to staffing, donation time, quality of plasma. I worked with Dr John Smith and my local biochemist. That work was presented as a poster in 1982 at the International Society of Blood Transfusion held in Budapest, although I could not attend so the director at the time, Dr Derrick Tovey presented it on my behalf.

785. Manual plasmapheresis had been used for several years and the main centres were Bristol, Manchester and Leeds to collect anti-D plasma from volunteers.

786. Manual collection took the donor at least two hours. They would have to attend the centre and the donor would be set up with a harness and they would donate one pint of blood, which was taken away and centrifuged and then the red cells returned and then another pint was taken, which was taken away and centrifuged and then returned to the donor and staffing was one on one.

787. Automated plasmapheresis took about 35 minutes because it is all integral in a closed system and the blood is bled into the machine, which spins and separates the plasma and the red cells are returned to the donor and the plasma separated. One donor attendant could supervise two machines with one nurse supervising and a trained donor assistant looking after the machines. This was based on my six-bed unit in Bradford.

788. I preferred automated plasmapheresis because of donor convenience, the ease of recruitment from the red cell donor panel and the safety from the donor point of view that this was a closed-system and the blood was never separated from the donor.

789. The automated machines were more expensive because the harnesses had an integrated centrifuge bowl, but what wasn't taken into account and the alternative included the cost of donor time, the technical time, staff supervision and the ease of scaling the process up.

790. Those were my arguments in favour of automated plasmapheresis over manual plasmapheresis.

791. My preferred method was machine or automated plasmapheresis, but Dr Harold Gunson disagreed as set out in document DHSC0002219_020, which is dealt with at question 150.

b. the relative cost differences between each method;

792. With automated plasmapheresis the capital cost of the machinery was more expensive and the cost of the harnesses was more expensive, but balanced against that in manual plasmapheresis is the cost of the donor time which is voluntary, the staffing costs in the technicians doing the centrifuging and the one on one staff supervision time.

793. Machine plasmapheresis is safer because it is a closed system and with manual plasmapheresis there is always the possibility, albeit very low risk, that the wrong red cells would be given back to the donor.

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

794. In automated plasmapheresis there would be one medical officer running the session with one donor attendant running two machines and one nurse supervisor.

795. Each centre had a different staffing base so those centres that could introduce plasmapheresis did and those that did not have the staffing base were encouraged to do so. All were dependent at that stage on their respective RHAs for financial support and setting up a plasmapheresis unit was a major expenditure.

d. whether, in your view, plasmapheresis would increase the amount of available plasma. Please answer in respect of your experiences as both an RTD and the Medical Director of the NBA.

796. There was no doubt in my mind that automated plasmapheresis would increase the amount of available plasma.

797. When I was the NBA Medical Director, plasmapheresis programmes were maintained in every centre and we had nationally agreed harness contracts, which is one of the greatest costs of the running procedure, and purchased the machines on a lease arrangement, negotiated by Barry Savery and the chief executive of the NBA.

149. In October 1981, you wrote to Dr Gunson highlighting your concerns about the BTS's then emphasis on manual plasmapheresis methods. You wrote that "until a properly conducted trial of manual plasmapheresis has been carried out in this country to establish 1. Equipment necessary, 2. Safety precautions...3. Staffing levels [and] 4. Factor VIII yields, manual plasmapheresis cannot safely be recommended as the most economic means of plasma collection" (DHSC0002211_072). Can you please explain the reasons for your view? Was a trial of manual plasmapheresis methods ever conducted? If so, what was the outcome of the trial?

798. The reasons are self-explanatory and set out in the document DHSC000221_072. These were: equipment, large centrifuges non closed system, lab technicians' time, safety (risk of transfusing wrong red cells because manual plasmapheresis is not a closed system), the one-to-one donor attendant nursing staff required for each donor and then the need to do rapid blast freezing to maximise factor VIII yield.

799. To my knowledge, a manual plasmapheresis trial was never carried out, most likely due to practicalities and donor recruitment and acceptance of such a programme.

800. By the time my pilot trial was published in 1982, automated plasmapheresis became the method of choice both commercially and in the voluntary sector.

150. Dr Gunson referred to your view on manual plasmapheresis in a letter to the DHSS in August 1982 (DHSC0002219_020). He disagreed with your view that an "unfair bias had been given to manual plasmapheresis" and proceeded to set out a range of reasons to justify his disagreement. Do you agree with Dr Gunson's points? Did you have sight of this letter, or have discussions with Dr Gunson on this matter, at the relevant time?

801. This question relates to Dr Harold Gunson's letter of **August 1982** to Mr Godfrey at the DHSS. I am not sure who Mr Godfrey was and I did not have sight of this letter. The first time I saw this letter was when it was provided to me by the Inquiry.

802. I was, however, well aware of Dr Harold Gunson's view, which was conflicting with my view about the arguments for and against automated plasmapheresis and we agreed to disagree.

803. From memory, I think that this is the one and only time I actually disagreed with Dr Gunson.

804. My reasons in favour of automated plasmapheresis are set out above. We set up the six-bed unit in Bradford in 1982 and this was very successful and most commercial centres in the US transferred to automated machines. The anti-D plasmapheresis programme was converted to automated and, as far as I know, no RTCs set up a manual plasmapheresis programme so no true comparative trial was ever undertaken. We did achieve a donor turnaround time of 35 minutes.

