**Witness Name: Jean Harrison**
**Statement No.: WITN7046001**
**Exhibits: WITN7046002-07**
**Dated: 18 March 2022**

# INFECTED BLOOD INQUIRY

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## WRITTEN STATEMENT OF DR JEAN HARRISON

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**I provide this statement in response to a request under Rule 9 of the Inquiry Rules 2006 dated 18 August 2021.**

**I, Dr Jean Harrison, will say as follows:**

## Section 1: Introduction

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

    1. My name is Jean Florence Harrison.

    2. My date of birth is GRO-C 1946.

    3. My address is known to the Inquiry.

    4. My professional qualifications are:

- B.A. Hons. (Animal Physiology) Oxford University June 1968 Class 2

- B.M. BCh Oxford University December 1971

- M.A. Oxford University December 1971

- D. Obst. R.C.O.G. Royal College of December 1973
- Obstetricians & Gynaecologists

- M.R.C.P. (U.K.) Royal College of Physicians November 1975

- F.R.C.P. May 1995

- M.R.C. Path (Haematology) Royal College of June 1979

- F.R.C. Path Pathologists 1991

- Accreditation in Haematology 1979

**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. 1 June 2011 - 2014:

Emeritus Consultant Haematologist
National Health Service Blood and Transplant (NHSBT)

6. PREVIOUS APPOINTMENTS

- 1 July 1995 – 31 May 2011:

Consultant Haematologist
National Health Service Blood and Transplant
Based at Colindale Centre
Colindale Avenue
LONDON
NW9 5BG

- 19 May 1981 - 1 July 1995:

Director & Consultant Haematologist
North East Thames Regional Transfusion Centre
BRENTWOOD, Essex
CM15 8DP

- 5 May 1980 - 18 May 1981

Consultant Haematologist
North East Thames Regional Transfusion Centre
BRENTWOOD, Essex
CM15 8DP

- 1 August 1978 - 4 May 1980:

Senior Registrar in Haematology, Sheffield Area Health Authority, and
Honorary Lecturer at the University of Sheffield.

- 14 February 1977 - 31 July 1978:

Senior Registrar in Haematology (in Sheffield), financed by the Leukaemia Research Fund.

- 1 April 1975 - 13 February 1977:

Registrar in Haematology to the Group Department of Haematology, Sheffield (Central and Southern Districts).

- 1 October 1974 - 31 March 1975:

Senior House Officer to the Coronary Care Unit and Intensive Care Unit,
The Royal Cornwall Hospital, Treliske, Truro, Cornwall (including secondment to the Department of Cardiology, The Brompton Hospital,
London).

- 1 August 1973 - 31 August 1974:

Senior House Officer in General Medicine, The Royal Cornwall Hospital, Treliske, Truro, Cornwall (a rotating appointment).

- 1 Feb. 1973 - 31 July 1973:

House Officer in Obstetrics in the Department of Obstetrics under Sir John Stallworthy, The John Radcliffe Hospital, Headington, Oxford.

- 1 August 1972 - 31 January 1973:

House Surgeon to Mr K Lloyd-Williams, The Royal United Hospital, Bath.

- 1 February 1972 - 31 July 1972:

House Physician to Dr G de J Lee and Dr J Ledingham, The Radcliffe Infirmary, Oxford.

- December 1971 - January 1972:

Medical Officer, Mengo Hospital, Kampala, Uganda, (a voluntary job).

7. It may help if I explain at the outset some aspects of my career as described in my CV above. In 1996 the organisation of the blood service became zonal and my role as Regional Transfusion Director did not exist anymore. I moved to Colindale in 1997 after a massive re-organisation. Prior to that we were working for the Regional Health Authority ("RHA"). Brentwood was supposed to close but it stayed open. I went part time in 2001 and then only

worked with donors and doctors. I was not involved with the hospitals. I used to review blood donor sessions and managed the medical staff in donor care. I was national Lead Consultant in donor apheresis. I remained in this position until I retired in 2011. I also used to sit on a committee to improve quality.

**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. MEMBERSHIP OF COMMITTEES

Member of:

- The NBTS Management Committee 1988 – 1993
- NBTS/BPL Liaison Committee 1991 – 1994
- National Provision of Donors Committee 1988 – 1993
- North East Thames Regional Transfusion Committee 1982 – 1994
- North East Thames Regional Association of Haematologists 1980 - 1995

Chairman of:

- National Apheresis Working Party 1989 - 1991
- Eastern Division of Consultants in the BTS 1991 - 1993
- Greater London Blood Supplies Group 1987 - 1991
- National Blood Service Working Group for computerisation of donor selection Criteria 1995 - 1997

- Apheresis Special Interest Group of the British Blood Transfusion Society 1995 - 1999

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

9. I read the Lancet and Transfusion Medicine. I would also read the American Publication, "Transfusion". I would have read other articles in different journals such as in the New England Journal if there were relevant papers. Often, an article would be referred to me by a colleague and I might pick up on a reference from other articles.

10. I went to American Association of Blood Banks annual meetings, but not every year as research and development does not progress that quickly. The travel and accommodation were sponsored by Baxter Healthcare. I thought the best thing was to go every 2-3 years, but I also thought my staff would benefit from going so I would send my head scientists, donor organiser and head nurse for example. Much of what was discussed was relevant to donor recruitment and to their roles. I think they got a great deal from it and they were required to write a report on their return. This meant someone from the centre attended each year.

11. I also used to go to the British Blood Transfusion Society conferences, and I used to organise annual one day meetings on subjects related to apheresis. At NETRTC we trained Nurse Managers from other UK Transfusion Centres and sometimes from abroad in blood collection techniques. We also provided training in Transfusion for Haematology Senior Registrars.

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.**

*Inquiries*

12. I have not been involved in any Inquiry previously, but I believe I provided papers that I held in order to assist in the case of A & Others v NBA. I also provided some papers to NHSBT for the purposes of this Inquiry.

*Investigation criminal or civil litigation*

13. I do not recall being involved in any investigations, criminal or civil litigation. I have not appeared in a court before, but I did once give evidence at an industrial tribunal relating to a dismissal.

## Section 2: Your role at the North East Thames Regional Transfusion Centre

**We understand that the North East Thames Regional Transfusion Centre ("NETRTC") was alternatively referred to as Brentwood Regional Transfusion Centre. For the avoidance of doubt, this request will use NETRTC throughout, even where the supporting documents refer to Brentwood.**

6. **Please describe the roles, functions and responsibilities you had at the NETRTC during your period as Director and explain how these changed over time, if applicable.**

14. As director I was manager of the whole Centre. There were 275 staff. I helped manage the budget. I had a group of managers and we formed a board. This comprised a head scientist, a head nurse, regional donor organiser, an administrator and a quality assurance manager. We talked regularly about problems and issues.

15. I used to liaise with the RHA through Paul Walker, the Regional Medical Officer and I also met with the administrator and treasurer.

16. We had a budget of approximately £11 million pa. I thought we did well, considering what we had. If we required more funds, we would need to perform a costing and present our proposals to the RHA for additional funding.

17. In particular, I was in charge of managing a number of medical staff who were responsible for blood collection with the donor collection teams. There were a lot of problems with staffing because of issues with morale before my appointment and I was a very junior sole Consultant initially. Dr Boralessa was then appointed and later became my deputy. Prior to him being appointed I had to ask for a Transfusion specialist Consultant to cover when I was on holiday. Geoffrey Tovey from Bristol and Professor Alan Waters, from St Barts provided cover for me.

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

**a. its structure and staffing and in particular to whom you were accountable (you may find NHBT0010587, page 4-5 of assistance);**

18. I was accountable to the RHA.

**b. how the NETRTC was funded and how this changed (you may find DHSC0101509 and DHSC0101508 of assistance);**

19. It was funded directly by the RHA before cross-charging was introduced in 1989.

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

20. The remit was to collect blood donations from donors in the regional area, test them, make blood components and supply blood, components and NHS blood products to hospitals in the regional area. We also provided a service to regional hospitals of investigation of transfusion problems and tissue-typing of donors and patients to provide matched products when requested. We investigated possible instances of transfusion-transmitted infection in patients who had received transfusions. We referred donors found to have transfusion-transmissible infections, anaemia or other abnormalities, for appropriate advice and treatment. We collected plasma from donors with 'wanted' antibodies such as anti-D for immunoglobulin production by BPL.

21. When we had enough processing capacity, we took over blood supply to UCH, Great Ormond Street and the Royal Free Hospitals. Until then, those hospitals were covered by North West Thames RTC. Provision of adequate blood supplies was easier when we had the agreement for supply from Oxford.

**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 (NHBT0000025_001; NHBT0000026_009);**

22. I thought the transfusion directors meeting was quite helpful. I did always try to fall in line with the national agreements that Dr Gunson tried to make. I thought it was very important that we acted as a national service although we were employed by different regional authorities. I entirely agree with Dr Gunson's statement and think that it is a very good description of the management structure and lines of responsibility.

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

23. We did have a link with Oxford and we were linked with North West Thames of which Tom Davies was the Director before Marcela Contreras. We were also linked to the South London Centre at Tooting and had a good relationship with the Director & staff there. We had to support each other for instance, if there was an issue with transport. We also provided teaching and training for Haematology senior registrars in blood transfusion. We ran a 1-week revision course that took place before their exams. Often, Senior Registrars came from other parts of the country to attend this course.

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

24. We had to follow whatever testing requirements there were. We were also subject to MCA inspection every two years and could not continue to operate without MCA accreditation. There was

also a lab accreditation required – this was usually dealt with by the head scientist and accreditor.

25. Any doctors and nurses would also have had to keep up their accreditation for the purposes of their personal registration to continue to practise.

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

26. We had a good relationship with BPL. We were producing plasma for them from whole blood. We had no relationship with any other processing laboratory in the UK or overseas.

27. We also helped develop some pouches. We processed plasma into these pouches and did initial trials with their use. We also did trials with blast freezing the filled pouches. Baxter produced the bags for trial, and we would make sure that they did not leak, for instance, and were easier to use. These pouches were eventually brought into general use in England and Wales, for collection of plasma for BPL from whole blood donations.

28. We also employed special staff who would work in the evening to ensure the maximum number of blood donations were processed to provide plasma for Factor VIII production. We had four members of staff who processed the blood in the evening, so it was all processed on the same day it was collected.

8. **In 1986, Dr Cash wrote a report which highlighted a number of very serious problems with the blood supply in London. He further stated that you "inherited a 'sick centre' and on her own, without the support of senior medical and administrative colleagues" (SBTS0000618_160, page13):**

**a. Did you agree with the findings and conclusions reached in that report? What difficulties did the NETRTC face during your tenure with supply and demand and what were the reasons for those problems?**

29. I agreed with some of what Dr Cash wrote, but not with everything. I believe I provided a response although I am unable to locate this, and it is not currently available to me.

30. I see that I did discuss this with Dr Cash as referred to in document [SBTS0000618_160]. Dr Cash states "*I can give an assurance that I have discussed them with Dr Harrison and have been delighted with her positive, constructive and supportive response. I welcome the news that NETRHA has appointed two excellent young consultants to the Brentwood Centre during the period of this study. Notwithstanding this I believe there is a continuing need for Dr Harrison to have ready access to continued senior and external support for the next 5 crucial years. At the same time, she should be positively encouraged to get out of the Centre and visit other Centres and attend international meetings. The new consultant recruits should now make this possible".*

31. I do not disagree with the statement that I "*inherited a 'sick centre' and on my own, without the support of senior medical and administrative colleagues".* With the deputy – Dr Blagdon - having left when I was appointed, I was on my own then, without the support of other Consultant colleagues. But I had excellent support from nursing, scientific and administrative colleagues and I think that we managed quite well in the circumstances.

32. There was also a longstanding issue over Bloomsbury and Islington and who was responsible for those hospitals (University

College Hospital, Great Ormond Street and the Royal Free). They were large London teaching hospitals with high demands.

33. I was concerned about taking them on because I did not think we had sufficient processing facilities and I was concerned that we would not have sufficient blood donations. The way we overcame this was by building a new extension which was completed in 1987 as mentioned in document [NHBT0010587] and then we were able take them on. This was also helped by the Oxford agreement which is discussed in more detail in questions 15 and 156 below. This meant we had more resources without having a negative impact on Oxford, as they always had sufficient blood.

**b. How did you tackle those difficulties?**

34. Please see my response to 8a.

## Section 3: Blood collection at NETRTC

**9. Please explain the system for blood collection at the NETRTC during your employment there and how it changed over time.**

35. It changed over time in that we had more sophisticated bags to assist with processing blood into more components.

36. There was also the introduction of optimal additive solutions. These enabled us to take more plasma from each donation. It involves re-suspension of the red cells in the additive solution after the plasma has been removed.

**10. Please describe the way in which donations were collected at the NETRTC during your time there. In particular:**

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

37. Initially sessions were run by doctors with donor attendants. We had difficulty recruiting sufficient doctors so I considered we could resolve this by extending the duties of trained nurses. We always had donor attendants (nursing aids) but they were led by a doctor who counselled donors, answered any questions they might have and actually put the needles in. Then we had a doctor in charge but sometimes we had a trained nurse to put the needle in. The difference I suggested we make, was that we put trained nurses in charge completely, with no doctors present.

38. I thought we could use nurses instead of doctors to bleed donors. Our regional head nurse was in agreement with extending the duties of the nurse in this way.

39. We put a proposal forward so that nurses would be trained to collect blood. Colleagues (other RTDs) were initially opposed to this idea. The Chief Medical Officer was asked for an opinion, and he advised that he did not want to go ahead with the scheme but would welcome a trial.

40. We set up a trial in which we trained nurses. Senior people, some of whom were sceptical of the proposed scheme were asked to come to review the work of the nurses at donor sessions as compared to doctor-run sessions. The reviewers were doctors, haemophilia specialists, Regional Directors and regional head nurses. The nurses proved to be very good at donor selection and following rules and guidelines, as they did not have clinical freedom which allowed them not to follow the rules.

41. We would often have two nurses: one might be in charge of taking the blood and another one might be explaining risks, answering

donor queries and looking after donors who suffered side effects. For this reason, I am not sure whether it saved any money, but that was not the intention. The purpose was to improve the quality of blood collection and it was driven by a resource issue as there were not enough doctors.

42. This change meant the quality of the service improved. The nurses were very good at explaining why donors might not be able to donate. People previously may have been turned away without having this fully explained to them, in a way they could understand, why they were not able to donate. For instance, we used to turn away everyone who had jaundice. Another example might be if we had to turn someone away because they had a sexual relationship with someone in Africa. The nurse would explain this to them.

43. I recall overhearing someone in a donor session saying something along the lines of "well at least they tell you why you can't donate".

44. It took us 5 years to move from having doctors to having just nurses running the sessions. By 1990, if not before, all the sessions at NETRTC were run by nurses. Other Centres started to adopt the same policy.

45. All NHSBT blood donor sessions were run by nurses long before I retired. This is discussed in the article, "Nurses in the Transfusion Service" Jean F Harrison. The Lancet. November 14. 1987 (SBTS0004256_114).

**b. Where did these sessions take place?**

46. Church halls, community centres, and industrial premises.

**c. How frequently could a person donate blood? You may find paragraph 7.6 of NHBT0000191_144 of assistance.**

47. There was a national rule about how frequently a person could donate blood. It was not something I could decide. Usually, it was three times a year maximum. Some donor centres would collect four times a year from men. There were guidelines that we followed in relation to this. These were documented in 'The Red Book' and the MAD guidelines. The rationale was to ensure that donors were not made iron deficient.

**d. How were blood donors recruited?**

48. There were national and local recruitment drives. We used posters, leaflets, radio appeals and street recruitment. We had a donor recruitment team that used to go out in a caravan to try to recruit people. If we wanted to increase donor recruitment in a particular area, we would ask council members or the mayor to host an event and we would get regular donors to try to recruit other donors. We would give awards for people who had donated 50 times, 100 times etc. under the national awards scheme.

49. I might make a speech at these events to thank the regular award-winning donors and advise them that the donation caravan would be in their local area for the next week. We would ask these current donors to volunteer an hour or two of their time to help recruit and be by the caravan. We hoped to get 2,000 names in a week, and we would then set up new sessions for the new donors.

50. There were also national campaigns, and we would discuss how best to recruit.

51. We tended to advertise for donors using posters which were more cost effective than television adverts. We also used radio advertising and local radio stations to announce when there was a local donor session.

52. I was on the national committee for advertising. We discussed how to manage the national budget and where best to spend our money. We hired a marketing agency for professional help with this and for design of advertising material.

53. We had some posters in the London Underground. One had an underground map that listed medical conditions in place of tube stops. I recall it said something like "*A tube full of Londoners will need blood today; if we don't get it, they may end up underground*".

54. There was another one based on the milk marketing board advert. It had a milk bottle and said something like "*10,000 donations today please. We aren't getting enough".*

55. There was one that looked like a bottle of tomato sauce which said: "*it works in the movies but not in the theatre*".

56. Over time we learnt that people liked to see people who had recovered on posters, rather than sick patients. There was one with a small healthy boy fastening on his roller skates which said something along the lines of "*surgery saved his leg, but blood saved his life*". I recall thinking that these were good posters, and they were effective. They were used all over the country, apart from the one in the London Underground.

57. There was also another one which was at a bus stop with a donor putting his arm out which said something like: "*put your arm out, this is a request*".

58. The marketing agency also agreed to put up blood donor posters for free on bus shelters whenever they could not sell the marketing space.

59. We did everything we could to get free publicity. For instance, issuing a statement to the radio and hoping they would broadcast it and maybe someone would be invited to comment on it.

60. We also used famous people to give blood for instance some members of the royal family. Prince Charles gave blood with the press present to try to show it was safe. Kenneth Clarke also gave blood and answered the donor questionnaire when he was Secretary of State for health. We also set up blood donor sessions for the sixth form at Eton College.

61. I note that in document [NHBT0097469_018_0005] it was suggested that the BBC should be approached to ask whether free advertising could be provided at peak times. It was also felt that advertising and information on radio and TV should be given about the scientific side of blood transfusion as well as just asking people to come forward and donate. It was also suggested that a video about the Blood Transfusion Service should be made for use in schools.

62. I note that in document [NHBT0097469_014] it was recorded that "*the Summer advertising campaign is a poster campaign to be mounted in major cities and towns in England and Wales. Two new posters have been produced".*

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

63. Please see my response to 10a-d regarding the change to blood collection.

64. As time went on, the budget for advertising became a national one, and it was taken out of the hands of the transfusion directors; other people dealt with it who were specialists in that area.

65. There were also fewer donation sessions in factories and offices and more in the community. I think this may have been to do with premises and time to allow people time to come and donate. Some of the factories and offices were employing fewer staff and reducing the size of their premises so were no longer willing to host blood donor sessions. Having sessions in the community allowed people to donate after work. But holding sessions in the workplace did encourage more people to donate.

**11. Did the NETRTC have donation collection targets that it was required to meet? If so, did the NETRTC 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? You may find page 3 of NHBT0006247 of assistance.**

*Blood Donation targets*

66. We were required to collect sufficient blood donations to meet the needs of the hospitals that we supplied. This was difficult at times especially during holiday periods or if there was bad weather. I believe that all Transfusion Centres had supply problems at times. The loss of factory sessions reduced supplies of blood donations. We mounted regular donor recruitment campaigns in local towns & undertook research to show that it was safe for volunteers to continue to donate from age 65 to 70 years. NETRTC's difficulties were greatly eased when we arranged a regular supply of blood from the Oxford region. Centres always helped each other if there was a problem in one area.

*Plasma Donation targets*

67. NETRTC had plasma collection targets. It appears from document [DHSC0002269_017] that the "*target for 1985 was 25,000 litres*" and I note that this document also states "*The target for Self-sufficiency that we have been given at Brentwood is 30,000 litres of plasma per annum. We have not made any plans to exceed that target but we hope that we will achieve the target by the end of 1986 at the latest".*

68. I note from document [NHBT0003370 page 2] that the target in 1990/1991 was around 35,000 kgs.

*Meeting targets*

69. I do not recall us having an issue meeting plasma targets. I note in my letter to Alun Williams on 29 April 1985 in document [DHSC0002269_017 _0001] I state: "*Our target for 1985 is 25,000 litres and I hope that we will achieve this*."

70. I note from document [SBTS0000618_160_0010] Dr Cash stated *"Dr Harrison and her colleagues are to be congratulated for reaching a fresh plasma processing efficiency of approximately 160 ml/donation collected: a figure that is above average by international and UK standards".*

71. I note from document [NHBT0003370] the NETRTC minutes from 2 August 1989 that: "*The original plasma target was 29,500 Kgs of recovered plasma and 1, 500 Kgs of apheresed. The target for apheresed plasma will not be met, but the shortfall will be compensated for by an increase in recovered plasma. Overall, the target will be achieved*".

72. I also note in document [NHBT0085861_002] which is a letter from Angela Robinson to John Kenny it states, "*On the other hand, Brentwood will easily meet its target and will have so much Factor VIII and albumin that they may even wish to sell it to hospitals in this Region*".

*What was done to improve and what were the barriers?*

73. The barriers and various steps taken to improve were as discussed in my response to question 10. I note that the document [NHBT0003370 page 2] lists the following as ways to reach the target as:-

a. "*increased SAG (M),*
b. *increased apheresis*
c. *new buildings*
d. *more funding*
e. *more staff*
f. *more donors"*

**12. The Inquiry understands that the NETRTC was intending to allow nurses to be responsible for blood collection sessions in the absence of a physician. Why did the NETRTC choose to do this? Was this implemented in NETRTC? Are you aware of any other RTCs that implemented this? You may find page 3 and 5-6 of DHSC0002245_002, page 4 of CBLA0001905 and BPLL0007206 of assistance.**

74. We did not have sufficient numbers of doctors to run the sessions and to improve the quality of blood collection. For more details, please see my response to question 10(a).

**13. What steps, if any, did the NETRTC take to publicise itself to potential donor populations in order to increase donations? How**

**successful were these steps? You may find paragraph 5 of NHBT0092834 and page 7-9 of NHBT0010587 of assistance.**

75. Please see my response to question 10(d).

76. To add to this, we did quite well with the publicity and had very innovative staff as described above. We tried to make the call-up information relevant to the time of year or the possibility of a shortage of donations. For instance, we would amend it for Christmas or summer holidays. We hoped that this would emphasise to donors the need to donate regularly throughout the year.

14. **In 1985 at an Eastern Division Consultants meeting, Dr Marcela Contreras stated that the £350,000 publicity budget was "still grossly inadequate" (NHBT0092834, point 5). Did you agree with this statement? If so, please explain why and whether the NETRTC struggled with funding publicity for blood collection.**

77. I do recall that we had to be very efficient in the way we used our publicity budget. For instance, television advertising was very expensive and therefore we did not find it to be cost effective. As discussed in my response to question 10d we used other forms of advertising and did what we could to try and obtain as much free advertising as possible. I do not think that I have sufficient knowledge of advertising costs to comment on the size of the budget. I know that we could not afford TV advertising, but I don't know how effective that would have been.

15. **In 1986, a report was prepared by Dr Cash which stated that blood collection in London was "well below a satisfactory standard" and that "There is no evidence at the present time to indicate that Tooting and Brentwood… have, over the last 3-5 years, been responding to the escalation in demand for blood… the blood**

**collection programme at Brentwood has steadily and consistently declined since 1981" (SBTS0000618_160, page 6). Do you agree with this assessment of blood collection in London and, in particular, at the NETRTC? If not, why not? What were the difficulties, if any, in increasing the blood collection at the NETRTC?**

78. We did some research which showed that our population was composed of a significant proportion of people who would not be able to donate at work because they were worried about keeping their jobs, and people who for religious and cultural reasons would not be willing to give blood. This research also showed that people who are struggling 'to make ends meet' tend not to donate blood.

79. Sessions held in factories or office premises did encourage people to donate. When these sessions reduced, we tried to address this with Oxford which was a more affluent area and did not have an issue with donor recruitment. Our research showed that more affluent people who were settled and often had young children, were more likely to donate blood. We took lots of steps to try to maximise the number of donors in our area, which included the City of London. People there did not have time to donate during the working day but would do so in their home areas – such as the Oxford Region, so it was sensible and fair for our shortfall to be supplemented by their surplus.

16. **In May 1988, the Independent wrote that Oxford RTC agreed to supply 200 units of blood a week to the NETRTC to meet a "chronic shortage in supplies" (DHSC0003993_022). What was the reason for this shortage? You may find paragraph 5 of NHBT0118872_002 of assistance.**

80. I discuss the reasons for this in my response to question 15. I note that document [NHBT0118872_002] which has been

supplied to me, states that I reported on the situation as regards the blood supply to Brentwood and that a contractual agreement had been drawn up with NET & Oxford RHAs to supply Brentwood with 200 units per week. Document [DHSC0003993_022], which has been provided to me is a newspaper cutting which states: "*A LONDON transfusion centre is in return for the contract, to pay the Oxford region £150,000 to increase its blood collection, and the North East Thames regional transfusion centre at Brentwood will pay around £15 a unit".* I am quoted as saying that the supply of 200 units of blood a week is to meet a chronic shortage in supplies.

**17. The Inquiry understands that NETRTC collected blood from military corrective institutions where donors were "all fit young men, well vetted by their supervisors" (NHBT0008628_001). Please identify and set out the number of institutions from which blood was collected and the frequency of sessions. In particular:**

**a. When did this practice cease?**

81. During my time at Brentwood, we did not collect from prisons. It was thought that prisoners were more likely to be carriers of Hepatitis B.

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

**c. What information, if any, was presented to donors before they gave blood**

**d. Whether the supervisors mentioned above were medically trained;**

82. I do not recall the practice of collecting blood from a military corrective institution.

**e. Were Hepatitis and HIV considered risks in this specific population? If so, how were these risks managed? You may find RLIT0001238 and RLIT0001239 of assistance;**

83. Please see my response to question 17(a).

**f. What were the relative costs of collecting blood from military correctives as compared to collecting blood at the NETRTC?**

84. I do not recall the practice of collecting blood from a military corrective.

**g. Were those at the military corrective provided with any form of incentive to donate blood? If so, what?**

85. I am totally opposed to providing incentives for giving blood. Blood donation in the UK is voluntary and remains so. I was opposed to anything that might be considered an incentive beyond the national award scheme which recognized the contribution of donors who had given a significant number of donations.

## Section 4: Plasma procurement and production of fresh frozen plasma at NETRTC

***Production of fresh frozen plasma***

**18. The Inquiry understands that NETRTC procured plasma from blood donor sessions to produce fresh frozen plasma ("FFP") to provide to BPL (NHBT0010587, page 28). Please explain:**

**a. where the production of FFP took place;**

86. Production of FFP took place in our component's laboratory.

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

87. The blood was centrifuged and divided into various components using a closed blood bag system. The capacity to manufacture FFP changed in light of the development of the pouch by Baxter as discussed in response to Question 7g.

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

88. We allocated as much as possible. The decision to do this was based on how quickly it could be processed as it needed to be frozen in a certain amount of time to retain the maximum factor VIII levels. I note from document [NHBT0003370_0002] that the NETRTC in response to the question "Proportion of whole blood used for plasma; SAG (M); Other" - states "100%".

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

89. We tried very hard to maximise the amount of FFP. I recall going around hospitals in order to attempt to persuade doctors not to use whole blood and use red cells in SAGM instead as a source of red cells for transfusion. Platelets and frozen FFP for direct transfusion would continue to be supplied as before.

90. We continued to make platelets, but we could do that whilst still collecting FFP from a single donation.

**19. Please describe the arrangements for supplying FFP to hospitals and haemophilia centres within the region covered by the NETRTC.**

91. Generally, we did not have any involvement with the supply of plasma to hospitals and haemophilia centres. This was sent to BPL for processing. We would on occasion supply frozen FFP when hospitals requested it for direct clinical use.

92. We did supply cryoprecipitate to hospitals.

**20. The Inquiry understands that it was agreed in 1986 that NETRTC would credit BPL FFP to Edgware RTC (SBTS0000618_160, page 16). At a meeting of Haematologists North East Thames Region meeting, you stated that you would "have considerable difficulty maintaining FFP supplies… to the Blood Products Laboratory when Brentwood BTC takes on additional Hospitals previously served by the B.T.C. Edgware" (BART0000673, page 2). In particular:**

**a. Why did NETRTC take on additional hospitals previously served by Edgware RTC? Did you agree with the decision to take on these hospitals? How did this arrangement work?**

93. When we took on the hospitals which were in our geographic region (as described above) but had previously been supplied by Edgware, I did agree as by then we had enough processing capacity and Edgware RTC advised they could not supply sufficient blood and components to these hospitals.

**b. Did NETRTC have difficulties maintaining FFP supplies? If so, what steps, if any, did NETRTC take in response to this? You may find DHSC0002441_043 and NHBT0085861_002 of assistance.**

94. It was thought that we would have to make lots of platelets and, thus, would not be able to produce as much FFP as before. Some FFP needed to be retained for hospital use but we did

everything we could to maximise FFP production for processing at BPL.

95. I note I stated that we would have considerable difficulty maintaining FFP supplies for Factor VIII concentrate production to the Blood Products Laboratory when the Brentwood RBTC took on additional Hospitals previously served by the N.L.B.T.C. We had more difficulty producing for BPL when I took over Bloomsbury and Islington as they required fresh frozen plasma supplies for direct clinical use and more platelets. This would reduce what we could send to BPL.

96. I note from document [SBTS0000618_160] Dr Cash stated, "*Dr Harrison and her colleagues are to be congratulated for reaching a fresh plasma processing efficiency of approximately 160 ml/donation collected: a figure that is above average by international and UK standards".*

***Plasma targets***

**21. Did the NETRTC 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? You may find BART0000679, NHBT0003370 and DHSC0002269_017 of assistance.**

97. We did have targets. They were set nationally by Dr Gunson together with BPL and with the agreement of RTDs. BPL had calculated the amount of plasma that would be required to produce sufficient product for self-sufficiency in England and Wales. The overall amount of plasma required was divided to provide targets for each RTC. I recall them being set according to the capacity of each centre. I do recall the targets changing at one point and they were then dependent on the population of

each Health Region. The aim was always to achieve self-sufficiency in blood products for England and Wales.

98. If we were able to convince the Hospitals not to use whole blood, we could meet our target from recovered plasma, and we did so.

99. I note from document [SBTS0000618_160] that I mentioned to Dr Gunson that the North East Thames RTC had a higher proportion of specialised teaching hospitals in the region than many others. Despite this, it appears that in 1985 we collected 27,000 litres of plasma for Elstree from 136,000 full donations of blood with an average of 200mls plasma from each donation. In 1987, we had to provide 53,000 units of platelet concentrate. It appears we provided 24,000 litres of recovered plasma to Elstree from 136,000 donations, so then an average of 177mls of plasma was sent to Elstree for every donation of blood collected by the Brentwood Centre.

**22. What impact, if any, did the setting of targets for the collection of plasma have on decision-making at the NETRTC?**

100. The targets had a massive impact. We decided to employ staff to work in the evenings, and we went round hospitals to encourage them not to use whole blood. We also did research with BPL and maximised donor recruitment using the methods I have discussed above.

101. We also continued to collect what we needed for red cells, and I recall that I developed a method whereby even if we were getting platelets and red cells from a single donation, we could also get some plasma so that we sent everything we could to Elstree.

102. I note that document [NHBT0003370 page 1] states *"Dr. Harrison plans to collect about 35,000 Kgs in 90/91 largely by increasing*

*recovered plasma and plateletpheresis. She will need to increase donor numbers, but this is already in hand. There are no plans for large scale apheresis, in Dr. Harrison's view this is not an economic way of collecting plasma"*. We worked on increasing recovered plasma and donor numbers before looking at incurring the expense of plasmapheresis (other than for specialist plasmas).

**23. What were the consequences if the targets were not met?**

103. There were no particular sanctions. I had no knowledge of what would happen in this scenario, but I assumed it meant the haemophilia directors would not be getting enough NHS Factor VIII for their patients.

104. In my experience, we would get the order and we would satisfy it with BPL product, and I do not recall anyone asking for more BPL Factor VIII.

**24. Were there any benefits to the NETRTC if the targets were exceeded?**

105. It would benefit local hospitals and if we got more plasma, BPL could make more Factor VIII which would be better for the country as a whole.

**25. In November 1988, you wrote a letter to Dr Gunson which stated that "we should seriously question Richard Lane's statement that there will be a requirement for 550,000 litres of plasma per annum for Factor VIII production" (NHBT0009593). Why was this? In your view, were the targets set for plasma collection realistic or necessary? If not, why not?**

106. I questioned this, as Brian Colvin, who was a haemophilia doctor, had told me about the use of Factor VIII going down at that time. I

can imagine that by 1988, haemophilia patients may have been wary about using Factor VIII.

107. I note from document [NHBT0009593] I state that: "*If the Centres could manage to collect an average of 200ml for every unit of blood collected, then the country would collect 400,000 litres of plasma for Elstree, without the need for any plasmapheresis".*

**26. At an Eastern Division of Consultants meeting in March 1989, it was noted that you indicated that you "had not been funded to procure plasma" (NHBT0118858, page 2).**

**a. As far as you are aware, how was plasma procurement at NETRTC funded throughout the 1980s?**

108. Before cross-charging, it was not specifically funded. I do not recall if we got any funding to set up the extraction into pouches and I am not sure if it was provided by the RHA or sponsored by Baxter Healthcare as they were involved in the research. We also obtained blast freezers.

109. We measured the volume of plasma harvested by weighing and I assume that the weight/volume of plasma submitted to BPL was checked on receipt.

**b. What was meant by this? Was the lack of funding to procure plasma a challenge for NETRTC? What steps, if any, were taken to address this?**

110. This was a challenge. Each unit of blood was processed as the blood came into the Centre from the donor sessions. We had four evening workers who processed the donations which came in after normal working hours, so it could also be processed on the day of collection.

111. I do not think this caused any problems when we were harvesting plasma from regular donations apart from having to get new recruits. I do not recall how we paid for these additional staff members. They may have been paid for by extra funds from the RHA or from our existing budget.

112. If we had to set up plasmapheresis we would have had to go to the RHA 'cap in hand' for more funding. This would have involved a doctor to supervise, staff trained to run the machines, and the provision of apheresis machines and harnesses as well as finding premises to site the machines and recruiting donors, which would have been very expensive.

113. I presented my proposals to the RHA about how to meet the target for plasma collection, but I do not recall if I received any more funding for this.

**27. In September 1989 at a meeting of the Haemophilia Working Party, you reiterated that the NETRTC "had never been funded for plasma collection and separation. The annual payment to the RBTC from the BPL for plasma is currently around £1.0m. However, the cost of buying back the Blood Products returned by BPL is over £3.0m" (BART0000667, page 2). How did the NETRTC fund the purchase back of blood products?**

114. For this reason, I had a conversation about whether the hospitals should pay for the Factor VIII. £1 million was paid by BPL but it cost £3 million to buy the processed product back, which the NETBTC could not afford.

115. I think we found money in our budget for the purchase back of BPL product for a period of time. Dr Keith Rogers and I tried to develop a type of charging system, whereby the hospitals paid for

the BPL product, but our concerns then were that the hospitals might try to use something cheaper other than BPL Factor VIII concentrate, which would not be desirable. What happened in the end was the introduction of cross-charging for all blood, components and blood products.

**28. At an Eastern Division meeting in 1992 it was noted that "communications between the BTS and BPL continue to be unsatisfactory from many points of view" (NHBT0016139, page 5). In your opinion, why was communication unsatisfactory? What impact, if any, did this have on the achievement of plasma targets? What, if anything, could have been done to improve communications?**

116. I considered that communication between BPL and NETRTC was good. However, I understand that other RTCs had a more difficult relationship.

117. I did try to work with BPL, and we did a lot of work with them regarding the pouches.

118. I note from the document [NHBT0016139] that with plasmapheresis BPL were receiving 2 pouches that had the same donation number and their system was not coping with that.

119. I do not feel able to comment on what would have "improved communications".

***Cross-charging***

**29. 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 (NHBT0057426_002). As far as you are aware, what effect (if any) did cross-**

**charging have on the plasma supply in England and Wales? You may find page 4 of NHBT0118859_002 of assistance.**

120. My understanding is that cross-charging was introduced to encourage people to understand better about the cost of producing blood and blood components, and to encourage a more judicious usage.

121. I note from document [DHSC0101509] that I state: "*I have also spoken to my fellow haematologists in the N.E. Thames Region and the majority of them feel that cross charging would be conducive to a more economic and rational use of blood and blood products in the Region*".

122. I note in the same document I suggest that they "*consider the idea that a charge should be made at cost price to hospitals for all blood and blood products*".

123. I note that I go on to state "*I believe that such a system would provide an excellent means of funding the regional transfusion centres. It would mean that if hospitals in the districts wanted to have further supplies of a particular blood product, then they would have the facility to decide to spend their money on this product and the Transfusion Service would then have adequate funds to produce this item. I quote from the paper which I have enclosed from a sentence under item 7: "It is also arguable that a free issue of any commodity is not conducive to its economic use and there may well be over-ordering and poor oversight on shelf life etc.*"

124. I note document [NHBT0057426_002] says "*Cross charging will distribute BPL's costs differently. RHA will pay for products which (per 5.5 and 5.6) they will get on a pro rata basis. If, however*

*more plasma is supplied by a RHA than is reflected in the amount of products it purchases, then its costs will be reduced.*"

125. However, I understood that at one point there was a budget from the RHA that funded production and transport. After cross-charging, those costs would then be paid for by the hospitals and hospitals would pay for the services we provided and the components and products they required. The RHA did not pay for the product; the hospitals paid for the product.

126. I note in document [RLHO0000001_017] I discuss the changes.

*Situation Prior to 1.4.89*

127. *"All blood transfusion centres within England and Wales collected plasma and sent it to the Blood Products Laboratory (BPL) in Elstree for processing to prepare NHS blood products. Blood products were sent to each transfusion centre pro rata to the quantities of plasma sent in. At that time there were insufficient NHS blood products to supply all patient needs and some products had to be purchased commercially. The Brentwood BTS was partly funded by the RHA for plasma collection and so sent out some Factor VIII to hospitals in the Region free of charge. Each Haemophilia Centre in the region had an agreed 'free allocation' of Factor VIII and any further Factor VIII supplies that were available from the NHS over and above the free allocation were charged for at the rate of 8.1 pence per unit of Factor VIII. This charge was made by the Brentwood BTS to cover the cost of plasma collection".*

*Situation From 1.4.89 to 31.3.90*

128. *"In line with Government policy the Department of Health (DoH) decided that BPL would "pay" the transfusion centres for plasma*

*sent in and "charge" for the returned product. The charges and payments were to be in line with government policy made by adjusting RHA budgets. In the financial year 89/90 the North East Thames RHA received the following income relating to blood Products made by adjusting RHA budgets*

*Approx. £1,200,000 for plasma sent from Brentwood BTS*

*Approx. £ 750,000 as a share-out of BPL's revenue budget from the Department of Health*

*Approx. £ 250,000 for plasma from Brentwood in a stockpile at Elstree*

*TOTAL £2,200,000*

*NETHRA Expenditure on Blood Products:*

*Approx. £3,000,000 cost of Regional Blood Products from BPL*

*Approx. £ 200,000 allocation to BTS for cost of collecting plasma*

*TOTAL £3,200,000*

*The shortfall was therefore approximately £l,000,000 and in March 1990 the RHA decided that districts in the region would be top-sliced to make. up the shortfall in proportion to their usage of blood products".*

*Situation in the year 1990/1991*

129. *"The. NETRTC "income" of approximately £2.2 million minus the £200,000 BTS costs, was redistributed to districts so that they could "purchase" their own blood products from BPL. I understand that this distribution was on a recurrent basis. BPL set prices for the various products (list enclosed) but the National Blood Transfusion Service (NBTS) negotiated a discount for users who order via their transfusion centre. I have managed to negotiate further price reductions in North East Thames for some products (North East Thames price list enclosed)".*

130. In summary, I did not think of cross-charging as something to increase plasma input to BPL but something to encourage more judicious use of blood products.