805. I have already referred to above the CPD anticoagulant formulation that I came up with in collaboration with the Seacroft hospital biochemist and we actually made that at the YRTC until the MCA shut that down and it had to be made commercially from then on.

806. My view remains unchanged then and now. My Regional Health Authority supported my costings and the case for automated plasmapheresis and my apheresis centres were well funded.

807. I was never made aware of this letter [DHSC0002219_020].

151. Please set out the extent of the plasmapheresis programme at YRTC during your tenure. As far as you are aware, did this programme differ from other RTCs? If so, why?

808. Bradford was the first centre of the RTC sited in a city centre and was a six-bed unit, operated five days a week. In the regional transfusion centre (Seacroft Hospital) we maintained a four-bed unit which continued in addition to the therapeutic procedures. This was then converted to a six-bed unit with four therapeutic beds as well. We performed stem cell collection. I believe the Bradford centre is still running to this day.

809. We also had the Leeds city centre unit on St Paul's Street with eight beds, which I believe opened in **1984**, which later moved into the Hedgerow High Street in Leeds. I am not certain whether this unit is still functioning.

810. Other centres equivalent to the YRTC would include Bristol, Cambridge, Oxford, North London, Manchester, Lancaster, Liverpool, Sheffield and Birmingham. This might not include all of the big-automated apheresis programmes, but I am sure that the centres I have just mentioned did have equivalent programmes to the YRTC.

811. The ways in which the YRTC differed was that we were the first centre to open a town centre site and were one of the centres that had joint transfusion and hospital posts, so there was linkage to a therapeutic programme which enabled me to provide a regional service to the bone marrow transplant unit and to all hospitals within the region. We did this for a lot of the other centres, but the closest in comparison to us was probably Bristol, run by Dr Geoffrey Tovey (not to be confused with Dr Derrick Tovey who ran the YRTC prior to me).

812. Very few RTCs offered a therapeutic service, which is where the YRTC differed and by offering therapeutic services we could very naturally go and start up a donor programme. In fact, all of my donors originally came from my treatment of child leukaemia patients which is when I got the cell-separator machines and could separate the white cells to treat the patients. The donations would often come from family members, so the beginnings of my donor panel were friends and relatives of cancer and leukaemia patients.

813. Yorkshire had the first bone marrow transplant unit outside London, so it was down to the YRTC to provide all of the components this service required. Our starting base therefore differed from other RTCs.

152. 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:

a. the plasma supply in England;

814. Document NHBT0057426_002 is not dated but has to be pre **1 April 1989** because it comments that cross charging will be commencing with effect from **1 April 1989**. It is clear that distribution of BPL products and supply of plasma to BPL is a new approach.

815. BPL was originally funded by top slicing the RHAs in the sum of £11 million per annum. The new BPL reached its full capacity in 1989 with a view to meeting demand in England and Wales for blood products. They thought that providing financial incentives to supply plasma to BPL would be a means of financing BPL without top slicing the RHAs.

816. The effect that this had on the plasma supply was that recovered plasma would be incentivised because by increasing the use of concentrated red cells and reducing the use of whole blood we would get funding for our recovered plasma, which was a reasonable incentive.

b. the production of plasma via plasmapheresis?

817. The price set for plasmapheresis plasma did not cover the YRTC's collection costs and we had in fact done better on a pro-rata distribution of plasma because the volume of plasma we supplied to BPL gave us bountiful returns in human albumin solution and factor VIII. This more than met Yorkshire's demands. So, in fact, initially, this did not provide me with an additional incentive at all. At this stage the transfusion centres were still funded by the RHAs. We still, however, carried on the plasmapheresis programme at the same rate as previously despite not being incentivised by the cross-charging arrangement. We had a strong belief in self-sufficiency and wanted to achieve this.

153. The Inquiry holds documents that suggest cross-charging was not financially beneficial to the Yorkshire region in the 1990s. In NHBT0003299, the Yorkshire Services Organisation stated that the price paid by BPL for plasma produced by RTCs was "significantly below the costs of production." It was suggested that the most effective way to reduce costs was to reduce plasma production, which conflicted with the national objective to achieve self-sufficiency. As far as you are able, please elaborate on these concerns and explain whether they were ever resolved (both in the context of the YRTC but also more widely).

818. NHBT0003299 Is a letter from the Yorkshire Services Organisation which managed the YRTC for about three years and this is the point at which our budgets were devolved to the hospitals to recoup our costs from charging for our blood and blood components.

819. The YSO letter dated 31 March 1992 from the Chief Executive Peter Ward was pointing out that cellular products were subsidising plasma production and that the RTCs producing the most plasma were the most

heavily penalised. The YRTC did not reduce its plasma collection but continued to cross-subsidise.

820. When devolution occurred, each centre devised its own budget, so costings varied across the country. If all costs were loaded on blood collection and the collection teams with a supplementary cost for the separation of the components like FFP, cryoprecipitate and platelets, manipulating the individual unit costs to cover the total cost, was one way to cross charge. There are a number of ways to achieve this, but the outcome will be the same.

821. At the YRTC the red cells that we provided to the hospitals were subsiding our plasma collection.

822. There was a centrally fixed price by BPL for recovered plasma and plasmapheresis plasma, but we had to make our own sums add up on everything else to cover our running costs.

823. The NBA began in **1993** and from that point on we began to have nationally set pricing which was consistent all over the country.