**30. What was the impact of cross-charging on NETRTC? You may find HSOC0002653_001 of assistance.**

131. Please see my response to question 29. I note document [HSOC0002653_001] stresses the importance of the pledge at the time for centres to become self-sufficient in all blood products. At the time there were a number of mainly American companies offering blood products at reduced prices. In my opinion, it was therefore vital that donors continued to give blood to avoid hospitals, who were mindful of their budgets, buying imported blood products at reduced prices.

132. I suppose the impact of cross-charging was that we got the money relating to the product that was issued to hospitals, so it made NETRTC finances more sound.

133. I understand that the impact on some RTCs may have been that the income from purchase of blood product supplied to hospitals didn't cover the production costs of plasmapheresis. However, the cost associated with producing recovered plasma was lower. As we supplied recovered plasma it did not have as much of an impact. I am not sure if it covered all the cost of the production of BPL products, but I do not recall it having a big impact.

**31. At an Eastern Division meeting in March 1989, it was stated that the meeting was in "unanimous agreement that this [cross-charging] had been introduced far too early with too little notice and without adequate consultation" (NHBT0118858, page 1). Did you share this view? If so, please explain the reasons for this view.**

134. I cannot recall how much notice we were given but I did share this view. I thought that the scheme was not well thought out because the cross charging only related to BPL products. I favoured cross charging for all components and products, otherwise hospitals might try to save money by ordering 'free' components. I presume that this meeting must have involved Brentwood, Tooting, Edgware and Cambridge Centre Consultants.

135. I note the document [NHBT0118858] states *"Drs Rogers and Harrison were both against the free allocation of products to hospitals by the RTCs and felt that all hospital should pay the RTC for BPL products. Dr Harrison indicated that she had not been funded to procure plasma."*

**32. At the same meeting it was stated that "Great concern was expressed that RTCs will have no control over the quantity of blood products hospitals will choose to use, nor where they would elect to buy from. If commercial products were cheaper, it is most likely that hospitals would purchase those" (NHBT0118858, page 1-2).**

136. I have separated the various questions in this question for ease.

**Did the RTC lose control as anticipated?**

137. I believe that most hospitals were committed to the use of BPL products if they were available, though I think that some hospitals may have purchased commercial products. NETRTC had no control over this. The decision was the responsibility of individual hospitals.

**Did hospitals, as far as you were aware, buy the cheaper commercial products?**

138. Once cross-charging came in, I am not sure if hospitals did in fact do this. See my answer 109.

**In May 1990, in a letter from Mansel Chamberlain to Dr Bernard Crowley it is stated that you "received a contract to sign on behalf of the Region, and… not prepared to accept this with the prices that are currently on offer", and that you supported self-sufficiency, but "this cannot be done at any cost" (NHBT0097035_023). As far as you can recall, were the prices set for cross-charging realistic?**

139. I note from document [NHBT0097035_023] that it was suggested that our desire was to support BPL to achieve self-sufficiency in blood products, but it could not be done if the cost of harvesting plasma by the RTCs was greater than the price of BPL product so that RTCs would not be reimbursed for their plasma collection costs. I cannot recall what the proposed prices for BPL products were, but they must have been too low in my view, so that they did not cover plasma collection costs.

**Did BPL take up the suggestion to offer their products on a 'not knowingly undersold' basis?**

140. I do not recall this.

**What impact did the price BPL were charging have on the collection of plasma for fractionation?**

141. I believe that we went on harvesting plasma as before whilst pointing out to the managers of BPL that we could not continue to do this if our costs were not fully reimbursed. So, we argued that BPL products should be priced accordingly.

***Plasmapheresis***

**33. As early as 1981, plasmapheresis was being considered as a means of increasing the plasma supply to help achieve self-sufficiency. The Inquiry is aware that you were Chairman of the Cell Separator Working Party (CBLA0002527; page 1-2 of DHSC0002245_002; PRSE0001275). Please explain, as far as you are able, what consideration NETRTC gave to implementing plasmapheresis, including:**

**a. whether manual or machine plasmapheresis was preferred;**

142. We preferred recovered plasma to either of these options. I helped formulate the guidelines. Plasma was recovered by separating it from whole blood donations. It was not manual or machine plasmapheresis.

143. To explain in more detail, manual plasmapheresis required Fenwal Software. A unit of blood is bled into a double pack. This unit is then centrifuged at 4,000 rpm for 7 minutes and the plasma removed. The red cells are then returned to the donor. Whilst the blood is being centrifuged, saline is dripped into the donor's vein to keep the bleed line open. The whole process is repeated a second time. The time taken for this double plasmapheresis is around 50-60 minutes. Manual plasmapheresis was not considered to be efficient when machine plasmapheresis became available. This was quicker and kinder to donors. It avoided the risk with manual plasmapheresis that the donor might be re-infused with the wrong unit of blood in error.

144. Following donation, the donor is able to drink tea or coffee, eat a biscuit and then they are able to return home. Donors undergo plasmapheresis at fortnightly, monthly, three monthly or six-monthly intervals depending on requirements for the antibody which is being harvested. If plasma is being collected for Factor VIII production by BPL, donors can attend every 2-4 weeks.

145. A Haemonetics 50 Machine was used at the time for machine plasmapheresis. At NETRTC, we did not need to incur the outlay for plasmapheresis, which also required static units, as we could provide sufficient plasma via recovery from whole blood donation. The cell separator working party, of which I was Chair, was responsible for setting guidelines for the use of cell separator machines for collection of plasma or platelets. We considered aspects of staff training, guidelines for safety, welfare of donors and quality of products, but we were not concerned with whether plasma for fractionation at BPL should be collected by apheresis or from whole blood.

**b. the relative cost differences between each method;**

146. It cost £80 per litre to collect plasma by plasmapheresis, and it was much cheaper to recover it, without the cost of plasmapheresis equipment or static centres.

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

147. We did not have the infrastructure to introduce machine plasmapheresis on a scale necessary to harvest plasma for BPL. Staff in our existing small apheresis unit had the expertise and could have trained others, but the cost of collecting plasma in this way is high and we considered that we should collect the maximum quantity of plasma from whole blood donations before considering plasmapheresis. With machine plasmapheresis a fixed site is normally required as plasmapheresis is not normally undertaken at a mobile donor site. And we would have needed a considerable increase in fixed clinic capacity to collect large quantities of plasma by apheresis.

148. We had a fixed blood collection site at Moor House in the City of London a centre at Brentwood for specialist plasma and platelets, and if we needed a third, we would have had to rent a site.

149. We could have sited the plasmapheresis machines at Moor House with a doctor to oversee it and nurses to run the machines. However, we never got to this point. We were able to supply our target from recovered plasma. If we required even more, we would have needed to rent another site to collect plasma and/or collect plasma at the Brentwood centre.

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

150. Yes, it could have increased the amount of available plasma. We did not take the steps discussed above in light of the fact we had not reached our limit in recovered plasma.

**34. Please set out the extent of the plasmapheresis programme at NETRTC during your tenure. As far as you are aware, did this programme differ from other RTCs? If so, why? You may find NHBT0003370 and page 13 of NHBT0010587 of assistance.**

151. I note that document [NHBT0003370] states "*Dr Harrison intends to develop plateletpheresis which she regards as a very economical way of collecting platelets – especially using the Brentwood modification to Haemonetics machine. The plateletpheresis will enable her to increase the amount of plasma recovered from whole blood because it will not be diverted for platelet manufacture.*"

152. As indicated earlier, document [NHBT0003370] states "*Dr. Harrison plans to collect about 35,000 Kgs in 90/91 largely by increasing recovered plasma and plateletpheresis. She will need*

*to increase donor numbers, but this is already in hand. There are no plans for large scale apheresis, in Dr. Harrison's view this is not an economic way of collecting plasma*".

153. The fact we supplied more recovered plasma than other centres and did not make any plans for large scale apheresis perhaps made the programme at NETRTC slightly different from other centres which may have opted for more large-scale apheresis, but recovered plasma was more cost-effective and we were able to meet our targets for BPL from recovered plasma.

**35. In July 1988, Dr Gunson stated "it would be necessary to increase supplies of plasma from plasmapheresis" (CBLA0004826, page 4). It appears to the Inquiry that you disagreed with this in a letter sent in November 1989, stating you felt "very strongly" that RTCs should make an "effort to obtain the greatest possible volume of recovered plasma before they go onto the much more expensive method of automated transfusion" (NHBT0009593). As to this:**

**a. Why did you feel this way?**

154. I felt this way because many litres of recovered plasma could have been obtained in my view if all centres had tried to maximise plasma harvesting in this way. When this had been achieved and if more plasma was still required plasmapheresis could be set up.

155. As I have said, I felt very strongly that all Transfusion Centres should make an effort to obtain the greatest possible volume of recovered plasma from normal donations before they went on to the much more expensive methods of automated plasmapheresis.

156. I note that in document [NHBT0009593] I mentioned, "*if the Centres could manage to collect an average of 200ml for every unit of blood collected, then the country would collect 400,000 litres of plasma for Elstree, without the need for any plasmapheresis".* In essence, I thought that 400,000 litres would have been enough which did in fact turn out to be correct as there ended up being a stockpile.

**b. What action, if any, did NETRTC take as a result of this?**

157. We continued to maximise use of recovered plasma. It did not become necessary for us to scale up and use machine plasmapheresis. I also spent lots of time trying to create a small battery-operated machine for plasmapheresis that was portable, and we succeeded, but it was never taken up. Such a machine could have been used at mobile donor sessions.

**c. As far as you are aware, did other RTCs take the same approach as you?**

158. Other RTCs did not necessarily take the same approach as they did not educate their users on the benefit of recovered plasma and that is why I wrote to Dr Gunson.

**d. Was the strategy for plasma collection the right one? If not, why not?**

159. There was not a national strategy and that was a problem. There were two options: -

1) Recovered plasma
2) Plasmapheresis

160. Centres could decide which method they would adopt. I was of the opinion that recovered plasma should have been maximised as I

have discussed above. Recovered plasma is available straight away. There is a lot of infrastructure required for plasmapheresis and it also takes more time. Therefore, if time was of the essence, the quickest thing to do in my opinion was to maximise recovered plasma. We were already sending some recovered plasma so I considered that we should just maximise this. I believe that this is one of the reasons that we produced the most plasma. Once heat treatment started then the amount of Factor VIII recovered was reduced so we then needed more plasma.

36. **At the final RTD meeting in January 1989, you stated that costing had been done at the NETRTC which indicated "that pheresis plasma costs £80.00 per litre to collect. There was a danger that her RHA would refuse to sanction plasma harvesting by apheresis arguing that it would be cheaper to buy the products on the commercial market" (NHBT0018188, page 3). As far as you can recall, was funding plasmapheresis difficult? You may find page 4 of NHBT0097469_018 of assistance.**

161. We did not get to the point where we required funding and we never had to ask for plasmapheresis to be funded because we were using recovered plasma. We maximised recovered plasma and then there was a stockpile, so we did not need to invest in the infrastructure and staff for plasmapheresis.

***Use of plasma reduced blood and red cell concentrates***

37. **In November 1988, you wrote a letter to Dr Gunson which stated "Many Centres are still issuing quite a high percentage of whole blood but,... we issue virtually no whole blood and this policy is accepted by clinicians in our Region" (NHBT0009593, page 2). In particular:**

**a. What steps, if any, did NETRTC take to persuade hospital clinicians to use less whole blood and more red cell concentrates and/or plasma reduced blood to release more plasma for fractionation? You may find NHBT0010587, page 27 of assistance.**

162. I certainly wrote to the hospitals asking them to accept red cells instead of whole blood. I would also go to the hospitals and we would try to persuade them that it was better for their patients sometimes as well because the patients did not get overloaded with fluid by receiving whole blood.

163. If they advised us that they needed plasma, then I would suggest using frozen plasma. Usually, a patient would require a particular blood product i.e. red cells or plasma. I spoke to them and had lots of conversations. Overall, they were very understanding, particularly if the hospital also required Factor VIII. They understood that we were trying to get the maximum amount of plasma in order to get them the Factor VIII they needed.

**b. As far as you can recall, how many centres were still issuing a high percentage of whole blood? In your opinion, what (if anything) could have been done to prevent this?**

164. I do not feel able to comment on this as I do not know whether other centres were still issuing a high percentage of whole blood. The steps I took as discussed above in response to question 37a helped reduce the use of whole blood at my centre.

## Section 5: Arrangements for obtaining and allocating blood products at NETRTC

**38. Please describe the arrangements in place in the North East Thames 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. **In a memo dated 19 January 1999 (BPLL0016082_024), you were noted as describing NETRTC acting as a wholesaler for BPL's products during the 1980's. What did this involve, why did it come about, and why did this cease in the 1990's?**

165. I do not think we ever distributed products from companies other than BPL. We never distributed commercial products.

166. In the 1990s, BPL started supplying directly to hospitals.

167. We did act as a wholesaler for BPL products. They would send us a supply of Factor VIII and then we would send it to the hospitals. I cannot recall the reason why we ceased being wholesalers. Perhaps this was because BPL set up its own distribution system.

b. **Please identify which haemophilia centres were supplied with such products by the NETRTC and over what period of time.**

168. I cannot recall what centres would have been supplied with BPL Factor VIII products. It would have likely been London Haemophilia Centres. From memory, we supplied Great Ormond Street, the Royal Free, Royal London, and UCH. I am not sure about St Barts. There were other Associate Haemophilia Centres in NET Region, but I believe that these were supplied by the main Haemophilia Centres. In the 1990s, when BPL developed its own distribution system, they supplied the Haemophilia Centres directly.

**c. Please outline the respective responsibilities of the NETRTC, BPL, the relevant Regional Health Authority ("RHA"), and haemophilia centre directors with respect to the purchase and holding of, and the allocation of blood products and how these responsibilities changed over time.**

**You may be assisted by point 5 of NHBT0108586_002.**

169. NETRTC would only have BPL products which we distributed in the 1980s. In the 1990s, BPL supplied their own products, and the hospital would have ordered from them without the involvement of the RTC.

170. Any commercial products would have been ordered by the hospital with no reference to the transfusion centre.

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

171. I am not aware of the arrangements in other centres, so I am not able to comment.

**40. In 1987, you wrote a document about the NETRTC which stated you had a "Regional Haemophilia Coordinator" who "works with the Transfusion Service and the Haemophilia Centres to coordinate the supply of NHS Factor VIII concentrate within the Region" (NHBT0010587, page 11-12). When was this role created? What role did this coordinator play in coordinating the supply of NHS Factor VIII? Please provide details. As far as you are aware, did other regions also have haemophilia coordinators?**

172. I cannot recall the answers to these questions but note that document [NHBT0010587] includes: "*Regional Haemophilia Coordinator - This Nursing Officer is on the staff of the Regional Transfusion Centre, but currently has her office at the Royal Free Hospital, where there is a major Haemophilia Centre. She travels throughout the North East Thames Region, giving advice and nursing care to haemophiliacs and their families in their homes. She also attends haemophilia clinics and works with the Transfusion Service and the Haemophilia Centres to coordinate the supply of NHS Factor VIII concentrate within the Region*". I assume this represents this position in July 1987 which is when this report was revised.

173. I do not know whether other Regions had Haemophilia Coordinators.

**41. Did you, or anyone else at the NETRTC, 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 taken into account when determining whether to contract with one pharmaceutical company over another.**

**You may find NHBT0000077_056 of assistance.**

174. No, we did not contract directly with any pharmaceutical company involved in the manufacture and/or importation and/or sale of imported blood products.

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

175. I do not think there was an impact on the transfusion centre. If there had been insufficient BPL product then theoretically, the hospitals could have asked the RTCs for cryoprecipitate. I do not recall this happening. If cryoprecipitate was needed for a particular surgery, then we would make it if requested.

**43. Was the NETRTC 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?**

176. No, NETRTC was not responsible for decisions about the choice of product used to treat patients in haemophilia centres and/or hospitals.

177. Document [RLHO0000001_017] notes that: *"My influence extends only to trying to negotiate discounts with BPL for North East Thames hospitals. DHAs are at liberty to buy commercial blood products if they wish, rather than NHS ones, but BPL prices are very competitive and I personally wish to support the national effort to achieve self-sufficiency in blood product use and avoid imported products".*

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

178. No, we did not have any influence over product choices. However, if asked we would always advise to use BPL product.

**45. What, in your view, were the key factors influencing the choice between NHS blood products and imported blood products? You may find RLHO0000001_017 and RLHO0000001_016 of assistance.**

179. We were not involved in these decisions, so I do not feel able to comment. I do not recall being asked for my opinion on this. However, my own preference would have been for products from local voluntary donors rather than imported products from paid donors.

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

180. I do not feel able to comment on the impact of clinical freedom on the relative use of NHS blood products and imported blood products choices as made by haemophilia directors. I am not aware of the criteria with which they made their choices. Thus, I do not feel able to comment.

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

181. I have no knowledge of this as I was not involved in the supply of those imported blood products.

**48. At a Regional Transfusion Directors meeting in October 1988, it was stated by Dr Lane that "the attainment of self-sufficiency in Factor VIII remained problematical and was made more difficult by the independent line taken by Haemophilia Directors" (NHBT0018189, page 4).**
**Did the Haemophilia Directors in the NETRTC region take an independent line? If so, what impact, if any, did this have on the NETRTCs planning for plasma procurement?**

182. I do think that some haemophilia clinicians did take an independent line and argued that they believed that imported product was just as safe as the BPL product. This was not my view.

183. I do not think this had any impact on the amount of plasma we procured as we tried to procure as much plasma as we possibly could. We were part of the national drive towards self-sufficiency.

***Association of Haematologists North East Thames Region - Haemophilia Working Party***

**49. The Inquiry understands that you attended meetings of the North East Thames Region Association of Haematologists Haemophilia Working Party meetings. The Inquiry has provided minutes of the meetings you attended in your capacity as Director of the NETRTC: BART0000666; BART0000673; BART0000674; BART0000675; BART0000677; BART0000676; BART0000679; BART0000681. Please answer the following:**

**a. Who established these meetings?**

184. I am not sure as they were established before my time as RTC Director. It may possibly have been Brian Colvin or Peter Kernoff.

**b. How frequently did you meet?**

185. About twice a year.

**c. What do you consider to have been the purpose(s) of those meetings?**

186. It was to discuss the management of haemophilia patients and to review the supply of blood and blood components for those patients.

**d. Do you consider that these meetings were conducive to fulfilling the purpose for which they were established?**

187. I do think they were helpful for me to be able to explain the situation with supply of products to BPL etc. and to find out what problems were arising with the management of haemophilia patients and what was required.

**50. Please explain whether any other forums were established between the NETRTC, BPL, 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 NHBT0097038_001 of assistance.**

188. There was the NBTS Management committee, where such arrangements may have been discussed. But I was not involved in any other meetings with Haemophilia Directors.

189. There would be informal contact by letter or by phone for instance between the haemophilia centre directors and the RTCs.

**<u>Section 6: Production of cryoprecipitate at NETRTC</u>**

**51. The Inquiry understands that NETRTC produced cryoprecipitate (NHBT0010587, page 28). Please describe:**

**a. where the production of cryoprecipitate took place;**

190. At Brentwood Regional Transfusion Centre, in the processing department.

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

191. I note in document [NHBT0010587] it is recorded that up to 3,000 donations per annum were processed for this product. The document states:

*"Cryoprecipitation is a method of preparing Factor VIII combined with fibrinogen and fibronectin. It is prepared from fresh plasma. It requires rapid freezing to approximately 60°C, then rapid thawing to approximately +1°C. Required clotting factors are precipitated at -60°C, and do not redissolve at +1°C. Excess plasma is then removed from the required product and may either be returned to bag containing the red cells or alternatively, this cryoprecipitate-poor plasma may be stored in the frozen state and used when thawed to provide some clotting factors for clinical use".*

192. The cryoprecipitate is stored at -40°C with a storage life at this temperature of 12 months.

193. It was not altered. We produced it in the quantities the hospitals requested. If there were special cases for example a young child with mild haemophilia who had to undergo surgery, cryoprecipitate could be used to avoid introducing them to a Factor VIII product which was made from larger pools of plasma.

194. Someone with mild haemophilia would not necessarily require Factor VIII – they may only need it if they were to undergo surgery for instance.

195. If we needed a large amount of cryoprecipitate for surgery, we would make some for that particular patient. Another example would be someone with von Willebrand's disease undergoing surgery, for whom cryoprecipitate would be required.

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

196. See my response to 18c.

**c. how much funding was provided by North East Thames RHA for the production of cryoprecipitate; and**

197. We had an overall budget and later there was cross charging. There was not any specific funding allocated to producing cryoprecipitate.

**d. how quickly the NETRTC could have increased its manufacture of cryoprecipitate, had it wished to, during the early 1980s.**

198. We could have quickly increased it, but this would be dependent on how much was required. If hospitals needed 3,000 units extra, it may have taken a few days. It really depends on how many donations are received that are suitable for cryoprecipitate production. We tried to prepare it from donations from donors of A blood groups or AB because they have higher Factor VIII levels than other blood groups. One of the problems with cryoprecipitate is that the amount of Factor VIII in each product is variable, since the level of Factor VIII varies from donor to donor. So, the 'dose' of Factor VIII given to patients, if cryoprecipitate is used, cannot be predicted, but only estimated.

199. There would not have been enough for all haemophiliacs to go onto cryoprecipitate as opposed to large pool Factor VIII product, even if all our resources were used to make cryoprecipitate. The patients might have to accept that they only had treatment when they had bleeding and not prophylactic treatment. Cryoprecipitate is a frozen product which is usually thawed at the hospital and administered through a drip. It would be difficult to organise daily treatment for all the registered Haemophiliac patients using this product.

**52. Please explain what consideration NETRTC 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. You may find page 2 of BART0000681 and page 2 of BART0000675 of assistance.**

200. Cryoprecipitate is made in individual bags – usually at least 5 individual bags are used for a 'dose'. The 5 bags can be pooled which give a volume of 100-200ml to be injected, usually by drip. The cryoprecipitate has to be thawed before use. As I have said in my answer to 6d, I do not think it is practical to give prophylactic cryoprecipitate to all Haemophiliac patients even if it was possible to produce enough cryoprecipitate containing adequate levels of Factor VIII. Haemophiliacs would have had to accept that they received treatment as and when they had a haemorrhage or needed surgery. They would need to take care to avoid bleeding.

201. I would have increased cryoprecipitate production had it been requested by the doctors who managed the Haemophilia patients. I did not feel that I had the expertise or the authority to tell these doctors what product to use.

202. We made every attempt to exclude high risk blood donors.

203. I note that document [BART0000681] which is a meeting of the Association of Haematologists North East Thames Working Party in Haemophilia on 22 April 1981 says, "*It was felt unnecessary to maintain a reserve supply of Factor VIII concentrate at Brentwood for emergencies or major operations. All Associate Haemophilia Centres are advised to maintain a stock of at least 5,000 units of Factor VIII and it was agreed that further supplies of Factor VIII concentrate could be transferred from the major Haemophilia Centres or be obtained from the commercial suppliers at short notice. In-patients who require prolonged or intensive treatment should receive cryoprecipitate or commercial Factor VIII concentrate. However young children who take to cryoprecipitate may receive NHS Factor VIII concentrate and should be considered as Home Treatment patients for the purposes of allocation of NHS Factor VIII concentrate to the four major Haemophilia Centres*".

204. I note it also says in document [BART0000681] that: "*Brentwood Regional Transfusion Centre wishes to decrease production of cryoprecipitate so that more of the available plasma can be sent to the Blood Products Laboratory, Elstree, as Fresh Frozen Plasma. Brentwood would continue to produce some cryoprecipitate and would be prepared to set aside cryoprecipitate on request for planned cases. Centres should be prepared to use commercial Factor VIII concentrate for in-patients, (and out-patients visiting the Haemophilia Centre) in place of cryoprecipitate. It was accepted that this may involve certain Centres in greater expense, but it is hoped that this will be offset by increased supplies of Factor VIII concentrate from Elstree. (Commercial products may be obtained at a cheaper rate per unit via the Royal Free Hospital which has a Regional Contract with nominated commercial firms)".*

205. I note in document [BART0000675_0002] which is a meeting of the Association of Haematologists North East Thames Working Party in Haemophilia on 22 May 1985 which has been provided to me by the inquiry it states "*the newer NHS dry heat treated Factor VIII product (F.VIII Y) is reported by trial users to be highly satisfactory, with high purity, good solubility and good Factor VIII post infusion levels. When sufficient is available this product will be the first choice for all newly diagnosed patients, children and others not yet exposed to the HTLV III virus and will replace cryoprecipitate as the preferred treatment in appropriate cases*".

206. I note it also says in [BART0000675 page 3] "*Dr. Colvin proposes to replace the use of Cryoprecipitate by NHS(HT)F VIII Y concentrate as soon as possible. In the meantime, patients requiring infrequent treatments should continue on DDAVP and Cryoprecipitate*".

207. So, whilst in general terms the movement was emphatically still away from Cryoprecipitate and towards factor concentrates there was consideration of use of Cryoprecipitate for patients requiring infrequent treatments.

**53. At an Association of Haematologists North East Thames Region meeting in May 1984, it was suggested that "it should be policy to avoid use of blood products except for essential treatments and to use cryoprecipitate or plasma instead of FVIII Concentrate whenever possible" (BART0000677, page 2). Who suggested this? Did you agree with this statement? To what extent was this accepted by clinicians in the North East Thames Region?**

208. I note that the full quote in document [BART0000677] says "*Dr. Harrison described the efforts made by the BTC Brentwood to exclude "at risk" donors by information and leaflets distributed at*

*Donor Sessions. It was noted that Commercial Suppliers also are now applying similar criteria in their donor selection. Heat treating concentrate has been tried but reported to cause loss of potency. It was suggested that until a positive test for AIDS and/or a vaccine is developed it should be policy to avoid use of blood products except for essential treatments and to use cryoprecipitate or plasma instead of FVIII Concentrate whenever possible*".

209. It is not clear who suggested this. I do not think I would have suggested this as I would not have known about the commercial suppliers applying similar criteria.

210. I may have been in favour of the policy of avoiding the use of blood products except for essential treatments as it seems like a sensible policy, but I am not sure it would have been accepted by the patients. At the time, heat-treated Factor VIII concentrate was not yet available. I also note that the minutes don't record whether the policy was accepted by the people attending the meeting or the clinicians in the region.

**54. Please describe the steps taken by NETRTC, if any, to increase the production of cryoprecipitate during this time. If no steps were taken, please explain why.**

211. There was not an increase as this was not required by the hospitals. At NETRTC we made the quantities of cryoprecipitate needed to fulfil hospital orders for this product.

**55. Please describe the arrangements for supplying cryoprecipitate to hospitals and haemophilia centres within the region covered by the NETRTC.**

212. We would supply cryoprecipitate if it was requested. We would deliver it directly to the hospitals. It is a blood component as opposed to a blood product so we would deliver it in the same way as we would deliver any other blood components, such as red cells or platelets.

## Section 7: Self-sufficiency

**56. During your time at NETRTC, what did you understand the term 'self-sufficiency' to mean? Did this change over time?**

213. I understand self-sufficiency to mean that the whole country would not have to import any foreign blood product. I consider that this should mean the UK produced enough domestic material for all haemophiliacs and all other users. I worked on the assumption that people would not choose foreign product.

214. I understood that the UK would not import or export red cells, platelets or any blood components (except perhaps for small quantities exported for the UK armed forces serving overseas). My understanding was that the country was self-sufficient in blood and components and would continue to be so. This did not change over time.

215. The question of self-sufficiency in blood products was a different matter. For plasma-based blood products manufactured at BPL we were not self-sufficient as the requirement for Factor VIII and other blood clotting factors increased. Over time, I came to understand the term 'self-sufficiency' as referring only to fractionated blood products and in particular to Factor VIII concentrate.

216. The document [RLHO0000001 _017[3] [JY4] ] which is a letter from me dated 28 November 1990 provided to me by the inquiry,

shows that I supported the national effort towards self-sufficiency. In this letter I state "*My influence extends only to trying to negotiate discounts with BPL for North East Thames hospitals. DHAs are at liberty to buy commercial blood products if they wish, rather than. NHS ones, but BPL prices are very competitive and* ***I personally wish to support the national effort to achieve self-sufficiency*** *in blood product use and avoid imported products*".

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

**a. plasma procurement;**

217. Plasma procurement was a key element to achieving self-sufficiency in manufactured blood products. It was clear that we would not achieve self-sufficiency without procurement of enough plasma.

**b. decisions with regard to cryoprecipitate production;**

218. We never imported cryoprecipitate. We could have produced more if required. We produced enough cryoprecipitate to fulfil hospital orders. But if we were trying to provide more cryoprecipitate, this would reduce the amount of recovered plasma that we would send to BPL for manufacture of factor VIII concentrate.

**c. purchases of commercial blood products;**

219. I am not able to comment on this as I was never involved in the purchase of commercial blood products. However, from memory I was aware that if there was not enough NHS product then hospitals would be likely to purchase commercial products.

**d. funding received from North East Thames RHA.**

220. I endeavoured to increase the amount of plasma sent to BPL without incurring much extra expense and tried to do it within my existing budget. This was done after discussion with the finance director of the RHA to whom I put forward my proposals. I made him aware that if we did not produce enough recovered plasma to achieve our target for BPL then I would have to request more funding to set up plasmapheresis.

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

221. I felt the UK could achieve self-sufficiency if all the RTCs had harvested more recovered plasma and then supplemented this with plasmapheresis.

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

222. Not entirely. Some other RTCs preferred to set up plasmapheresis as they did not think they would be able to achieve self-sufficiency from recovered plasma or were unable to convince their clinicians that they would not need much whole blood.

223. I do think that the aim of self-sufficiency was supported by the blood transfusion service, but it was the means of getting there where opinions may have differed somewhat.

224. I note that in document [NHBT0018188] it states that Mr Crowley "*went on to express some reservations about the later years of the programme for plasma harvest. He remained unconvinced about fractionating so much plasma just to achieve self-*

*sufficiency for F8 and indeed had reservations about the concept of self-sufficiency since he was sure that some Haemophilia Directors would always want a product other than that available from BPL. Mr. Crowley appealed for any information which could be gleaned from tenders for Albumin by Regions*".

**60. At an Eastern Division of Consultants meeting in March 1989, it was noted that "working out a distribution system would be difficult as BPL does not have the capacity to produce all the country's requirements of Factor VIII" (NHBT0118858, page 2). What was your understanding of BPL's ability to produce all the country's requirements of Factor VIII? Did this affect what was meant by 'self-sufficiency'?**

225. Initially, the transfusion centres were given targets for the quantities of plasma required by BPL for the production of sufficient Factor VIII concentrate to achieve self-sufficiency.

226. My understanding was that BPL could not produce enough Factor VIII concentrate for self-sufficiency as they did not receive sufficient plasma, but there may have been an issue with processing capacity at BPL.

227. The comment in question 60 appears to have been made by Dr Rogers. The full quote is "*I note that Gaynor has said Drs Rogers and Harrison were both against the free allocation of products to hospitals by the RTCs and felt that all hospitals should pay the RTC for BPL products. In reply to a question by Dr Contreras regarding the basis on which BPL prices were established, Ms Gaynor Fryers replied that the prices were based on a paper costing exercise done a few years ago for the Department of Health and taking into account the cost of raw plasma. The meeting felt that the prices had been picked by the Department of Health rather than derived and that no real account had been*

*taken of commercial prices, nor of the world glut of albumin. (The list price of some commercial albumin preparations is less than the BPL discounted price.) Therefore, BPL will undoubtedly be vulnerable to commercial attack".*

228. If BPL could not process all the plasma that they received, then it would have impacted on the ability to achieve self-sufficiency.

229. I do not feel able to comment on this.

**Section 8: Services for donors at NETRTC**

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

230. Potential donors would be sent documents in the post advising them not to come in if they were at risk. The list of groups of people considered to be 'at risk' of developing or transmitting HIV, HCV, or HBV was clearly stated in the documents. These lists were as agreed nationally by the Transfusion Service on the basis of advice from appropriate experts.

231. Leaflets providing the same information would be given to potential donors at blood donor sessions. The donors would be asked to read the leaflets and be given an opportunity to ask questions. Staff would then go through the leaflets with each potential donor and satisfy themselves that the donor had understood the information.

232. Potential donors were then asked to sign a document to confirm that they understood the leaflets, that the restrictions did not apply to them, that they consented to the microbiological and blood group tests and agreed to donate blood.

233. Before there were national leaflets for HIV, we decided at NETRTC that there would be new leaflets every 6 months. These leaflets would carry the nationally agreed text listing risk groups, but as the leaflet looked different each time a donor attended, we felt that repeat donors would be more likely to read the new leaflet even if they had seen the previous ones. I believe that I supplied some of these leaflets to a previous inquiry, but I am not certain of this.

**62. What counselling and psychological services were available for donors who tested positive for Hepatitis or HIV? Were such services delivered by NETRTC or were referrals to other agencies made? Please describe the process. You may find DHSC0002279_046, DHSC0002279_041, NHBT0000189_148, NHBT0000192_132, and NHBT0000072_057 of assistance in answering this question.**

234. Prior to the commencement of HIV testing, senior Transfusion Service medical staff received some training in counselling from a team from St Mary's Hospital in London. Then, when testing was introduced, donors who had tested positive for HIV were seen by a Transfusion Service doctor, usually together with a doctor from their local hospital. The donor would be sent a letter advising them to come in. They were not told their results by post.

235. At the interview, the donor would be informed of the positive result and offered support.

236. The donor would be asked about their lifestyle in order to ascertain whether the donor was in a recognized risk group. Sometimes the origin of the infection was never discovered, but at other times the donor was in an 'at risk' group but had not understood that they should not have donated.

237. At the interview we would take a further blood sample in order to confirm the diagnosis. Then if confirmed positive for HIV, the donor would be referred to a hospital specialist for further management.

238. We would also ask for the donor's authority to tell their GP. We would advise the donor to inform any sexual partner of their infection.

239. Dr Angela Gorman was later designated as Consultant with special responsibility for microbiology at Brentwood RTC. Then donors were seen by specialised counsellors at the Royal Free Hospital and referred to an appropriate Consultant for further management.

240. We did spend a lot of time trying to make sure that donors with positive results were seen, counselled and referred appropriately. Donors who did not at first respond to a letter asking them to attend for a meeting were sent further letters including one by registered post.

241. I note in document [DHSC0002279_046] which is a letter dated 18 September 1985 from me to Dr. M. Sibellas that I state the following: -

*"The system for testing and counselling people within the Blood Transfusion Centre will be as follows: If a donor has a positive test and this test is still positive when repeated at the Blood Transfusion Centre, a sample of blood will then be sent to the Public Health Laboratory for confirmation. When confirmation has been received, one of the two Blood Transfusion Centre's Consultants will contact the donor concerned, interview him or her, give initial counselling and take a further blood sample. At that point, the donor's permission will be asked for his or her G.P.*

*to be informed of this positive result. My survey of G.P 's has clearly shown that the majority of G.P's do not feel able to counsel their own patients about AIDS without some assistance. Referral of the blood donor to a specialist for further counselling and medical follow-up will therefore be necessary. Before the Blood Transfusion Service can start its AIDS testing therefore, we need to have the name of a Consultant or Consultants in the region who are willing to provide this further counselling and follow-up service. In my opinion, these Consultants should not be Consultants at sexually transmitted disease clinics nor at genito-urinary clinics. Some of the blood donors who are likely to prove positive in HTLVIII antibody tests, may be the wives of men who, unknown to them are bisexual. There is also likely to be a proportion of persons who have a false positive test result. It would be extremely distressing and quite unfair to such persons to expect them to attend a sexual transmitted diseases or genito-urinary clinic".*

242. Riva Miller was a specialist in the liver department at the Royal Free hospital which dealt mainly with people infected with Hepatitis– particularly Hep B and C – and she would probably have counselled in the liver department. I am not sure about the HIV. Pat Hewitt was the lead on that.

243. I note in document [NHBT0000192_132] which has been provided to me by the inquiry I state, "*We will be informing donors whose tests are confirmed as positive largely because we feel that this information should be known to the donor and his/her doctor, and also because we will have to withdraw these donors from our panel. We feel that the donor's General Practitioner is in a far better position to advise him or her than a previously unknown doctor at the Transfusion Centre. Furthermore, it would obviously be inappropriate for BTC staff to initiate any long term investigation or treatment (were this to prove necessary) without*

*the GPs involvement. For this reason, we plan to ask the donor's consent to inform his/her General Practitioner of our findings. We have obtained advice from Dr Murray-Lyon (Consultant Physician at Charing Cross Hospital) and Dr Dusheiko (Consultant Physician at the Royal Free Hospital) who have kindly offered to see and advise any patients whom you (or your local gastroenterologist) might wish to refer to them. Obviously, local specialists also are very much aware of this problem and know that testing of all blood donors is imminent*". This supports my description above and refers to donors testing positive for Hepatitis B and C.

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

244. The transfusion service would not be responsible for giving advice to the recipients of infected donations.

245. There were 2 situations. Firstly, we would investigate the past donations of any donor who tested positive as far as that was possible, by testing stored samples. If there were any positive results, we would inform the hospitals to which the donations had been sent, so that they could identify and counsel any recipients.

246. Secondly, a case would be referred to us by the hospital and they would say – my patient has been diagnosed with Hep C for instance and they were definitely negative before the transfusion.

247. Then we would investigate donors from whom they had received blood. We would retest the samples then we might call the donors depending on how many there were. We would

investigate donors' blood received after the last point that the recipient tested negative.

248. If we found that a donation tested positive, we would deal with it in the same way as if a donor had tested positive through routine testing and we would ensure that their blood is not given to anyone else. Any blood components still 'on the shelf' would be discarded, as would any plasma sent to BPL and the donor would be permanently withdrawn from the panel.

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

249. Yes, I think so. However, I cannot comment on the arrangements for recipients of the blood products. Our role in that sense was to investigate the donors from whom they received blood and dispose of any donations provided by a donor who tested positive.

250. After HIV testing commenced in 1985, I understand that in England there were only 2 donors whose blood was found to have transmitted HIV.

**65. In August 1985, the Terrence Higgins Trust wrote to you to state that prior to HIV testing "donors should be specifically and individually informed that their blood will be tested, together with a brief explanation of what this means", and that "appropriate counselling" was required, as "It is not necessarily sufficient to refer him/her to his/her G.P." (NHBT0039762_134). Were donors informed that their blood would be tested for HIV? If not, why not? If so, how was this done and at what stage during the donation process?**

251. This is answered above in question 62.

252. Donors were also advised their blood would be tested for HIV.

253. It was done by letter when they were called to give blood and at the donor session prior to donating, when they were asked to sign to confirm agreement to testing and donating.