824. Plasmapheresis became more cost effective when platelets and plasma were collected because you could obtain half a litre of plasma plus the equivalent of two to three platelet concentrates. This became a more cost-effective proposition from when UK plasma was no longer used as these could be converted to platelet only apheresis collection centres, which meant the resources were not wasted.

825. We had nationally arranged agreements with the machine manufacturers and nationally arranged contracts with the harness providers which reduced costs further so by becoming a national service we were able to bring the costs down.

Section 17: Your relationship with commercial organisations

154. Have you ever:

826. I have answered no to the following questions, but I would like to make it clear that whilst I have never acted as a paid consultant for any pharmaceutical company, I did provide consultancy advice to the main cell separator companies with regard to developmental advice and quality control. These companies were Haemonectics and IBM (which subsequently became COBE, which I believe was then taken over by Baxter Travenol) but I was involved as a consultant advisor only on cell-separator machines and the development of these machines to meet the requirements of the transfusion services and plasma production. Whilst I was never paid a fee or salary for providing this advice they acted as a kind of sponsor and would provide travel, accommodation and expenses to attend international meetings and advanced seminars in apheresis.

827. The arrangement with the companies Haemonetics and IBM/COBE were mutually beneficial and I recall that on one of the advanced seminars run by Haemonetics I travelled to Boston to speak directly to the workers in their factory about how important quality control was. I spoke about how if there was one tiny leak in the harness then the whole donation would have to be discarded.

828. All personal associations with these companies ceased upon my appointment as national Medical Director, and that was possible because I was provided with a travel budget so I was not dependent on anyone else subsidising any meeting I needed to attend: I could use my travel budget to attend these meetings with expenses paid by the NBA.

a. Provided advice or consultancy services to any pharmaceutical company involved in the manufacture and/or importation and/or sale of blood products?

829. No.

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?

830. No.

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?

831. No.

d. Received any financial incentives from pharmaceutical companies to use certain blood products?

832. No.

e. Received any non-financial incentives from pharmaceutical companies to use certain blood products?

833. No.

f. Received any funding to prescribe, supply, administer, recommend, buy or sell any blood product from a pharmaceutical company? If so, please provide details.

834. No.

155. 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?

835. The only external sponsorship I ever received prior to becoming the National Medical Director of the NBA was for travel and accommodation expenses to enable my attendance at International Blood Transfusion Meetings taking place abroad. This had to be declared when applying to the RHA for Study leave to attend such meetings, a system with which I always complied. Once I became the National Medical Director of the NBA, I was provided with an annual travel budget so from then on, no further external sponsorship was ever requested or required

156. 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.

836. No.

157. Have you ever provided a pharmaceutical company with results from research studies that you have undertaken? If so, please provide details.

837. No.

158. 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?

838. Not applicable in view of my above answer.

Section 18: Other issues

159. Please provide a list of any articles you have had published relevant to the terms of reference.

839. I refer to my CV.

160. 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).

840. I have dedicated my professional life to health services users and ensuring the safety of all the services I was involved in providing so that every patient could be as safe as possible. Personally, and as part of the service, I faced many challenges such as the requirement to meet plasma production and the introduction of screening, then trying to work out the threat from CJD and how best to address it.

841. There were huge changes during my career, not just in terms of HCV, HIV and CJD but for example in the treatment of cancer. I used to give a talk to medical students – '*A Bloody Doctor's Tale*' – in which I talked about being the Senior Registrar to Prof Mollison and being asked by him to give the first ever injection of vincristine – effectively one of the first ever attempts to treat cancer by chemotherapy in 1967. From this very first intervention it became possible to cure childhood leukaemia by the end of my career. Medicine never stands still.

842. I learned how to treat haemolytic disease of the new-born so that the significant number of stillbirths to Rh negative women could become a thing of the past and something that is almost forgotten, but had been very terrible to see.

843. I was fortunate in that I worked in a joint hospital post and so could maintain my clinical connection. This was one of only two such posts at the time, the other being in Bristol.

844. I consider myself fortunate that whilst I was a senior registrar, Derrick Tovey managed to get funding for me to attend the Council of Europe course on blood transfusion medicine. Only one place was usually allocated per year for a person to attend from the UK and a transfusion technician was selected that year, but thanks to Dr Derrick Tovey and Dr Gunson I was sent on this course and spent 2 weeks of intensive training in Helsinki. This is

where I first forged international links that I maintained throughout my career. This was in an age before the internet allowed us to share scientific discoveries in an instant. I forged links with specialists in France, Holland, Germany, Norway, Sweden, Denmark and Finland and they were able to share international knowledge and experience and build on these to provide many effective treatments.

845. I would like to recognise and give thanks to our ever willing and committed donor population (both generally and those who volunteered for different types of apheresis procedures) whose courage and selfless service to others saves the lives of people every day.

846. I would like to conclude in paying tribute to those who have been infected and affected through NHS treatment. If I have played any part in that and could and should have done things differently, I apologise unreservedly to anybody infected or affected by that failure and to their families and loved ones.

Supplementary Rule 9 Request dated 16 April 2021

161. 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?

847. To my knowledge, the UK was self-sufficient in its need for whole blood transfusion and all the fresh components derived therefrom such as concentrated red cells, fresh frozen plasma, platelets and cryoprecipitate.