254. I note that this quote actually refers to the appropriate counselling for the "positive donor". With HIV they were also referred to a specialist. They were never just referred to their GP.

**66. In a letter you wrote to Dr Gunson in December 1989, you stated that "if we spend some time preparing the ground in the way I have suggested, then we should achieve the most suitable care for donors who are anti-HCV positive without putting an enormous burden on the NBTS" (NHBT0000072_057). In particular, in your opinion:**

**a. What did you feel would cause an 'enormous burden on the NBTS'?**

255. The need to counsel donors who were anti- HCV positive. There was quite a high proportion of donors (1 in 1,500) who might be positive. Relative to HIV there would be a much higher proportion of positive HCV donors initially. I felt that they should be referred to a liver specialist rather than counselled by NBTS staff. To counsel all the donors who were anti-HCV positive would be a huge burden on us as a service.

**b. Was the NETRTC able to 'spend some time preparing the ground'?**

256. Yes, NETRTC and other RTCs took steps to prepare the ground. We tried to educate the donors. A national leaflet was produced and sent to all donors about anti HCV and what that meant. All donors called to sessions would have also been sent a leaflet explaining about the anti-HCV testing and its

significance and assuring them that HCV has no relationships to AIDS.

257. Importantly we also had a chance to speak with liver specialists who would be willing to counsel and treat donors who were positive.

258. I am not sure whether all GPs nationally were informed about testing. We arranged for GPs to be informed if donors were found to be HCV positive.

259. I also produced an information letter for dentists as seen in document [NHBT0016533]. This provided information regarding Hepatitis and the risk of transmission. It is quite possible that I would have given this letter for donors to give to their dentist.

**c. Were any of your suggestions in this letter implemented?**

260. Yes, see 66b above.

**67. In Dr Gunson's transcript of evidence to the *A & Others* litigation, Dr Gunson states that you "had a major advantage in that Professor Zuckerman was her consultant, who looked at liver problems" (NHBT0000148_001, page 16). Do you feel you had a 'major advantage'? If so, in what way did Professor Zuckerman help the NETRTC with the services provided to donors? Were you able to move more rapidly than other RTCs in introducing HCV testing or did you have to wait for national agreement? Please provide details.**

261. Yes, we did have a major advantage as we were able to ask him for advice.

262. Professor Zuckerman was Director of LSTM. He was a very eminent liver specialist. We had an advantage as he could advise us on how best to manage donors with these diseases. He would advise us on the best way of doing a 'look back' to investigate past donations of a donor who tested positive for instance.

263. However, we always followed national agreements when introducing testing because we agreed with the way the decision was made. When introducing a new screening test, you need to ensure there is not a significant percentage of false negatives and false positives, otherwise there is no point in testing. It is also vital that all RTCs Introduce the same test at the same time.

264. Most RTCs had agreements with liver specialists but we had one who was a leader in the field of virology.

265. Having Professor Zuckerman as adviser did not mean that we could move more rapidly than other RTCs in introducing HCV testing. He would have been advised by the virologists about false negative and false positive results for instance. We also needed a screening test that was reasonably quick to produce results. It was also agreed by Government Advisers and the National Blood Service that testing should not commence until a 2nd generation test had been assessed.

**68. At an Eastern Division Consultants meeting in January 1991, the "Division felt that there should be a national policy regarding the counselling of donors found to be positive for antibodies to HCV" (NHBT0097472_009, page 4). Was a national policy ever implemented? You may find NHBT0010896 and NHBT0046832_001 of assistance.**

266. I note that in 1996 there was not a national policy. "A degree of variation in practice has been identified which has generated a number of areas for discussion".

267. I understand that later on there was a national policy as per document [NHBT0046832_001] which is dated 25 Feb 1999.

**Section 9: Meetings of various committees**

***Meetings of Regional Transfusion Centre Directors***

**69. The Inquiry holds meeting minutes between the Directors of RTCs in the United Kingdom from approximately 1948 to 1989, some of which you attended in your capacity as Director of the NETRTC. The Inquiry has provided minutes of the meetings of this group which you attended in the below schedule for your assistance. Please answer the following:**

**a. Who established these meetings?**

268. I don't know. They were already well established when I joined the blood service.

**b. What do you consider to have been the purpose(s) of those meetings?**

269. To discuss matters of common interest, discuss important developments to make sure everyone was acting together. For example, to help establish rules on donor selection, testing and various services that the transfusion service provided. We needed to make sure that we were nationally coordinated so we weren't giving different advice in different parts of the country. The aim was to improve the care of transfusion recipients and donors, to

keep up to date with new developments and to agree to the introduction of new procedures as appropriate.

**70. 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.**

270. Yes, we were empowered to make collective decisions. For instance, we made the decision when to test based on clinical developments and the availability of suitable tests. We agreed on advice to donors based on clinical advice. We could not make decisions in relation to funding as this was dependent on the funding from our own health authorities.

271. Decisions tended to be made at the RTDs meeting and then the information was disseminated in the minutes and by email or letter. The minutes were circulated to all Regional Transfusion Directors. At NETRTC, copies of the minutes were passed on to Consultants and other senior staff and relevant items were discussed.

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

272. I think they were. National decisions were made and all Regional Transfusion Directors (RTDs) were urged to implement changes or new procedures as agreed. In general, all RTDs did their best to comply even though funding from RHAs was sometimes a problem. I found that the RTDs meeting was useful in helping me to keep up to date with clinical and research developments in Transfusion Medicine and to discuss these with colleagues.

**72. The Inquiry understands that you attended the final meeting between the Directors of RTCs in January 1989 (NHBT0018188). The minute also notes that "there was no discussion of the advantages and disadvantages of dissolving the RTC meetings". Why were these meetings dissolved? Were the advantages and disadvantages of doing so discussed? If not, why not? What were, in your view, the advantages and disadvantages of this decision? You may find page 3 of SBTS0000628_011 of assistance.**

273. The Transfusion Service in England and Wales was reorganised to have a National Director (Dr Gunson). The organisation was called the National Blood Transfusion Service (NBTS). The NBTS was to coordinate the work of all the RTCs in England and Wales. But each RTC was still managed and funded by a different RHA. The Director of the new NBTS wanted to establish its structure and committees. It was suggested that these new committees would replace the old RTDs meeting, otherwise there would be more than one committee with a similar remit. In my view, most RTDs supported this recommendation so there was not much need for discussion.

274. I note in document [NHBT0018188] that there were various other meetings which I attended where RTDs met to discuss relevant matters, particularly the care of patients and donors and new clinical and research developments.

275. The advantages and disadvantages would have been discussed, but as I commented in paragraph 242, there was general agreement to the changes.

276. My view of the advantages of dissolving it was that, otherwise, there were going to be too many committees doing the same thing. I imagine that one of the disadvantages might have been

that if an RTD was not on one of the new committees he/she might not feel that they had a voice.

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

277. See my answer to 72 above.

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

278. There were also at least three other forums where RTC directors met:-

i. NBTS management committee
ii. CBLA
iii. Provision of Donors Committee

279. These smaller committees could allow the meetings to be more focused. They were more specialised and discussed fewer subjects in more detail than had been the case with the larger RTDs meeting.

280. There would also be scientific one day meetings where clinical developments and research were presented and discussed and the British Blood Transfusion Society held an annual meeting where attendees would meet to consider scientific papers.

**75. 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 NETRTC.**

281. N/a See my response to Q74 above.

***NBTS/CBLA Liaison Committee***

**76. 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 plasma supply. Please explain your involvement in this Committee. In particular:**

**a. What was the function and remit of this Committee?**

282. I was asked by Dr Gunson to serve on this committee, partly because of NETRTC's relative success in providing large volumes of recovered plasma for production of Factor VIII and other BPL products. Also, I was an enthusiast for the idea of self-sufficiency in manufactured blood products in the UK. Our discussions within the committee mainly focused on plasma and the safety of the manufactured product. We also discussed all products made by BPL, how they could be made in sufficient quantity and rendered safe for transfusion. The subject of heat treatment of products and the methods were considered. The minutes would then be sent to the RTDs as seen in document [NHBT0000077_037].

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

283. Dr Gunson would attend the meeting then he would report to the Department of Health ("DOH"). We did also send information to the other RTD's.

284. The meetings occurred around four times a year.

285. The meetings occurred in person, usually at the BPL offices.

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

286. The committee would have been advisory in the sense that we would all agree what we wanted to do then we would advise the DOH of our recommendations via Dr Gunson, but ultimately any decision would rest with the DOH.

**d. Was the Committee an effective point of discussion and resolution of issues between the two bodies?**

287. Yes, I think it enabled each Regional Transfusion Centre (RTC) and BPL to understand the problems of the other and to plan together how they could be overcome and what was achievable.

**The Inquiry has provided minutes of the meetings of this group which you attended in the below schedule for your assistance.**

***National Directorate of the NBTS Management Committee***

**77. It appears to the Inquiry that you attended the meetings of the National Directorate of the NBTS Management Committee. Please explain your involvement in this Committee. In particular:**

**a. Please explain, as far as you are able, the decision-making remit of the group. Were attendees 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.**

288. Collective decisions were made and recommendations passed to RTDs for comment. Any comments could be referred to Dr Gunson for further discussion and brought back to the committee if necessary. The DOH would need to approve decisions before any changes could be made.

289. The committee's deliberations and the fact that data could now be kept nationally was also very helpful for keeping an overall view on blood stocks. Blood could then be moved around the country to cover shortages.

290. Agreement was achieved on minimum stock levels and the need to monitor national stocks on a daily basis.

*Decision-making process*

291. From memory we used to come to a collective decision. If people did not agree who weren't at the committee meeting, they could make representations to the committee see paragraph 257. The majority of the subjects discussed were not controversial at all.

*How decisions were disseminated.*

292. By minutes and other correspondence – people would be asked to comment, and we would discuss at the next meeting.

293. We did have the power to make collective decisions, but we also sought the opinion of the RTDs. It was very helpful for disseminating information.

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

294. Yes, I do consider these meetings were conducive to fulfilling the purpose(s) for which they were established, because it made things coordinated nationally rather than having RTCs working independently not knowing what was going on.

295. For example, in terms of blood supply it was very successful in helping us manage the stocks.

296. It also enabled some RTCs to become specialised eventually.

297. It meant there was coordination between all RTCs to provide services so there was no surplus of services somewhere and a shortage elsewhere. This enabled us to share blood components.

**The Inquiry has provided minutes of the National Directorate for the NBTS that you attended in the below schedule for your assistance.**

***Eastern Division of Consultants in Blood Transfusion***

**78. The Inquiry understands that you attended meetings of the Eastern Division of Consultants Committee. Please explain your involvement in this Committee. In particular:**

**a. Please explain, as far as you are able, the decision-making remit of the group. Were attendees 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.**

298. Eastern Division meetings were attended by Consultants from North East Thames, North West Thames, South West/South East Thames and Cambridge RTCs. Consultants from other RTCs attended either the Northern or the Western Division meetings. The purpose of these meetings was to allow all Transfusion Consultants an opportunity to discuss and comment on topics and recommendations made by National Committees and raise further subjects for discussion. The minutes of these meetings were passed to Dr Gunson and the contents considered at national meetings. The Eastern Division did not make policy decisions but through their discussions and proposals, the Consultants influenced national policy.

299. Eastern Division Meetings were also useful in exchanging views, ideas and raising local problems with colleagues. Each RTC had particular problems. For instance, NETRTC had difficulties with delivering blood and components in Central London because of heavy traffic. They also had blood shortages as detailed previously. We could discuss these local issues and try to find ways of resolving them. Some of the Consultants worked in hospital transfusion departments as well as at the RTC. These colleagues would attend Eastern Division meetings also and they would be able to advise us of any useful developments in the hospital. Problems within hospital transfusion departments could also be raised.

300. BPL would also attend meetings by invitation to answer technical questions relating to BPL as per document [NHBT0097473_001].

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

301. Yes, see above my response to question 78(a).

**The Inquiry has provided minutes of the meetings of this group which you attended in the below schedule for your assistance.**

**79. At an Eastern Division meeting in June 1991, it was noted that the "general feeling of the Eastern Division members was there seemed to be many committees whose roles sometimes overlapped and some of whom did not seem to have a clear function or to be making much progress", and that members were "frustrated because there seemed to be a lot of business type meetings of NBTS Committees discussing small items, but no major forum where policy decisions are made" (NHBT0097473_001, point 7.9).**

**a. Did you agree there were many committees who did not seem to have a 'clear function'? If so, why did you feel this way? Do you know which committees these were?**

302. I feel the committees I served on did have a clear function and were quite useful. I think there may have been other committees whose function was not quite clear. Perhaps there was insufficient coordination between committees.

303. One of the problems that the NBTS National Directorate had with making and implementing policies nationwide, was that each RTC was still managed and financed by a different RHA. The NBTS National Directorate had to coordinate the work of RTCs by persuasion and discussion.

**b. Which committees were the forums for policy decisions to be made? Did this change over time?**

304. The RTD's meeting used to be a forum for policy decisions to be made and this changed to the NBTS management committee. As per document [NHBT0097473_001] the National Provision of Donors Committee also helped establish and create policies for donors.

**c. Were the concerns noted in the meeting of June 1991 ever raised at a meeting with broader participation in so far as you are aware?**

305. I cannot recall.

***National Provision of Donors Committee***

**80. The Inquiry understands that you attended meetings of the National Provision of Donors Committee. Please explain your involvement in this Committee. In particular:**

**a. What was the function and remit of this Committee?**

306. I was asked to be a member of this committee because of my interest in donor recruitment and retention. I note that in document [NHBT0004016_006] the remit is recorded as follows: -

"*Remit*

*It was agreed that the remit of the Committee would be:*

*1. To consider and advise the National Director on measures to ensure that sufficient donors are recruited and retained to reach and maintain the targets for blood and plasma collection in the most economical manner.*

*2. To devise and advise on National strategies to meet the objectives and to advise on the effective disposition of the central publicity budget.*

*3. To maintain an awareness of Regional initiatives and advise on their co-ordination as appropriate. It was agreed that small teams would be set up to deal with specific matters such as posters, films and leaflets as required.*

*It was emphasised that this committee would be the driving force in all policy matters concerning the provision of donors. The Committee would have the responsibility for the central publicity budget although it would formally be held by the HS division of the D.O.H".*

307. From memory, it mainly related to marketing and donor recruitment and retention.

**b. Who did the Committee report to, how frequently and by what means?**

308. We met once a month and reported to the National Directorate.

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

309. It was advisory. We would have some powers in respect of marketing i.e we would recommend how much was spent on what marketing, but it would still need to be approved by the National Directorate.

310. Once the publicity budget had been agreed, we could then commission companies to design the posters and marketing material. But we still needed authority before we took any action.

311. Crispin Wickenden was commissioned to do some 'market research' to determine which sections of the public would be most likely to volunteer as blood donors. He provided a useful report.

312. My deputy, Dr Boralessa, and I investigated the possibility of extending the upper age limit for blood donation to age 70 from 65 for established donors. We published our results and our recommendations were accepted and implemented by the National Directorate.

**d. Was the Committee able to make decisions that were implemented nationally?**

313. We were able to commission some publicity campaigns, but in general we made recommendations to the National Directorate as described in 80c above. Fortunately, the publicity budget was allocated by DOH so we did not have to rely on funding from Regional Health Authorities (RHAs).

**We have provided minutes of the meetings you attended in the below schedule for your assistance.**

**Section 10: Information handling by and information sharing between RTCs**

**81. Please describe the record keeping system in place for blood donations and blood donors at the time of your directorship of NETRTC. In particular, please explain:**

**a. What records were kept, in what form, where and who had access to them. You may find page 2 of NHBT0092842 of assistance;**

314. Before we had computerization the donor records were kept on cards called 101 cards.

315. The donor records department would have had access to the cards, as would medical staff if dealing with correspondence from donors. The 101 cards were used by the staff when the donors came to a session. 101 cards had information about donor identity and details such as blood group and dates of previous attendances. The microbiology test results were kept in the laboratory and not detailed on the card. If a donor had been withdrawn from the panel, this would be stated on the card. If details on a card were not clear or the donor had been withdrawn or suspended, the session staff would question the donor and could phone medical staff at the RTC if they had any queries.

316. The information from the 101 cards was eventually transferred to the computer. As per document [NHBT0092842], we had an absolute ban on removal of these records from the Centre for the purpose of transfer to the computer and all staff had to sign an undertaking not to disclose facts about individual donors.

**b. How long these records were kept for; and**

317. From memory these records were archived for years so we had the records. I am not sure for how long we kept the donor records after the last donation. Then records were transferred to computer

and later there was a 30-year requirement to keep the records after the donor last gave blood.

318. A serum sample from each donor at each donation was frozen and stored for 3 years.

**c. What policy or practice was adopted by NETRTC in relation to the destruction of these records.**

319. I do not remember. After several years of storage, I assume records would have been disposed of under a policy of non-disclosure – i.e they would have been disposed of confidentially.

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

320. Yes. We had a system of 'blacklisted' donors at one point. This was in relation to donors who had been told not to come but persisted and came to donate. The great majority of these donors were people who insisted on donating more frequently than was safe for their health. The staff at a session where one of these donors normally attended would be informed that particular donors should be deferred. After computerization, the record of any donor who attended would be printed out and the fact that a donor had been withdrawn or was 'blacklisted' would be noted. The donor would then not be bled. On the whole, donors who tested positive in microbiological tests and had been informed and withdrawn from the panel, were very responsible and did not try to donate again as they would not wish to harm anyone. There could be a problem if a donor attended, gave a false name and pretended to be a new donor. I do recall one person who gave a false name in order to give blood more frequently than was safe,

but was identified as they provided their actual date of birth so they were not permitted to donate. We never had a person who was HIV or HCV positive trying to donate again.

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

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

321. We started testing for HIV in 1985 and I was involved in counselling a few donors who were HIV positive, but by 1989 when this database was being maintained, I would not have been involved in counselling donors or reporting or recording the results of positive donors.

322. I cannot recall whether I was aware of it and at what point I would have become aware of this. My colleague, Dr Angela Gorman, dealt with the positive donors and she did that in conjunction with specialists from other RTCs, for instance Dr Pat Hewitt. Dr Gorman was responsible for microbiology and counselling and supporting positive donors at NETRTC. I was not specifically aware that they were reporting to this database, but I am sure that they would have done so.

**b. Who proposed the creation of the database?**

323. I do not feel able to comment on this because I do not know.

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

324. I assume NETRTC did contribute data on HIV positive donors to the database and the staff worked to collect this information and report it as appropriate.

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

325. I assume they did contribute data.

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

326. We would have recorded who was HIV positive. I do not feel able to comment further in light of the reasons discussed in response to 83(a) above. I do not recall there being many positive donors as the steps put in place to stop potentially positive people from giving blood were quite successful.

327. When records were computerised, it would not have been possible to print a donor session slip (the computerised equivalent of the 101 card) in order for someone to donate if they had tested positive for any microbiological test and been withdrawn from the panel.

**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 the existence of this system? If so, please answer the following questions regarding this system, as far as you are able:**

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

328. I do not recall the original system.

329. Mr Peter Howell was the Head Scientist at Manchester RTC and it appears that document [NHBT000538] was sent to everyone in his department. It is not clear whether this was circulated nationally. It may have been a local system.

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

330. Peter Howell in Manchester.

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

331. I think that this was a local system, probably to record the details of donors who had previously been involved as part of the investigation of possible post transfusion jaundice. Other RTCs would have had their own systems of recording such details.

d. **Was the proposal for the re-introduction made to a committee or forum similar to the regional transfusion centre directors' meetings?**

332. I am not able to comment.

e. **What was your view of the proposal for the re-introduction of the system? How was the proposal received by other RTC directors?**

333. I am not able to comment as I do not recall the proposal which appears to have been local to Manchester, as noted above.

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

334. I have suggested the likely purpose of the system in paragraph 298.

**g. Did the NETRTC contribute data to it? If so, what data?**

335. I am not able to comment. I believe NETRTC had its own system.

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

336. I do not know. It may have been introduced at Manchester RTC.

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

337. I am not able to comment.

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

338. I am not able to comment.

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

339. We did share information with other RTCs about excluded donors, donors that posed a risk to the safety of the blood supply, or infected blood donations.

340. Information would have been shared through the Consultants responsible for microbiology at each RTC. The doctors who were responsible for microbiology at the London RTCs would meet regularly and the information would be shared. The meetings would be on a formal basis and the minutes would be noted. The records of excluded donors would be marked. I am not sure how this would operate with the 101 cards but certainly after the records were computerised you would not be able to give blood if you had tested positive or were at risk.

**86. In his statement in *A and Others*, Dr Gunson expressed the view that "there was no central organisation to ensure that...all RTCs operated in a uniform manner" (NHBT0000025_001; 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?**

341. Dr Gunson made a general remark about lack of coordination in the NBTS because, as National Director of the NBTS he had no executive power as each RTC was still managed and funded by an individual RHA. I agree with his general remark, but in the matter of donors who tested positive for transfusion transmissible diseases, the RTCs worked closely together, particularly in London. It would be relatively easy for someone living in London, to attend a donor session run by one of the London RTCs, then attend again at a session run by one of the other London RTCs.

342. When donors were found to test positive in a microbiological test, they were seen and counselled. They were informed that they should not donate blood again. In my experience, donors were extremely cooperative. This is because they are volunteers and they would not wish to harm anyone with their blood donation.

343. The microbiological specialists at each London RTC met together and shared information about donors who tested positive. When 101 cards were in use, there was a 'blacklist' of donors which could be sent out to donor sessions. The session staff would be advised not to accept as a donor, anyone on the list. After computerization, the previous record of any donor who came to the session could be accessed and they would be refused if they had previously tested positive. In fact, once computerisation came in, blacklisted donors would be unable to donate as the computer would not be able to print off their donor record which would enable them to donate. I do not recall any cases of donors testing positive for transmissible diseases who wilfully tried to continue. The 'blacklisted' donors were usually people who insisted on giving blood too frequently.

**87. At a Regional Transfusion Directors meeting in April 1984, the Eastern Division reported that the implementation of "HC/84/7 (Blood Transfusion - Record Keeping and Stock Control Arrangements) would require additional funding" (page 6, CBLA0001836). What were these guidelines and who would they apply to and require? Was additional funding supplied?**

344. These were national guidelines, produced by a committee of experts which would apply to every RTC. Each RTC would be expected to follow these guidelines. I do not recall whether additional funding was supplied.

88. **At an Eastern Division Meeting in September 1992, it was stated that "The Department of Health plus legal advisers should be asked to state quite clearly what records should be kept within the Blood Transfusion Service, how long records should be kept and which should be kept in hard copy or disc. Guidelines on record storage should be made absolutely clear so that every Transfusion Centre stores the same records" (NHBT0016139, page 2). Did the RTCs ever receive guidance on which records to store? As far as you are aware, did each RTC collect the same records or was there some variation?**

345. I recall that we received guidance from the DOH. As far as I am aware, all RTCs would have made every effort to store the records for the same period of time and I imagine they would have collected the same records. One reason why the Eastern Division wanted a clear directive from DOH was because in 1992, each RTC was still managed by a different RHA and if the DOH gave a directive, the RHA would be more likely to provide adequate funding for the storage project.

346. I note that in this document it states: -

"*Members wished to emphasise the view of the Eastern Division as stated at the last meeting. The Department of Health plus legal advisors should be asked to state quite clearly what records should be kept within the Blood Transfusion Service, how long records should be kept and which should be kept in hard copy or on disc. Guidelines on record storage should be made absolutely clear so that every Transfusion Centre stores the same records. It was felt that provision of a storage area for each Centre and provision of facilities for copying records onto microfilm or disc at each Transfusion Centre would not be cost effective. It would be less costly and more efficient if several Centres could use the same facilities for storage and transcription on to disc and central*

*facilities for the whole country in terms of blood transfusion records should be considered and transcription on to disc and central facilities for the whole country in terms of blood transfusion records should be considered".*

347. I don't think that centralization for archiving was ever introduced.

348. Records were archived at individual RTCs in hard copy, on microfilm and later on computer. But even after computerization, session slips (donation records from each donor printed from the computer), were stored in hard copy. These contain the donor's signature confirming consent to donate and be tested as well as confirming that the donor is not in a 'risk' group.

**89. In 1999, a memorandum from E. W. Gascoigne at BPL stated that at Brentwood "details of all product issues were recorded in a log book which was lost or destroyed during the re-organisation within the NBA London and South East zone. She therefore believes that it would be almost impossible for the existing staff at Brentwood to confirm that Southend received a particular batch during the 1980s" (BPLL0016082_024). Please describe:**

349. By 1999 I had transferred to Colindale and I was no longer at Brentwood.

350. Document [BPLL0016082_024] is in relation to someone who had received Anti-D Immunoglobulin and developed some adverse effects. We were not sure at that stage if it related to commercial or BPL product. I argued that the staff at Southend Hospital should be able to confirm whether they purchased Anti-D commercially or from BPL. The record book that was 'lost' would have given details of batches of BPL products issued to hospitals. Southend Hospital should have records of batches of anti-D immunoglobulin issued to each patient. If Southend didn't

use BPL anti-D for this patient it would not have been recorded by the RTC. I suggested to the solicitors that they contact the team at Southend to find out, otherwise it would be impossible to trace the donors.

**a. When were these records lost or destroyed?**

351. I believe this happened during reorganisation when I was no longer Director of NETRTC.

**b. What implications, if any, did this have on look back exercises?**

352. The log book related to the 1980s, which referred to the distribution of BPL products. It would not have contained donor records. It was a record of distribution eg. what batch of Anti-D went to which hospital. The hospital should also have a record of which batch they received so we could trace it that way. We were a wholesaler so there would have been other records held by BPL and the hospital about the batches. I am not sure what, if any, implication the loss of this log book would have had on look back exercises as I was not involved at the time.

**90. In a Medicines Inspectorate report from June 1989 it was stated that "microbiology test results were written onto a Results Sheet described in the Report as "a rather unofficial-looking piece of paper which is not signed" and that "Further improvements, particularly to documentation and record-keeping should be made" at the NETRTC (NHBT0006250, page 7). Did you agree with this conclusion? If so, why? If not, why not? What steps, if any, were taken following this report?**

353. I would agree with the Medicines Inspectorate's conclusion. The RTC was required to write at the conclusion of the inspection to

say what remedial action they were going to take and the timescale.

354. After this report we would have written to advise the Medicines Inspectorate that we were going to implement the recommendations and the timescale. We would then be expected to write again to confirm that those actions had been taken.

**91. The Inquiry understands that you may have been a member of the Working Party on Record Keeping in the Blood Transfusion Service (NHBT0053351). Please explain whether this Working Party was established. If so:**

**a. Why was the Working Party established? What was the function and remit of this Working Party?**

355. I assume its brief was to establish unified systems for record keeping across the blood service so each RTC was keeping the same records and for the same time.

**b.What was the result, if any, of the Working Party?**

356. I cannot recall what the result of the working party was.

**Section 11: Knowledge of risk of infections while at NETRTC**

***HIV/AIDS***

**92. During your time at NETRTC, 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?**

357. As far as possible I kept up-to-date by reading the popular and medical press to acquire knowledge of HIV. I would have read the Lancet, New England Journal, the American Publication, "Transfusion", the journal of virology and specific blood related publications such as "Blood Transfusion" as discussed in response to Q4 above. Often, an article would be referred to me by a colleague and I might pick up on a reference from other articles.

358. As soon as I realised that infections could be transmitted by blood-to- blood contact, I became aware that this would have serious consequences for the blood transfusion service. It became apparent that some people were more at risk of acquiring and transmitting infection through donated blood than others and we immediately took steps to prevent these people from giving blood by giving out leaflets and information.

359. Issues relating to HIV were discussed at RTC meetings and all relevant meetings throughout the blood transfusion service.

360. Consultants in Transfusion Medicine received training from a team from St Mary's Hospital, Paddington about counselling donors who had tested positive for HIV.

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

361. I cannot recall the exact time I became aware that there might be association between HIV/AIDS and the use of blood and blood products. It would have been at the same time when I learned that HIV was transmitted by blood-to-blood contact.

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

362. Investigation and enquiries regarding the risks of transmission and tests would have been carried out nationally. It would not have been for individual RTC's to investigate this. As risk groups were identified by experts in the field, RTCs were informed. A list of groups of people who should be told that they should not donate blood, was drawn up nationally. I do not recall having any involvement in investigating the risk of transmission, but we did have a role in investigating when there had been a transmission and the RTC Consultants had been trained to provide initial counselling of donors who tested positive. There would have been a national microbiology committee to investigate the various tests which were most appropriate for blood donors.

363. It was also our responsibility to deter high risk donors from donating. We did have our own leaflets detailing the list of risk groups agreed nationally which were updated every 6 months and aimed at deterring high-risk donors. At NETRTC the appearance of the leaflet was changed every 6 months to encourage donors to read it each time they came in.

364. We would have collated the information about donors who had tested positive. We asked them about any risk factors and why they had come to donate. This would be used to assist us in deterring high risk donors from donating in the future, since occasionally someone in an "at risk" group donated blood because they did not understand the leaflet. This would prompt us to review the wording to make things clearer.

365. For example, a case that was reported to me was of a regular donor who came from Southern Africa. She had tested negative

for HIV when she previously donated, but then became positive. It transpired that her husband who had been living in Africa and then had come to live in the UK was HIV positive and that is how she had contracted HIV. Details of this case were reported nationally and fed back to the DOH and shared with other RTCs. This led to a change in national policy from "you can't donate if you have had a sexual relationship in sub-Saharan Africa" to "you can't donate if you have had a sexual relationship in sub-Saharan Africa or a sexual relationship with someone who has been in sub-Saharan Africa and may have been sexually active there. .

***Hepatitis***

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

366. When I first joined the blood service the risk of transmitted Hepatitis B was understood but it was known that there was another type of Hepatitis which could be transmitted by blood. This was not Hepatitis A which is not normally transmitted by blood. This was also not Hepatitis B as we had adequate tests for that.

367. One way we tried to deter donors who might have NANB Hepatitis was to exclude people who had ever had Jaundice. Also, we considered that NANB might be a variant of Hepatitis B, so we investigated more detailed testing of donors' blood to see if they had some positive markers for Hepatitis B other than the surface antigen (which is the normal marker for which we tested).

368. These tests proved not to be very useful as some donors who were found to have transmitted Hepatitis to a patient did not have any markers of Hepatitis B.

369. That is what I understood at the time. My knowledge developed over time as I eventually understood that excluding people who had jaundice was not very effective in preventing the transmission of NANB Hepatitis. I also came to understand that people who were transmitting Hepatitis B tested positive in at least one of several tests available, but people who had NANB did not test positive in any of the tests available for Hepatitis B. Another test that was considered nationally was a test for a raised liver enzyme (ALT) in the blood. It was eventually decided that this test was not sufficiently specific as several conditions apart from Hepatitis can cause the ALT to be raised.

370. I cannot remember the date, but I recall hearing the important news that antibodies to Hepatitis C had been identified. The researchers did not identify the virus itself, but this was a huge development. I was working with Professor Zuckerman at the time, and I recall he provided me with relevant articles from virology journals. At first it was not certain that people who had Hepatitis C antibodies were still infected with the virus or had been infected and were now immune.

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

371. As part of my training as a haematologist I became aware of the association between Hepatitis B and the use of blood, blood components and blood products.

372. I was aware of this association before I joined the blood service in 1980. I was also aware of the association between NANB/Hepatitis C and the use of blood, blood components and blood products but until the Hepatitis C antibody was identified and a test developed, we could not identify the carriers of this virus.

373. As soon as the antibodies were identified, I became aware that it was NANB/Hepatitis C.

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

374. Enquiries and/or investigations about the risk of transmission would have been carried out nationally. The microbiology team at NETRTC was involved in assessing the tests to look for antibodies to Hepatitis C. This would have been a difficult process due to the time constraints for suitable rapid screening tests and the importance of having tests that were both sensitive and specific. A test is only suitable for use for screening blood donations if there is only a sufficiently small percentage of false negative and false positive tests.

**98. 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?**

375. See my response to question 95 for my understanding regarding the nature of transmission of blood borne Hepatitis viruses.

*Hepatitis A*

376. Hepatitis A is transmitted primarily by the oral/faecal route and is not blood borne. It causes acute Hepatitis and there is no carrier status. That means that after you have recovered from Hepatitis A you do not have carrier status. You cannot transmit the virus to other people through blood transfusion.

*Hepatitis B*

377. Hepatitis B is transmitted by blood-to-blood contact and is highly infectious. A proportion of people who recover from Hepatitis B develop a carrier status. This means that although they are apparently well, they can transmit Hepatitis B to others by blood-to-blood contact. In addition, people who are carriers of Hepatitis B may develop severe liver disease including liver cancer in the long term.

*Hepatitis C*

378. Hepatitis C can be transmitted by blood-to-blood contact particularly from the use of needles (unsterile needles), e.g. in people who are recreational drug users. As far as I am aware, we still do not know all the ways in which Hepatitis C can be transmitted. Hepatitis C has a carrier status and people with antibodies can infect others by blood-to-blood contact. Only a small percentage (about 20-25%) of people with Hepatitis C become unwell at first. They may have jaundice, feel unwell, have pale stools etc. When Hepatitis C antibody was first identified the severity of the disease was not really understood and there was no treatment available. It is now known that the carriers of Hepatitis C can go on to develop severe liver disease including cancer.

379. Treatment for carriers of Hepatitis C has become available since the time that I was director of the RTC at Brentwood.

380. Whilst I was at Brentwood it was not known that people with Hepatitis C antibodies could go on to develop severe liver disease and there were no treatment options. The antibodies had been discovered but the virus had not been identified.

**99. In a scientific paper dated October 1986, Dr Gunson stated that the best estimate of the incidence of transfusion-associated NANB Hepatitis in the UK from published data at the time was 3% (SBTS0001120). He further noted that 'if one assumes that the 2.3 million donations in the U.K are transfused to 750,000 recipients annually...then one would expect 22,5000 icteric or anicteric cases of NANB Hepatitis each year.' Please answer the following questions:**

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

381. I was aware of the paper and the findings. I recall that Dr Gunson may have informed us at a committee meeting. I have certainly read the paper and considered its findings.

**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.**

382. The prevalence of NANB was discussed by RTC directors and consideration was given to whether surrogate testing of donations using ALT or anti-HBc would be useful.

383. Eventually it was decided that these surrogate markers would not be useful in identifying the majority of NANB cases.

384. Dr Gunson's initial figures were probably thought to be high as people who were at risk of HIV were later excluded. This is because people who had used recreational drugs were then excluded from donating and they were at high risk of carrying NANB Hepatitis. If people who had used IV drugs were self-excluding, then that took a significant number who were likely to be Hepatitis C antibody positive out of the pool. In addition, Dr Gunson's statistics assume that each patient had one transfusion of 3 units of blood. But in practice many patients such as those with cancer, leukemia, thalassemia, sickle cell disease or following road accidents, would have several transfusions per annum, so the number of people potentially infected with Hepatitis C through transfusion would be considerably fewer than Dr Gunson predicted. This is not to deny the potential seriousness of Hepatitis C transmission.

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

385. Please see my response to question 98 and question 99. A more accurate idea of the prevalence of Hepatitis C in the donor population, (although people who had used IV recreational drugs were excluded), was gained when screening of donor blood was first introduced in 1992.

**101. In June 1989, Alan Kitchen wrote to you about the Ortho Diagnostics HCV test and proposed "that as soon as the test is available, we test all our stored jaundice enquiry samples to provide some basic information on the incidence of anti HCV in a population of healthy donors implicated in cases of NANB Hepatitis" (NHBT0000187_086). Did this study go ahead? If so, what did this reveal about the incidence of anti-HCV?**

386. I cannot recall whether this went ahead. I cannot see why it would not have gone ahead as it was an important study and was a very good suggestion.

**102. In July 1991, you wrote to Professor Allain to question his study on the recipients of blood products. In particular, you state that "we will know whether donors are anti-HCV positive or not before the patients receive their transfusions" (NHBT0000075_007). Please explain your objections to the study, what the study was intended to find out, and whether the study went ahead. You may find NHBT0000075_004 of assistance.**

387. I cannot recall the study. I cannot comment further about the study without seeing the proposal or protocol for the study.

**103. What role, if any, did you play in educating general practitioners and dentists about the risk of Hepatitis transmission and how it could be prevented? You may find NHBT0016533 of assistance.**

388. I did not play a particular role in educating GPs and dentists about the risk of Hepatitis transmission and how it can be prevented.

389. However, it seems I drafted a letter to dentists [NHBT0016533] which provided information regarding Hepatitis and the risk of transmission. It is quite possible that I would have given this letter to donors to give to their dentist. I do not anticipate I would have written to individual dentists.

390. I would not have had contact with the GPs – this may have been the role of Dr Gorman who was responsible for arranging the counselling of donors. Often, donors who tested positive for Hepatitis C antibody, were referred to hospital but from memory,

at first, the Hepatitis C positive donors may have just been referred to their GP.

***General***

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

391. We made a determined effort to deter all potential donors who were at risk of transmitting HIV or Hepatitis C.

392. This was done by sending out leaflets listing the at-risk groups. These at risk groups were agreed nationally.

393. At Brentwood we made our own HIV leaflets and updated the leaflets every 6 months, so donors never received the same leaflet twice. We made it look different, had different titles, colours etc. This was only until such time as there was a national leaflet.

394. These leaflets were also at the donor sessions and our staff were trained on how to counsel donors who had queries about any information in the leaflet.

395. We did follow the national guidance on who were the "at risk" groups. There were national policies which were agreed and changed over the course of time. When the national leaflet was introduced, we would use that.

396. We would make sure all potential donors had read the leaflet before they donated and would invite them to ask any questions.

397. After the national leaflets were introduced, we would use them. At NETRTC, we believed that all RTCs should follow national policies.

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

398. We followed national guidance and structures and policies discussed above.

**106. What if any role did NETRTC 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.**

399. All the hospitals were encouraged to report any adverse effects of blood transfusion including red cell reactions or development of any infection that might be transmitted by blood or blood components. The RTC would then investigate the donations/donors involved.

400. They were also advised that if we rang them and reported a problem with a donation that they should identify any blood or components that they had received, whether these components had been transfused and which patients had received the blood or components. The unused components should be returned to the RTC for investigation and disposal and also the empty bags after transfusion if available. The hospital staff would be responsible for investigating, counselling and treating any patient who had potentially received infected blood or a component. The hospital and the RTC would report their findings to each other and the RTC would report the results nationally. Any adverse reactions to BPL blood products would be reported directly to

BPL by the Haemophilia Directors or other users. If BPL wanted an investigation to be performed to identify and test donors whose plasma had been part of a pool processed to make a BPL product, the relevant RTCs would be contacted by BPL.

401. Hospital staff were educated in this regard and we ran courses for Haematology Senior Registrars (SRs). It was compulsory for Haematology SRs to undergo training by the blood service as part of their training for the MRCPath qualification. We also ran a revision course for SRs for a week prior to their examinations and SRs attended from all over the country. Laboratory and Nursing staff also attended training courses as part of their education in Transfusion.

402. I also wrote to all the hospitals about how important it was to have enough plasma to supply to BPL and how we hoped they would cooperate and would use red cells in SAGM rather than whole blood as discussed in my response to question 37(a).