162. During your tenure, 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?

848. During my tenure I was not aware of patients being given blood transfusions with red blood cells imported from the USA.

849. The only possible rare exception may have been the frozen red cell bank held at Birmingham Transfusion Centre of very rare blood cell types but it is unlikely that any of these came from the USA. This was subsequently replaced by an international list of rare blood cell types held and maintained at IBGRL, available internationally for any patient in need and individual donors would be called to donate anywhere in the world should the need arise for a particularly rare blood cell type. All these donors were from fully screened voluntary non remunerated donor panels so would not have caused any anxiety with regard to their usage.

850. I am personally not aware that any rare blood donations from the USA were ever actually imported for use in the UK.

Statement of Truth

I believe that the facts stated in this witness statement are true.

Signed _____

Dated _____

Table of exhibits:

Date	Description	URN
	Curriculum Vitae	WITN6926002
xx/11/1991	Yorkshire Blood Transfusion Service Business Plan 1991/92	NHBT0097056_002
12/07/1990	Letter from Dr. E. Angela Robinson, Yorkshire Regional Health Authority, National Blood Transfusion Service, to donor, re: budget devolution	NHBT0027504
03/01/2000	Hepatitis Litigation (A and Ors.), Witness Statement of Harold Hastings Gunson,	NHBT0000026_009
09/04/1992	Letter from John D Cash, Scottish National Blood Transfusion Service (SNBTS), to Dr. E. A. Robinson, Leeds Regional Transfusion Centre	SBTS0000056_036
22/03/1989	Letter from Dr. E. Angela Robinson, Yorkshire Regional Health Authority, National Blood Transfusion Service, to Dr. H. H. Gunson, National Blood Transfusion Service	NHBT0027512
17/01/1990	Memo from Mr S C Barrett, Donor Services Manager to Dr Robinson, re: launch of the BTS Safety Awareness Campaign.	NHBT0000077_103
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 Welsh Regional Transfusion	NHBT0008628_001

	Centres.	
05/10/1990	Letter from Dr. E. Angela Robinson to Dr H H Gunson re copies of correspondence re minimum standard for donation.	NHBT0003804
10/04/1991	Minutes of the NBTS/CBLA Liaison Committee tenth meeting, 10 April 1991	NHBT0000077_056
26/09/1990	Minutes of the NBTS/CBLA Liaison Committees 8th Meeting, 26 September 1990	NHBT0017193
04/12/1984	Notes of a meeting held on 4 December 1984 re Heat Treated Factor VIII.	PARA0000008
29/11/1990	Letter from Dr. E, Angela Robinson, Yorkshire Regional Health Authority NBTS, to Dr. H. H. Gunson	NHBT0000534_003
09/01/1991	Letter from R. S. Lane to Dr. A. E. Robinson (Regional Transfusion Centre), re: high purity factor 8 and 87 (09/01/1991);	BPLL0005770
01/10/1986	"Alanine Amino-Transferase (ALT) and Anti-hepatitis B core (Anti-HBc) Screening of Blood Donations: Proposals for a Multi-Centre Study" by UK Working Party on Transfusion Associated Hepatitis	PRSE0002161
06/07/1983	Letter from W. Wagstaff, National Blood Transfusion Service to Colleagues regarding Final form of the AIDS leaflet	NHBT0020668
04/04/1986	Minutes of the 198th Regional Transfusion Directors' Meeting at Hannibal House, London, 22 January 1986	NHBT0018200

27/08/1992	Meeting of the Northern Division of Blood Transfusion Consultants, 27 August 1992	NHBT0016142
12/06/1986	Letter from Dr. Angela E. Robinson, to [GRO-A], re: apologising for AIDS posters about homosexual men, asking not to donate	NHBT0052209_262
15/02/1990	Minutes of the Northern Division of the National Blood Transfusion Service meeting, 15 February at Sheffield Regional Transfusion Centre.	NHBT0070258
16/01/1992	Minutes of National Directorate of the NBTS National Management Committee 18th meeting, 16 January 1992	NHBT0097469_014
02/09/1991	Minutes of National Directorate of the NBTS National Managements Committee 16th meeting, 2 September 1991	NHBT0071771
21/02/1990	Letter from Dr. E. Angela Robinson, to W. J. M. Lovel, Yorkshire Health Legal Department,	NHBT0096473_014
09/01/1992	Meeting of the Northern Division of the National Blood Transfusion Service, 9 January 1992	NHBT0097469_049
05/07/1990	Minutes of National Directorate of the NBTS National Management Committee tenth meeting, 5 July 1990	NHBT0046958_002
10/12/1991	Minutes of the Advisory Committee on the NBTS - Working Party to Advise on Plasma Supplies for Self-Sufficiency in Blood	CBLA0003298