403. The hospitals would also be told when we were going to start testing.

**Section 12: Reduction of risk of infections while at NETRTC**

***Donor selection***

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

**a. AIDS/HIV;**

404. Please see my response in relation to question 104.

**b. NANB/HCV; and**

405. For Hepatitis C, once the antibody was identified and the antibody testing commenced there was a nationally agreed leaflet listing at risk groups and explaining to donors about HCV. We used these at the donor sessions and the staff were trained to answer questions.

**c. HBV?**

406. Testing for carrier status for HBV was introduced in the 1970s. So, policies and processes were in place prior to my tenure at NETRTC. The risk groups for blood-to-blood contact were well known. I do not recall the process changing during my tenure but the "at risk" groups for Hepatitis B tended to be the same 'at risk' groups for HCV and HIV. For instance, recreational intravenous drug users were considered 'at risk' groups for all three viruses (HIV, HBV and HCV).

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

407. These decisions were made nationally. I would have been present at meetings when the 'at risk' groups were identified. The experts in microbiology would say what they considered to be the "at risk" groups and we would discuss cases of donors testing positive and examine the risk factors. The experts in microbiology would collect the data and provide it to everyone else.

**109. Were there any difficulties in implementing the exclusion of high-risk donors at NETRTC?**

408. Not that I can recall. I would say that in my experience donors are very responsible and if they realised they were in a risk group they would refrain from donating because they would not wish to cause harm. Some donors would contact us to ask about the reason for the choice of the risk groups and we could provide the statistics and explain why some groups were considered to be "at risk".

409. Regular discussion took place about the various "at risk" groups as discussed per document [NHBT0097469_014] which has been provided to me by the Inquiry. This discusses the risks "With respect to ear piercing, acupuncture, electrolysis". The WHO recommendation includes "unless these are performed under sterile conditions".

**110. 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 NHBT0039762_088, BMAL0000024, NHBT0020668, paragraph 3.1 of NHBT0097469_014, and item 4.4 of NHBT0046958_002 of assistance.**

410. I have discussed the production of leaflets in my response to question 104 above.

411. I note in document [NHBT0039762_088] which has been provided by the inquiry it states: "*New yellow AIDS information leaflets have been issued by the DHSS. The Minister of Health has stated that a leaflet must be given to each potential donor to read before he or she gives blood, so that donor has an opportunity to decide not to donate if he/she is in one of the "high risk" groups. The Brentwood Transfusion Centre will, from March 1985 onwards, be sending out the leaflets to each donor with the "call up". Until that time however, driver/clerks at our donor sessions should hand an AIDS leaflet to each donor as he/she*

*registers. After March 1985, the driver/clerks should hand a leaflet to each new or "walk in" donor at registration. When the leaflet is handed to the donor, he/she should be told that it is most important to read the new leaflet".*

412. I note in document [BMAL0000024] it states: "*All donors called to sessions are sent, with the card of invitation, a copy of the enclosed letter and the Departments AIDS leaflet (attached). Donors presenting at sessions are provided with a copy of the letter and leaflet to read before they are registered. All donors and nurses who manage donor sessions in North East Thames BTS have been trained to deal with questions about AIDS, and donors who wish to ask questions on this subject are referred to them. If the Medical Officer or Nurse Manager is unable to answer a question put by a donor, they are able to contact one of the consultants at the Regional Transfusion Centre (RTC) by telephone. A consultant haematologist is on call 24 hours a day and 7 days a week at the Centre. There is a policy that if any doubt exists about the donor being in an 'at risk' group, the donor is not bled but referred to the RTC for advice. Donors who seek advice are encouraged to contact the consultant on duty at the RTC by telephone or to write. It has been found that many donors have telephoned for advice. Dr Jean Harrison believes that donors prefer to take this course rather than to ask for advice at donor sessions, where there may be little opportunity for any privacy for discussion*".

413. At NETRTC we were one of the RTCs that were sending out the leaflet with the call up card and giving them out at donation sessions – I think it was important to send them out because then people have the time to read the leaflet and so not turn up to give blood at all. Also, it provided them with an opportunity to call the RTC and ask any questions.

414. I note in document [NHBT0046958_002] there is discussion regarding a questionnaire. Eventually there was a nationally agreed questionnaire which had a slip for signature. We initially relied on donors reading the leaflets and staff answering questions but later a questionnaire was devised. With any leaflet there is a list of "at risk" groups. Donors had to read and sign on the questionnaire that they had read the leaflet and questionnaire and they were not at risk. I cannot recall when this was brought in.

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

415. Initially at NETRTC we updated our own leaflets every 6 months. We also updated the information when we received notification from the DOH. I cannot recall how often the DOH updated their advice, but they would notify us if there was a new "at risk" group for instance.

416. Prior to the issue of a national leaflet, the content of our leaflets would be formulated by using national guidance from the DOH and with information from national meetings and input from the RTCs meeting.

417. After the national leaflet was agreed and issued, we used it to send to NETRTC donors and to give it to donors at the sessions.

**112. In July 1986, you wrote to Dr Ian Fraser about the new AIDS leaflet (DHSC0002331_018). How much input did the RTDs have in the contents of this leaflet? Was the leaflet amended after you raised these concerns? You may find NHBT0097469_021 of assistance.**

418. The contents would be discussed at the divisional and RTD meetings as well as national meetings.

419. I note that [DHSC0002331_018] suggests that we were sent the leaflets in advance of them being finalised. In this document I state that, "*I realise that this leaflet will be discussed both at our divisional meetings and at the forthcoming RTD 's meeting on 9th July*".

420. There was a lot of discussion about the contents of the leaflet at the RTD meeting and there may also be discussion after the meetings as indicated in documents [DHSC0002331_018] and [NHBT0097469_021].

421. I do not recall whether the leaflet was amended after I raised concerns. I would not have the final say on the contents but all RTDs had plenty of opportunity to express their views and be involved in the discussion.

422. From memory, my concern that was raised in document [DHSC0002331_018] regarding shortening the period that people had been in sub-Saharan Africa, did result in the at-risk group being changed.

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

423. People were encouraged to ask questions after receiving the leaflet and donor sessions and could call the RTC if they were at all concerned. Information would be provided in response to any questions posed.

424. The person who provided the donor with the leaflet at the donor session would ask the donor to read the leaflet and ask the nurse if they had any questions about its contents.

425. Later on, a questionnaire would also be provided.

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

426. It is difficult to know for certain, but the minimal number of positive tests would suggest that they were an effective deterrent to at risk groups.

427. I do recall that people were asking questions about the leaflets and raising this when they received the leaflet in the post by phoning the RTC or asking questions when they arrived at the donor sessions.

**115. In July 1986, you authored a memorandum which stated "donor sessions are often very public places and it is inappropriate to question people about sexual practices unless the donor specifically asks a question about sexual practices" (NHBT0039762_136). Please explain your view. Has your view changed over time? Was this always the practice at NETRTC during your tenure?**

428. Sessions are very public places and quite often there would not be enough room for there to be a space in a session for it to be completely private. The donors had an opportunity to call the RTC and ask about the leaflet when they received it at home. Members of the public who were not donors were also welcome to phone the RTC to ask questions and many people did this. At the donor session the staff would go through the leaflet with the donor and make sure they had understood the questions.

429. Staff would go through the leaflet with the donor. Staff were instructed to ask the donors "have you read this question? Are you in this group?" that way they did not have to ask them openly.

430. The donor would then be expected to complete a health questionnaire. Next, they are questioned by a donor attendant about their health including whether they have gone through the leaflet and they are asked to confirm whether they are in an "at risk group". From memory, they had to sign on the 101 card to confirm that they were not "at risk".

431. Aside from that, I did not think it was appropriate to question people about sexual practices unless they specifically asked the staff about such practices. The sexual relationships which meant that a volunteer would be in a "risk group" were clearly described in the leaflet.

432. I am not sure it would have been feasible to have a private booth at most donor sessions.

433. We did our best to stop people who were at risk from coming in the first place.

**116. Please refer to PRSE0002062 (points 4d and 7) and CBLA0001937. These documents relate to discussions surrounding donor leaflets and screening which you appear to have been party to. It is apparent from these documents that RTD's felt some frustration, "there being as yet no new leaflet, no finance, and no positive move towards full donor screening."**

**a What were your thoughts on these issues, and why? Did you share the frustration of the other RTD's?**

434. I did share the frustrations regarding the delay in providing the leaflet, but we did continue to use our own until the national one was available.

435. I did not find the testing was frustrating because I understood the reasons why it was important to select an effective screening test which could be used for blood donations and had a sufficiently small number of false positives and false negatives. Until such a test was available, screening tests could not commence.

436. When the screening test was available, it was vital that all RTCs started testing on the same date. Also, as stated in the document [PRSE0002062], a screening test must be freely available outside the national blood service otherwise people might use the blood service to test their blood for HIV: "*The meeting felt strongly that we should not be pressurised by commercial sources to accept a test which is not ideal for our purposes and that we should act together. The DHSS should be pressed to make any test available to the community before its use in blood donor screening, otherwise unsuitable donors will be attracted*".

**b. What reasons were given for the delay in implementing the new leaflet?**

437. I cannot recall the reasons for the delay, nor can I ascertain this from the documents provided.

**c. How did the issues mentioned impact on blood collection at NETRTC, if at all?**

438. I am not sure if the delay in leaflets had an impact on blood collection at NETRTC as we continued to use our own leaflets until the national one became available.

*Introduction of virally inactivated products*

**117. What role did you consider NETRTC had (or should have had) in pushing for factor concentrates to be virally inactivated in the late 1970s and early 1980s? In particular, was the need for safe products raised by you or anyone else at NETRTC with BPL and/or pharmaceutical companies (or anyone else) during this period? If so, please give details. If not, why not?**

439. I joined NETRTC in 1980 so do not feel able to comment about the late 1970s.

440. I cannot recall if there was discussion about safe products being raised with BPL in the early 1980s.

**118. In December 1984, B. T. Colvin wrote to you to state that "at your request I am writing to confirm I am willing to continue to use non heat-treated NHS concentrate for the time being" (BART0000519). Why did you make this request? Please provide details of the introduction of virally inactivated products, and how it was decided who they should be given to.**

441. In document [BART0000519] which has been provided to me by the inquiry, Dr Colvin was confirming a decision which was made at the Regional Haemophilia Directors meeting to the effect that that the attendees preferred to use non heat-treated NHS product rather than commercial product. This was not a request made specifically by me. I may have requested that he confirm what had been decided in writing.

442. Some Haemophilia Directors were using non heat-treated products. They would rather use NHS product un-heat treated than risk using commercial product which had been heat treated.

443. I understand that heat treatment was introduced in December 1984. In 1984 some trial batches of heat-treated material were produced and the Haemophilia Directors were responsible for deciding which patients should receive this material. This would have been outside my area of responsibility. I understand that from about August 1985, all BPL Factor VIII concentrate was heat treated.

**119. In January 1985 in a letter from Mr Knight, it was stated that the district was going to be "faced with having to obtain all its supplies commercially for the time being", as the Blood Transfusion Service was unable to supply heat-treated factor VIII (BART0000525_002). What, in your view, were the obstacles in introducing heat treated concentrate?**

444. Despite what the author of the letter in document [BART0000525_002] says, the Haemophilia Directors in the region had discussed this and agreed it that it would be better to use NHS untreated than use commercial product that was heat treated.

445. In January 1985 I note that there was insufficient heat-treated Factor VIII from BPL to meet demand as per the document [BART0000525_002].

446. I was not responsible for heat treating Factor VIII concentrate. I understand that in order to introduce heat treatment, a process has to be developed which, whilst reducing the virus load and infectivity, preserves as much of the Factor VIII as possible as the process reduces the yield of Factor VIII.

**120. Could heat-treated factor VIII have been introduced sooner?**

447. I do not feel able to comment on this. I was aware that staff at BPL were working on introducing it for some time.

**121. Please refer to the 1989 report of the WHO Collaborating Centre for Reference and Research on Viral Hepatitis (DHSC0003583_073, page 9-10). This report mentions your involvement in a collaborative investigation into "the effect of gamma irradiation on HIV and a range of other viruses on plasma coagulation factors." Please explain:**

**a. Whether further studies on gamma irradiation were conducted with particular focus on the effects of irradiation on plasma components and the formation of breakdown products;**

448. The research mentioned was reported in a paper entitled 'Effect of Gamma Irradiation on the Human Immunodeficiency Virus and Human Coagulation Proteins' and published in Vox Sang. 1989, 56: 223-229. In this report we concluded that '*gamma irradiation is a clean, safe, simple procedure which can be applied to human plasma to inactivate effectively a range of infectious agents, while apparently causing minimal deleterious effects on plasma proteins'.* We did suggest that further, more detailed studies of the effect on plasma proteins should be performed, but I am not aware that any further studies were done.

**b. Whether, to your knowledge, gamma irradiation was considered for use in BPL, PFL, and PFC as a means of treating FFP and cryoprecipitate during the 1980s?**

449. Our paper was published in 1989 and stated that gamma irradiation may '*provide a means of assuring the safety of as yet untreated products such as cryoprecipitate and fresh frozen plasma.*' As far as I know, this method was not considered for the

treatment of cryoprecipitate, fresh frozen plasma for clinical use, or frozen plasma prior to fractionation. I do not know why.

**c. Whether you were involved in any other research on methods of virally inactivating viruses from the blood supply.**

450. Not that I recall. I did always try to look for innovative ways to improve the way we did things, and this included any possible means of virally inactivating viruses from the blood supply. I was disappointed that the method of inactivation using gamma irradiation was not followed up.

***Provision of diagnostic screening kits***

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

451. There was a group of people looking at diagnostic testing kits including John Barbara, Patricia Hewitt and my head microbiologist Alan Kitchen. They would assess the test kits and report back to the National Blood Service. I took advice from them and Alan Kitchen. We would discuss the matter at RTD meetings prior to 1989. Later on, we had a KIT evaluation advisory group. They would always report to the National Committee. We were advised nationally which test kits to use. It would be agreed that we would implement testing on a certain date.

**123. Did you, or anyone else at NETRTC, contract directly with any pharmaceutical company involved in the manufacture and/or sale of screening kits, or were contracts negotiated on a national basis? You may find NHBT0000188_043 of assistance.**

452. Companies would first be invited by the national service to provide kits for assessment. When kits had been evaluated and the most suitable selected, negotiations for the purchase of kits would be done nationally and not by individual RTCs.

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

453. There were various important factors, for example:

i) How accurate the test kits were;

ii) How many false positives and negatives there were - we had to have a screening test which did not have too many false negatives or false positives.

iii) Results had to be available very quickly after testing since results must be available rapidly to allow for the issue of blood and components. particularly platelets which had a 5 day shelf life.

iv) The tests also had to be easy to use for mass screening (10,000 donations of blood were collected daily).

v) A more specific confirmatory test was also needed which can be used for donors that initially test positive.

vi) It is likely that more than one screening kit and more than one confirmatory kit would be selected in case of failure of supply.

**125. 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?**

454. I do not know what influence pharmaceutical companies retained after supplying screening kits to the UK or whether pharmaceutical companies provided advice on the implementation or use of the screening kits. I was not responsible for the implementation of the use of the screening kit. This would have been the responsibility of our microbiologist.

*Introduction of HIV testing*

**126. The Inquiry understands that HIV screening was to commence on 14 October 1985. Did NETRTC commence screening on this date? What steps were taken to ensure that NETRTC could begin screening on this date?**

455. Yes, NETRTC commenced screening on this date. To ensure that NETRTC could begin screening on this date, we made sure that staff were appropriately trained and that all the kits were available. Alan Kitchen had been working with John Barbara in relation to the kits and deciding on the most suitable test for use and most effective. We conformed to the national position as set out by Dr Gunson. I assume that if it was possible, we would have back tested.

**127. Please describe the implementation of HIV screening at NETRTC. In particular:**

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

456. I do not recall specifically but as far as I am aware, we conformed to the national agreement about what screening kit to use and how to screen donors.

457. I recall that people who had donated blood before were sent notification that HIV testing was to start, with their 'call up' letter. All donors were informed at the donor session that their blood would be tested. When they signed their form to consent to giving blood, they would also agree to having an HIV test and they gave consent to that as well as confirming that they were not in an 'at risk' group.

458. A sample would be taken from each donor and an additional HIV test would be done. Then there was confirmatory testing which would be done if a donor tested positive.

**b. What happened to all the unscreened blood that had been collected prior to HIV screening being implemented? You may find page 2 of DHSC0002365_002 of assistance.**

459. I assume that if it was possible, we would have back tested as agreed and referred to in document [DHSC0002365_002]. NETRTC kept samples of all donations in an archive for a period of time and therefore it would be possible to back test all the donations and blood in stock.

460. I am sure any fresh blood in stock would have been tested from the samples. Blood samples for frozen blood could be tested before such blood was issued for use. I cannot recall the position in relation to blood that had already been issued to hospital and not yet used.

461. Any blood or blood components issued from 14 October 1985 would have been tested for HIV.

**c. 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.**

462. When a donation was found to be infected with HIV, the donor was initially counselled by an NBTS consultant and a trained counsellor from their local hospital. NBTS consultants were

trained in HIV counselling by a team from St Mary's Hospital, Paddington.

463. The NBTS consultants were involved in their counselling initially and it was not long before there were specific HIV counsellors in hospitals.

464. The donor was initially contacted by letter. The letter would not advise them of the fact they had tested positive, but it would invite them in to discuss a problem.

465. We did not inform third parties, just the donor. At the counselling session, the donor was advised to tell any sexual partner. We would also advise them to tell their GP and dentist, but donors could not be forced to do this.

466. When counselling the few donors who had tested HIV positive, we tried to ascertain what their risk factor had been and whether the occasion when the donor had become infected could be determined. I only ever recall going through this process with new donors not repeat donors. We did take steps to try and investigate the risk factor when a donor tested positive. I recall one donor where we never discovered what his risk factor was. Donors would be referred to a local hospital for advice and treatment.

467. The donors I recall counselling were first time donors but if they had previously donated, we would have investigated the cause for the infection and tested previous donation samples. If it was discovered that other previous donations tested positive, then we would contact the hospitals to which the previous donations and components had been issued, so that the recipients of the donations could be advised, tested and counselled. However, I cannot personally recall seeing any positive donor who was not a first-time donor.

**d. What impact did the introduction of HIV screening have on NETRTC, including but not limited to the financial impact of screening, the impact on those working at NETRTC, and the impact on the risk of transmission of HIV through blood donations?**

468. I cannot recall how the finances worked but I am sure we would have had some funding from the RHA as HIV testing was a priority.

469. The introduction of training for HIV testing gave staff a degree of confidence that HIV would not be transmitted by blood transfusion, as donors testing HIV positive would be barred from giving further donations and the index donation would be destroyed. All staff handling blood were trained to treat every sample as though it was positive for a transfusion transmitted infection, so avoiding the risk that staff might be accidentally infected. No staff member was infected during the time when I worked at NETRTC.

470. Since testing started in 1985, I am only aware of 2 cases of HIV transmission in the UK through blood donations. Therefore, the impact of testing must have greatly reduced the risk of HIV transmission through transfusion.

471. However, it is worth noting that the donor self-exclusion had been very efficient so very few donors were actually found to be positive. I do think that, in general, donors were responsible and did not wish to harm others by donating their blood if they thought they were at risk. Our system of blood donation exclusively by volunteers means that donors give their blood entirely to help and certainly not to risk harming others.