	Products on 18 December 1981	
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.	NHBT0000188_039
08/03/1993	Letter from Dr E Angela Robinson, Yorkshire Blood Transfusion Service, to Dr H. Gunson, National Blood Transfusion Service	NHBT0016058
29/12/1989	Letter from Dr Angela Robinson to H Gunson re: ALT testing of Plasma derived from Apheresis	NHBT0000188_158
19/02/1990	Letter from Dr E. Robinson (Yorkshire Regional Transfusion Centre) to Dr H. Gunson (National Blood Transfusion Centre)	NHBT0000078_015
20/01/1990	Letter from Dr. Angela Robinson, Director of the Yorkshire regional Health Authority, to Dr. Harold Gunson, Director of the National Blood Transfusion Centre	NHBT0000189_028
28/02/1991	Letter from Dr E Angela Robinson to Mr B J Crowley	NHBT0000027_022
26/02/1990	Letter from H.H Gunson, National Director, The National Directorate to Dr Angela E Robinson	NHBT0000189_060
29/01/1991	Letter from Dr. E. Angela Robinson, National Blood Transfusion Service, to Dr. H. H. Gunson, re: Anti-HCV testing blood donations	NHBT0016205
18/01/2000	Witness statement of Dr Elizabeth Angela Robinson in the Hepatitis litigation of	NHBT0000234_001

	FCHD003	
07/06/2001	Letter from Professor, M. S. Losowsky, St. James's University Hospital, to Dr. E. A. E. Robinson, Regional Transfusion Centre	NHBT0034922
10/07/1991	Letter from J. Craske, Consultant Viologist, to Dr. A. Robinson, National Blood Transfusion Service (NBTS)	NHBT0033635
13/05/1991	Letter from Dr H H Gunson, National Directorate, to Dr E A Robinson	NHBT0033630_001
03/04/1991	Letter from H. H. Gunson, National Blood Transfusion Service, to All RTDs	NHBT0000073_065
24/06/1991	Letter from H L Lloyd to Dr H HGunson re: Hepatitis C Testing. Concern that UK testing has not begun	NHBT0000076_009
02/05/1991	Letter from Dr H L Lloyd to Dr H H Gunson, and Professor J D Cash, re: hepatitis C testing	NHBT0000074_014
13/06/1991	Meeting of the Northern Division of the National Blood Transfusion Service, dated 13 June 1991	NHBT0071757
04/07/1991	Letter from H L Lloyd to Professor J D Cash regarding Hepatitis C Testing	PRSE0001183
09/05/1991	Memo from J C Dobson to John Murphy ID re Hepatitis C Antibody Screening	NHBT0000062_060
23/12/1991	Letter from Dr E Angela Robinson to Dr H Gunson re financial support for anti-HCV testing.	NHBT0000193_095
01/07/1991	Minutes of National Blood Transfusion Service (NBTS)/Central Blood	NHBT0000066_031

	Laboratories Authority Liaison Committee (CBLA) eleventh meeting, 21 June 1991	
17/06/1993	Letter from Dr. Angela Robinson to Dr. Harold Gunson regarding anti-HBc testing of blood donations.	NHBT0006078
08/10/1993	Final, signed letter from H. H. Gunson, Medical Director of National Blood Authority to Dr Angela Robinson	NHBT0006053_001
23/01/1992	Preliminary Discussion Paper for ACTTD: Two topics related to transfusion safety by Dr Marcela Contreras and Dr John Barbara	NHBT0000044_095
13/02/1990	Letter from Dr. E. Angela Robinson, Regional Transfusion Centre, to Dr. H. H. Gunson	NHBT0019492
13/01/1995	Letter from Dr. E. A. Robinson, National Blood Authority, to Dr. J. Metters, Department of Health	NHBT0009664
03/01/1991	NORTH LONDON BLOOD TRANSFUSION CENTRE COLINDALE: complaint made by clinician in relation to a member of staff	NHBT0000052_016
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.	NHBT0005388
20/09/1991	Faxed letter from Dr. E. A. Robinson, to GRO-A et al, re: Blood donation refusal	NHBT0007423_004
18/01/1989	Minutes of the 210th Regional Transfusion Directors Meeting held in	NHBT0018188

	the Library of the Regional Transfusion Centre	
28/09/1989	Informal Notes of the Meeting of the Northern Division of the NBTS, 28 September 1989	SBTS0000096_052
19/10/1989	Informal Notes of the Meeting of the Northern Division of the NBTS, 19th October 1989	SBTS0000096_076
14/12/1989	Informal Notes of the Meeting of the Northern Division of the NBTS, 14th December 1989	SBTS0000097_008
20/04/1990	Informal Notes of the Meeting of the Northern Division NBTS on 12 April 1990 at the Regional Transfusion Centre, Liverpool	SBTS0000097_022
13/12/1990	Meeting of the Northern Division of the National Blood Transfusion Service, 13 December 1990 at Manchester Regional Transfusion Centre	NHBT0070264
21/02/1991	Meeting of the Northern Division of the National Blood Transfusion Service, dated 21 February 1991 at Leeds Regional Transfusion Centre.	NHBT0071759
13/06/1991	Meeting of the Northern Division of the National Blood Transfusion Service, dated 13 June 1991 in York.	NHBT0071757
22/08/1991	Meeting of the Northern Division of the National Blood Transfusion Service, Thursday 22 August 1991 at Leeds Transfusion Centre	NHBT0097471_051
17/10/1991	Meeting of the Northern Division of the National Blood Transfusion Service,	NHBT0097471_023

	Thursday 17 October 1992 at Manchester Transfusion Centre.	
09/01/1992	Meeting of the Northern Division of the National Blood Transfusion Service, 9 January 1992 at Leeds Transfusion Centre.	NHBT0097469_049
26/03/1992	Meeting of the Northern Division of the BTS Consultants, 26 March 1992 at Leeds Transfusion Centre	NHBT0097468_024
18/06/1992	Minutes of the Northern Division of Blood Transfusion Service, 18 June 1992 at Leeds Transfusion Centre.	NHBT0097466_006
19/11/1992	Meeting of the Northern Division of Blood Transfusion Service Consultants, 19 November 1992 at Leeds Regional Transfusion Centre.	NHBT0071593_001
24/02/1993	Minutes of the Northern Division of Blood Transfusion Service, 11 February 1993 at North Western Regional Transfusion Centre	NHBT0015638
04/01/1990	Minutes of National Directorate of the NBTS National Management Committee 7th meeting, 4 January 1990	NHBT0071870_002
05/07/1990	Minutes of National Directorate of the NBTS National Management Committee tenth meeting, 5 July 1990	NHBT0046958_002
03/09/1990	Minutes of National Directorate of the NBTS National Management Committee 11th meeting, 3 September 1990	NHBT0071715

25/10/1990	Minutes of National Directorate of the NBTS National Management Committee 12th meeting, 25 October 1990	NHBT0071860_002
01/02/1991	Minutes of National Blood Transfusion Service National Management Committee 13th meeting, 1 February 1991	NHBT0071804
16/04/1991	Minutes of National Directorate of the NBTS National Management Committee 14th meeting, 16 April 1991	NHBT0000191_144
20/06/1991	Minutes of National Directorate of the NBTS National Management Committee 15th meeting, 20 June 1991	NHBT0071673
30/09/1991	Minutes of National Directorate of the NBTS National Management Committee special meeting, 30 September 1991	NHBT0001877
16/01/1991	Memorandum/Minute Minutes of National Blood Transfusion Service/Central Blood Laboratories Authority Liaison Committee ninth meeting, 16/01/1991 at Gateway House, Manchester	NHBT0000065_019
17/06/1993	Letter from Dr. Angela Robinson to Dr. Harold Gunson regarding anti-HBc testing of blood donations.	NHBT0006078
08/10/1993	Final, signed letter from H. H. Gunson, Medical Director of National Blood Authority to Dr Angela Robinson, of Yorkshire regional transfusion centre regarding anti-Hbc testing of blood donations	NHBT0006053_001
04/04/1989	Minutes of the first meeting	NHBT0000041_003

	of the Advisory Committee on the Virological Safety of Blood, 4 April 1989	
29/09/1994	Minutes of Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation 3rd meeting, 29 September 1994	PRSE0003670
15/12/1994	Minutes of Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation 4th meeting, 15 December 1994	PRSE0003635
25/05/1995	Minutes of Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation 5th meeting, 25 May 1995	MHRA0023194
13/10/1995	Minutes of Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation, 13 October 1995	SBTS0000516_001
08/01/1996	Minutes of advisory committee on the microbiological safety of blood and tissues for transplantation (MSBT), on 8 January 1996	DHSC0020692_118
02/05/1996	Minutes of Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation meeting, 2 May 1996	SBTS0000518
02/07/1996	Minutes of Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation meeting, 2	SBTS0000519

	July 1996,	
18/11/1996	Minutes of the advisory committee on the microbiology safety of blood and tissues for transplantation meeting, 18 November 1996	DHSC0004018_090
25/03/1997	Minutes of Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation meeting, 25 March 1997	NHBT0006016
08/07/1997	Minutes of Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation meeting, 8 July 1997	NHBT0019394
27/10/1997	Minutes of Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation meeting, 27 October 1997	SBTS0000522
26/02/1998	Minutes of Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation meeting, 26 February 1998	SBTS0000523
14/10/1998	Minutes of the Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation (MSBT) meeting, 4 June 1998	DHSC0004026_033
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
08/01/1996	Minutes of Advisory	SBTS0000517

	Committee on the Microbiological Safety of Blood and Tissues for Transplantation meeting, 8 January 1996	
18/11/1996	Minutes of Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation meeting, 18 November 1996	NHBT0006005
20/09/1995	Letter from Dr. E. Angela Robinson, National Blood Service (NBS) to Dr. Jeremy Metters, Department of Health (DOH)	DHSC0006906_013
19/10/1994	Minutes of UKBTS/NIBSC Standing Advisory Committee on Transfusion Transmitted Infections (SCTTI) on 19th October 1994	NHBT0010970
13/02/1995	Minutes of UK BTS/NIBSC Standing Advisory Committee on Transfusion Transmitted Infection (SACTTI) held on 13 February 1995	NHBT0000088_009
03/03/1995	Minutes of SACTTI special meeting held on 3 March 1995	NHBT0017284
31/01/1996	Minutes of the meeting of THE UK BTS/NIBSC STANDING ADVISORY COMMITTEE ON TRANSFUSION TRANSMITTED INFECTIONS (SACTTI), on 31st January 1996	NHBT0009458_002
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	NHBT0000088_013
14/05/1996	Minutes of Standing	NHBT0005590

	Advisory Committee on Transfusion Transmitted Infection (SACTTI) Special Meeting to Consider HTLV and Blood Transfusion on 14 May 1996	
01/07/1996	SACTTI meeting minutes from 1 July 1996, at the North London Blood Centre	JPAC0000109_025
04/11/1996	Minutes of the UK Standing Advisory Committee on Transfusion Transmitted Infections (SACTTI) on 4 November 1996	NHBT0010921
14/04/1997	Minutes of meeting between SACTTI and SAC on Tissue Banking, on 14th April 1997	NHBT0001142_077
09/07/1997	Minutes of UK BTS/NIBSC Standing Advisory Committee on Transfusion Transmitted Infections (SACTTI) Meeting on 9 July 1997	NHBT0000088_017
21/01/1998	Minutes of UK BTS/NIBSC Standing Advisory Committee on Transfusion Transmitted Infections (SACTTI) held on 21/01/1998	NHBT0000088_020
12/03/1998	Minutes of UK BTS/NIBSC Standing Advisory Committee on Transfusion Transmitted Infections (SACTTI) Meeting on 12 March 1998	NHBT0000088_021
19/05/1998	Minutes of UK BTS/NIBSC Standing Advisory Committee on Transfusion Transmitted Infections (SACTTI) held on 19 May 1998	NHBT0000088_022
29/09/1998	Minutes of UK BTS/NIBSC Standing Advisory Committee on Transfusion Transmitted Infections (SACTTI), meeting on 29	NHBT0000088_023

	September 1998	
23/12/1998	Minutes of UKBTS/NIBSC Standing Advisory Committee on Transfusion Transmitted Infections (SACTTI) meeting on 24 November 1998	NHBT0004601_001
19/01/1999	Minutes of UK BTS/NIBSC Standing Advisory Committee on Transfusion Transmitted Infections (SACTTI) Meeting on 19 January 1999	NHBT0000088_025
16/11/1999	Minutes of UK BTS/NIBSC Standing Advisory Committee on Transfusion Transmitted Infections (SACTTI) on 16 November 1999	NHBT0000088_030
21/01/2000	Minutes of the UKBTS/NIBSC Standing Advisory Committee on Transfusion Transmitted Infections (SACTTI) meeting on Monday 21st February	JPAC0000089_020
07/03/2000	Minutes of meeting of UK BTS/NIBSC Standing Advisory Committee on Transfusion Transmitted Infections (SACTTI), held on 7 March 2000	NHBT0002623_001
05/07/2000	Minutes of the UK BTS/NIBSC Standing Advisory Committee on Transfusion Transmitted Infections (SACTTI) on 5 July 2000	NHBT0002594
13/03/2001	Minutes of the UKBTS/NIBSC advisory committee on transfusion transmitted infection (SACTTI) meeting held on 13 March 2001	NHBT0017175
03/07/2001	Minutes of UK BTS/NIBSC Standing Advisory Committee on Transfusion	SBTS0000413_008

	Transmitted Infection (SACTTI) meeting [number unknown], 3rd July 2001	
04/09/2001	Minutes of the UK BTS/NIBSC Standing Advisory Committee on Transfusion Transmitted Infections (SACTTI) Video Conference meeting held at National Blood Authority, Watford and CSA HQ, Edinburgh on Tuesday 4 September 2001	NHBT0003420
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	JPAC0000029_158
15/01/2002	Meeting of the UK BTS/NIBSC standing advisory committee on transfusion transmitted infections (SACTTI) held on 15 January 2002	JPAC0000081_032
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)	NHBT0001954_001
21/05/2002	Minutes of the Video Conference Meeting of UK BTS/NIBSC STANDING ADVISORY COMMITTEE ON TRANSFUSION TRANSMITTED INFECTIONS (SACTII) held at Edinburgh/Manchester/Watford Tuesday 21 May 2002	NHBT0002575
17/09/2002	UK BTS/NIBSC Standing Advisory Committee on Transfusion Transmitted Infections (SACTTI) meeting, Tuesday 17	JPAC0000084_002

	September 2002	
14/01/2003	Minutes of the UKBTS/NIBSC Standing Advisory Committee on Transfusion Transmitted Infections (SACTTI) meeting, held at National Blood Service Watford, on 14 January 2003	JPAC0000029_079
20/05/2003	Minutes of the UK BTS/NIBSC Standing Advisory Committee on Transfusion Transmitted Infections meeting, 20th May 2003	JPAC0000114_012
06/01/2004	Minutes of UKBTS/NIBSC Standing Advisory Committee on Transfusion Transmitted Infections (SACTTI) meeting, 6th January 2004	JPAC0000117_008
02/03/2004	Minutes of the UK BTS/NIBSC Standing Advisory Committee on Transfusion Transmitted Infections meeting, 2nd March 2004	JPAC0000118_009
27/07/2004	Minutes of meeting Minutes of the UKBTS/NIBSC Standing Advisory Committee on Transfusion Transmitted Infections (SACTTI), 27th July 2004	JPAC0000117_003
17/05/2005	SACTTI Report from NBS NAT Strategic Review meeting, 17 May 2005	DHSC0011031
19/07/2005	Minutes of SACTTI Video Conference, 19 July 2005	JPAC0000061_023
20/09/2005	Minutes of SACTTI meeting, 20 September 2005 at NBS Birmingham	JPAC0000065_033

20/07/1990	Letter from H.H. Gunson to Dr. A.E. Robinson, re: Proposal for a Nationally Managed Service, with Letter from Angela Robinson to Dr. H.H. Gunson	NHBT0001871
08/08/1991	Report, "Future Organisation of the NBTS", by H. H. Gunson, August 1991	NHBT0001089
21/10/1991	Letter from Angela Robinson, Yorkshire Blood Transfusion Service, to Regional Transfusion Directors in England and Wales	NHBT0001882
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"	PRSE0001236
29/04/1994	Letter form Dr. Lorna Williamson, National Blood Transfusion Service, Cambridge, to Dr. Angela E. Robinson, Regional Transfusion Centre, Leeds	NHBT0017278_001
04/05/1994	Handwritten note of a discussion with Terry Walsh, re: IV anti-D from Ireland	NHBT0017278_002
29/11/2000	Email from M. McGovern, to A. Robinson, re: Italian Brief, with paper on 'Line to take: Deferral of Potential UK Blood Donors by Italy and Italian nationals resident in the UK from 1980 to 1996 banned from giving blood'	NHBT0009473
29/05/1996	Letter from Dr. E. Angela E. Robinson, National Blood Authority (NBA), to Dr. A.	NHBT0008473

	Rejman, Department of Health (DoH)	
13/10/1995	Letter from Patricia E. Hewitt, National Blood Service, to Dr. Angela Robinson, The National Blood Authority,	DHSC0003538_003
06/01/2005	Letter from Dr E. A. E. Robinson to GRO-A, re: a complaint against the professional conduct of a doctor in relation to autologous donation.	NHBT0002286
02/02/1995	Memo from A. Robinson, to J. Cash, re: Quarantining of FFP.	NHBT0009371
05/04/1995	Letter from Dr. E. Angela Robinson, National Blood Authority, to Dr. F. Ala, West Midlands Regional Transfusion Centre;	NHBT0015504_001
01/07/1994	Letter from Dr. E. Angela E. Robinson, Medical Director, NBA to Dr. F. A. Ala, Medical and Scientific Director, Regional Transfusion Centre regarding SACTTI	NHBT0008013_001
26/02/1998	Minutes of Advisory Committee on The Microbiological Safety of Blood and Tissues for Transplantation [MSBT] meeting on 26 February 1998	DHSC0020709_063
15/12/1994	Draft Report from the MSBT Subcommittee. Meeting convened at the request of the Chairman, Dr Jeremy Metters held on 03 November 1994	NHBT0005791
03/04/1995	A letter from Dr Kenneth C Calman, Chief Medical Officer, regarding Hepatitis C and Blood Transfusion Look back guidance and	NHBT0002764_001

	procedures	
04/05/1995	Letter from Dr. Angela E. Robinson, National Blood Authority, to Dr. Andrez Rejman, Department of Health	DHSC0003595_040
01/09/2002	'Transfusion transmission of HCV infection before anti-HCV testing of blood donations in England: results of the national HCV lookback program' by the English National Blood Service HCV Lookback Collation Collaborators	NHBT0097156_004
22/05/1996	Clinical Directors Meeting on 22 May 1996 (22/5/1996), held at Watford	NHBT0009899_001
25/11/1998	Letters between Dr Angela Robinson (NBA) and Dr Philip Mortimer (PHLS)	NHBT0036358
17/02/1995	Fax from Dr Mary Ramsay, Public Health Laboratory Service, to Angela Robinson	NHBT0036685
05/09/1995	Letter from Dr N. A. B. Anderson, Consultant Haematologist, to Dr J. B. Tisdale, The Surgery, Probus	NHBT0052419_004
08/08/1995	Letter from Dr N. A. B. Anderson, to Dr J. B. Tisdale	NHBT0052419_006
16/01/1995	Transcript recorded from Transmission of BBC-1 Panorama "Bad Blood"	NHBT0000236_020
12/04/1996	Notes of a meeting to discuss the possible implications of a likely new variant of Creutzfeldt-Jakob Disease (CJD) for UK transfusion services, on 9 April 1996, at the Royal College of Physicians of	DHSC0020783_088

	Edinburgh	
13/11/1996	Letter from Dr. Peter Flanagan to Prof. J. R. Pattison	NHBT0008231
28/10/1999	Minutes of Advisory Committee on the Microbiological Safety of Blood and Tissues for Transplantation 19th meeting, 28 October 1999	NHBT0004333
15/01/2002	Meeting of the UK BTS/NIBSC standing advisory committee on transfusion transmitted infections (SACTTI) held on 15 January 2002	JPAC0000081_032
14/04/2000	Letter from Dr. Angela Robinson, (cc: Dr. P. Hewitt, Dr. M. Mcgovern, Mr. W. M. McClelland, Prof. I. Franklin, Dr. H. hambley, Dr. G. Williams), to Dr. Ailsa White, DOH	NHBT0004047_002
12/07/2000	Letter from Dr Ailsa Wight to Dr Angela Robinson	NHBT0004046
08/03/2002	Letter from Dr. Pat Troop, Department of Health (DOH), to Dr. Angela Robinson, National Blood Service (NBS)	DHSC0038507_060
23/02/1981	Minutes of the second meeting of the Advisory Committee on the National Blood Transfusion Service	CBLA0001287
12/08/1982	Letter from H. H. Gunson, North Western Regional Health Authority, to S. Godfrey, Department of Health and Social Security	DHSC0002219_020
01/10/1981	Letter from Dr. Angela Robinson, Yorkshire Regional Health Authority, to Dr. H. H. Gunson	DHSC0002211_072

01/04/1989	Proposal re: distribution of BPL products and supply of plasma to BPL	NHBT0057426_002
31/03/1992	Letter from P. Ward, Yorkshire Services Organisation, to R. M. T. Schofield, Department of Health	NHBT0003299