**128. In March 1985, you and many other Regional Transfusion Directors ("RTDs") wrote to the Lancet to state that you strongly supported HTLV-III antibody testing but "would advise that this is delayed until test systems have been appropriately evaluated and efforts have been made to give all members of the public access to HTLV-III antibody testing" (PRSE0004824, page 2). Why did you take this view? Have your views changed over time? Were your concerns allayed by the time HIV testing was introduced?**

472. The reason I took this view together with many of my colleagues was because we did not wish for people to come and give blood in order to have an HIV test. If this happened, the blood supply might be adversely affected. It was vital that HIV testing was made available in the community before we started testing. My views have not changed over time.

473. I believe that the NHS listened to this advice because HIV testing was made available in the community prior to the commencement of testing by the Blood Service. In addition, the fact that free testing was available in the community, was advertised by the NHS together with information about HIV.

**129. In March 1991, Dr A. Gorman wrote to Dr Gunson to confirm whether anti-HIV positive donors could be readmitted. He states that "the recommendation is that six months after the original donation if both the RTC and Reference Laboratory tests are negative, then the donor's blood can be used at the next - or third - attempt. Now that we have the final recommendations, we realise that we had not in fact been following these" (NHBT0009201). Did the NETRTC begin sending the donations to the Reference Laboratory for testing? If not, why not? Do you know why Professor Zuckerman thought you could rely on the in-house screening tests only?**

474. Dr Gorman wrote to Dr Gunson to ask about readmission of donors who had a screening test positive and confirmatory test negative. We at NETRTC, on the advice of Professor Zuckerman had been re-testing the donors six months after the initial positive tests and re-admitting them if both the screening test and confirmatory test was negative.

475. As far as I was aware, other RTCs had been following the same procedure.

476. Dr Gunson recommended that, in addition, a sample should be sent to a reference laboratory for a further confirmatory test after we had done a confirmatory test 6 months later. I cannot recall if we ever did do this.

477. I note in document [NHBT0009201] it states "If our second test was negative at the RTC, we had not been sending them to the Reference Centre for confirmation. Professor Zuckerman was with us on the particular day on which we were discussing this matter and gave us his opinion that we could rely on the RTC screening test without referral". Professor Zuckerman was an expert, so it appears we relied on his advice.

478. In paragraph two, the recommendation is that six months after the original donation if both the RTC and the Reference Laboratory tests are negative, then the donor's blood can be used at the next - or third - attempt. When we received Dr Gunson's final recommendations, we realised that we had not in fact been following these.

***Surrogate testing***

**130. Whilst you were employed at NETRTC, what was your opinion of surrogate testing as a potential method of donor screening, and how**

**did this change over time? Please comment on each infection with reference to specific surrogate tests:**

**a. HIV; and**

479. I cannot recall if there was a surrogate test for HIV.

480. Before HIV testing was available, there was a time when it was understood that a lot of people who had HIV had the same risk factors as those who were carriers of Hepatitis B and NANB.

481. We were already testing for syphilis before we were able to test for Hepatitis B. When I first joined the service, there was some discussion about whether we should stop testing for syphilis as it is rarely transmitted by blood, but we realised that it could be used as a surrogate test for Hepatitis B and then HIV. So, we continued syphilis testing.

**b. NANB/HCV.**

482. Before Hepatitis C had been identified we used exclusion of people who had ever had jaundice as a type of surrogate testing. Then it was suggested that ALT (a liver enzyme) testing could be used as a surrogate and finally it was suggested that a different test for Hepatitis B - core antibody test - could be used as a surrogate for NANB.

483. I believe that investigation of ALT and core antibody testing showed that these were too nonspecific to identify NANB Hepatitis.

**131. A report prepared by Dr Gunson in August 1987 set out the conclusions of a Working Group established by the Council of Europe Committee of Experts on Blood Transfusion and**

**Immunohematology to consider the introduction of routine surrogate testing for NANB ('the Working Group report') (NHBT0008816_002). The Working Group concluded it could not provide a recommendation on the introduction of surrogate testing in light of the following considerations:**

**a. the use of surrogate tests to reduce the incidence of transfusion associated non-A non-B Hepatitis (NANB) and its possible value as a public health measure remained controversial;**
**b. there was no guarantee, in a given country, that there would be a significant reduction of NANB;**
**c. the introduction of surrogate testing in some countries could lead to a severe depletion of donors which could compromise the blood supply; and**
**d. if surrogate testing was introduced, provision would have to be made for interviewing, counselling, medical examination and treatment of anti-HBc positive donors and donors with raised ALT.**

**Please advise whether you were aware of the Working Group's report. If you were, did you agree with the conclusions reached by the Working Group? If not, why not?**

484. I was aware of the working party and I agree with the conclusions.

**132. The Working Group's report from 1987 commented: "If a stance is taken that blood should have maximum safety then the tests would be introduced" (NHBT0008816_002). Please explain your views on this statement. In your view, did the decision not to introduce routine surrogate testing indicate a decision not to provide "maximum safety"?**

485. There is no guarantee that surrogate testing would result in the reduction of transmission of NANB Hepatitis. If it was introduced

a lot of donations would be lost, from donors who did not have NANB Hepatitis. If a significant number of blood donations were lost, then blood shortages may result.

486. A balance has to be maintained between trying to reduce every risk and the need to have sufficient blood for the transfusion needs of the population. It should be borne in mind that, at the time, the chronic nature of NANB Hepatitis and its possible seriousness was not fully understood.

**133. In October 1989, Dr Gunson, the Chairman of the Advisory Committee on Transfusion Transmitted Diseases ('ACTTD'), recommended: "The routine introduction of non-specific tests should be deferred, unless this is necessary for the acquisition of product licences in the UK for fractionated plasma products" (NHBT0000188_072, paragraph 7.5). Then, in November 1989, the ACVSB concluded that there was no case for using surrogate testing for non-A non-B Hepatitis (NHBT0005043). Please advise whether you were aware of the decisions made by ACTTD and ACVSB. If you were, did you agree with the decisions made by ACTTD and ACVSB? If not, what were your objections?**

487. I agreed with their decisions in relation to surrogate testing for NANB.

488. I would have been aware of the decisions as they would have been discussed at other meetings I attended.

489. I was aware that there was considered to be no case for surrogate testing for NANB Hepatitis since this was likely to identify a minority of the cases. At the same time, there was already a more specific test for Hepatitis C in development. They wanted to focus on developing this more accurate test.

**134. Please advise whether surrogate testing (namely ALT or anti-HBc testing) was introduced at NETRTC during your tenure.**

490. No, it was not.

**135. If surrogate testing was introduced at NETRTC, please explain what impact this had on NETRTC. In particular:**

**a. How was the surrogate testing performed?**
**b. What was the process for screening donors and/or blood donations?**
**c. What happened to the unscreened blood that had been collected prior to surrogate testing being implemented?**
**d. What happened when a donation tested positive? Please set out the steps that had to be taken, both with respect to the donor, and in terms of passing on information to third parties and/or identifying recipients of previous donations from that donor**
**e. What were the circumstances in which NETRTC stopped surrogate testing?**

491. I do not feel able to comment on this as surrogate testing was not performed at NETRTC.

***Introduction of anti-HCV screening***

**136. The Inquiry is aware that NETRTC was one of the centres used for the pilot studies of anti-HCV screening (NHBT0000014_082; NHBT0071870_002).**

**a. In November 1989, Dr Gunson wrote to you to state that "I do not think that we can recall donors at this time as the significance of a positive result without confirmation is not yet clear" (NHBT0032954_310). Did you agree with this statement? If so,**

**please provide details. Were the donations that tested positive used? Have your views changed over time?**

492. I agree with the statement by Dr Gunson. If there was not a confirmatory test the donors might have had a false positive test and it is not appropriate to counsel donors unless you know they have a true positive confirmatory test. This would cause undue stress for the donor.

493. Donations that tested positive were never used as mentioned in the document [NHBT0032954_310].

494. My views on this have not changed. If there was a true positive confirmatory test, I would always inform and counsel the donor.

**b. In response to the above letter, you wrote to Dr Gunson to state that "we do have severe staffing problems and it will be very difficult for us to complete the anti-HCV trial in the time scale allowed" (NHBT0000188_108). As far as you can recall, what was the time scale allowed? Did the NETRTC complete the trial in the time scale allowed? To your knowledge, did any other RTCs experience similar issues?**

495. I cannot remember the timescale allowed, nor can I recall whether other RTCs had similar staffing problems.

**137. When did NETRTC begin anti-HCV screening? You may find NHBT0000073_038, NHBT0000075_025 and NHBT0000075_007 of assistance.**

496. We began testing for HCV on the date agreed nationally.

**138. 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.**

497. Yes, I agreed with Dr Gunson – it is important to evaluate all the available tests to identify the most appropriate, sensitive and specific ones.

**139. 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?**

498. I supported a uniform start date because I considered that the blood service should be a national service and that donors from every part of the country should have the same standard of care. The alternative might result in a postcode lottery, as some blood donors would be tested, and others would not depending on where they were based. I would be concerned about a lack of confidence in the blood service as a result of this inconsistency. It should be borne in mind that blood and components might be moved from one part of the country to another e.g. specially matched blood or platelets.

**140. 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.**

499. I disagree with Dr Lloyd because I did not feel and still do not feel that I have the knowledge and expertise in virology to make a decision as to which was the best test to use. Also, as stated above, I feel that all donors and patients throughout the country, should receive the same level of care no matter where they are in the UK. A patient in one part of the UK may require specially matched blood or blood components and they may receive these blood components which may have been collected in another part of the country.

**b. Have your views changed since then? If so, why?**

500. My views have not changed. Dr Gunson's decision to delay testing was based on the advice of expert virologists and I still agree that to follow such advice was the best course of action. A suitable test must be sensitive and specific, and it must have a sufficiently small percentage of false positives and false negatives. I also think it is much better to have a deadline that everyone has to meet as it would mean all centres had to start on the same date. The DOH would have been informed and agreed to the start date. RHAs would have been encouraged to provide the appropriate funding to enable all RTCs to be ready on time, with testing facilities and counselling services in place.

**You may be assisted by NHBT0000076_009 and PRSE0001183.**

**141. What impact did HCV testing have on NETRTC? In particular:**

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

501. I do not recall specifically but as far as I am aware, we conformed to the national agreement about what screening kit to use, how to screen donors and the procedure for performing confirmatory testing.

502. Donors were informed at the donor session that their blood would be tested. They would be given a nationally agreed leaflet about it. When they signed their form to consent to donating blood, they would also agree to having an HCV test and they gave consent to that.

503. A sample would be taken from each donor and an HCV test would be done. Then there was a confirmatory test which would be performed if a donor tested positive in the screening test.

**b. What happened to all the unscreened blood that had been collected prior to the HCV testing being implemented?**

504. I cannot recall. I assume that we would have back tested as agreed. NETRTC kept samples of all donations in an archive for a period of time and therefore it would have been possible to back-test all the donations and blood in stock.

505. I am sure that blood in stock would have been tested from the samples. Blood samples for frozen blood could be tested before such blood was issued for use. In relation to blood that had already been issued to hospital and not yet used, I would have expected that hospitals would identify any blood in stock but not yet transfused. Such donations would have been placed in quarantine until they had been tested.

506. Any blood or blood components issued from the nationally agreed start date would have been tested for HCV.

**c. 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. Please include donations that had a false positive result.**

507. The responsibility for contacting donors who had a positive HCV test was delegated to Dr Angela Gorman, a Consultant on my staff who specialised in Transfusion Microbiology. She would arrange for counselling and referral for the donor to an appropriate expert in liver disease. We would not provide the information to any third party aside from the expert to whom the donor was being referred. This expert would then advise the donor about who should be informed about the infection.

508. I cannot recall what action we took regarding previous donations from a donor who had a positive test for HCV, but it is likely that we would have performed a 'look back' and tested samples from previous donations. Then we could have notified hospitals who had received the donations to allow them to identify recipients.

**d. What impact did the introduction of testing have on the risk of transmission of HCV through blood donations?**

509. At first, it would have had a considerable impact. From memory, it was something like 1 in every 1500 donors who tested positive. But, once those donors had been advised not to donate again, the numbers of persons testing positive would have been greatly reduced, and those would almost exclusively be first time donors, so there would be no need to 'look back' at previous donations.

**142. What funding and operational support was NETRTC provided with to aid in the implementation of testing? Did this have an effect on NETRTC's ability or willingness to commence testing earlier? You may be assisted by NHBT0000193_081, page 37-40 of NHBT0000026_009, and page 4 of NHBT0097472_009.**

510. I cannot recall if we had additional funding from the RHA. But the Government took the view that testing for HCV was important and I assume they instructed the RHAs to provide adequate funding. I note in document [NHBT0000026_009] it states "*the earliest date for commencement of testing, is 15th April 1991. However, delays until 1st May or even 1st June would be preferable*". The reasons for this were given as a move into a new microbiology department and the recruitment of additional staff.

511. But we were not asked to commence testing until later, when we were quite ready to start. Our ability to start testing on the nationally agreed date was not influenced by any problems with funding.

**143. In a letter you wrote to Professor Allain in July 1991, you stated that "I do think that we may currently be exposing ourselves to possible litigation through not starting anti-HCV testing as soon as a test is available" but that NETRTC "could not possibly start testing at the present time since we have neither the funding nor the equipment and our staff have yet to undergo training" (NHBT0000075_007).**

**a. Why did you feel you may be exposing yourself to 'possible litigation'? What steps, if any, did you take to minimise the likelihood of exposing yourself to litigation?**

512. Some patients had heard that HCV screening tests had been implemented in other countries and they may have felt that the UK

blood services were not quick enough in introducing HCV testing which could put them at risk. I thought this might result in patients who receive a lot of donations such as people with haemophilia, possibly taking legal action.

513. I was firmly committed to commencing HCV screening as part of the national service – i.e at the same time as all the other RTCs. I would not want to commence HCV screening until suitable tests had been identified and we had been advised by national experts that the tests were sufficiently accurate so there was a very low percentage of false positives and negatives. As part of the national effort to implement HCV testing, I decided we would not implement testing until advised to do so.

514. I made every effort to ensure we answered any questions about HCV, so that patients, donors and the general public would understand why we did not implement testing as soon as the first antibody tests were available.

515. We also took all necessary steps to ensure that we were ready for HCV testing by the nationally agreed testing date.

**b. Please describe the difficulties NETRTC faced in introducing HCV testing and the steps, if any, you took to circumvent these.**

516. We were not ready to start testing on the original proposed date of 1 July 1991 because as per [NHBT0000075_007] which is a letter from me to Professor Allain, I state "at *Brentwood we could not possibly start testing at the present time since we have neither the funding nor the equipment and our staff have yet to undergo training*". But in any case, the start was delayed as we were advised that second generation tests needed to be evaluated before national commencement of testing.

517. I note in document [NHBT0000073_065] which is a letter from Dr Gunson dated 3 April 1991 it states "*The Department of Health has agreed that there should be a "second-round" comparative evaluation of anti-HCV test kits at the Newcastle, North London and Glasgow RTCs, together with appropriate confirmatory testing. It has not yet been possible to commence the evaluation using production batches of the second-generation tests referred to above and one of these will not be available until later this month. It is undoubtedly in our interest that this evaluation takes place. However, to complete this study and become operational by 1st July 1991 is too tight a schedule. It is difficult to state precisely a revised date, but I think we should aim to commence routine screening for anti-HCV by 1st September 1991*".

518. The first-generation testing kits were not entirely satisfactory and evaluation of the second-generation testing kits proved to be complicated. This was because kits from all manufacturers resulted in some false positive and false negative results and, occasionally, a single test kit would give a negative result for one test and a positive result for a second test for the same blood sample. Consideration was given to testing each sample twice using two different kits to achieve the most sensitive and specific result possible. Finally, the expert virologists agreed on the best testing regime to use - one which had the minimum possible false positive and false negative results.

519. Identifying the best testing regime to use took some time, which resulted in a delay in the commencement of routine HCV screening of all donations.

520. The importance of minimising the number of false negative and false positive results, should be stressed. If a result is a false negative, this could result in the transfusion of infected blood to

patients and the donor might continue to donate, with possible further false negative results.

521. The possible consequences of a false positive result were that it could result in a blight on the lives of people who were informed and it was important to ensure that the information they were given was reliable. The impact of Hepatitis C might eventually be serious for some people but the symptoms might not appear for 30 years. At the time the tests were being evaluated, there was no treatment for Hepatitis C and the prognosis was unknown. Even by the time of the lookback in 1995, the treatment available was new and recently licensed. There was a real risk of causing extensive harm to people by informing them they had an incurable illness, when for as many as 9 out of 10 of them that may not have been the case.

***Recall practice and procedure at NETRTC***

**144. Please give an overview of product recall practice at NETRTC, and how this changed during your tenure. You may find BPLL0001837_002 of assistance.**

522. If a donor tested positive or there was an indeterminate result, any primary packs and any components from the donation would be quarantined until further tests had established whether the test was confirmed to be positive or negative. Any blood or components from a positive donation would be destroyed. In the unusual event that any components from a donor who tested positive or indeterminate had been issued to BPL or a hospital, they would be immediately recalled. Staff in the hospital Blood Bank would be called and advised and it would also be followed up in writing.

523. A lot of checks were done to make sure that positive or indeterminate components were not distributed as seen in document [BPLL0001837_002]. Where errors were made, there were sufficient checks to ensure that the components that had been issued would be recalled and discarded.

524. The system became much more secure after the introduction of computerisation. This substantially reduced the possibility of human error.

**145. What, if anything, do you remember about any formal recall or/notification procedures in place?**

525. I discuss this in response to my question to question 144. I do recall BPL and hospitals being very helpful in response to any request for recall. Hospitals were very helpful in reporting if a patient had a reaction, for example to a platelet transfusion and would report to us so we could recall the associated red cells and any other components made from the same donation. Hospital staff would also return the empty bag of the platelets which had caused the reaction. We could then investigate by testing any remaining fluid in the bag and would recall the associated red cells and any other components made from the same donation.

**146. In your opinion, were such practices and procedures effective? From your experience, did clinicians generally comply with recall requests and if not, do you recall why not?**

526. As I state in my answers to question 144 practices and procedures were effective and there were lots of checks, but I think the procedure became more effective when computerisation was introduced.

527. As I state in my answers to question 145, hospitals were helpful and compliant in returning any product we suspected might be faulty. BPL also responded very helpfully in returning plasma which had been sent to them for processing. Since BPL had a stockpile, it was unlikely that they would have processed any plasma we sent to them as soon as it was received.

**147. In September 1984, Dr H. Boralessa wrote a memorandum to you to state that Factor VIII concentrate from certain batches should not be used but that there has been "a delay of three months in reporting the case of post transfusion Hepatitis to us" (NHBT0022301_002). How common was it that there was a delay in reporting post transfusion Hepatitis? What steps would the NETRTC take after being notified of a case of post transfusion Hepatitis? You may find NHBT0005379_002 of assistance.**

528. Document [NHBT0022301_002] is actually addressed to all the Haemophilia Directors in the region as well as to me.

529. I cannot recall how common a delay in reporting post transfusion Hepatitis was. I remember there sometimes being a delay in reporting post-transfusion Hepatitis and by the time it was reported the patient may have received many more donations of blood. Sometimes the clinicians were not sure whether the patients tested Hepatitis positive before being given any transfusions.

530. After receiving a report of post transfusion Hepatitis, we would re-test all the donations involved in that transfusion, by testing all of our stored samples. If any donation was found to be positive or indeterminate in any test, then the donor would be recalled for testing of a further sample. If any products or components from the donor was still unused, they would be recalled.

**148. In December 1989, a memorandum from Dr A Gorman to you states that it had been discussed with Dr Gunson the "possibility of continuing to accept donors positive for Hepatitis C, but using their blood for plasma only… because of this conversation, we will not be asking BPL to withdraw the plasma batches from the donors involved in this post-transfusion Hepatitis" (NHBT0010011). What view did you hold in relation to this? Was it decided to continue using Hepatitis C positive donations for plasma only? If so, why? Have your views changed over time?**

531. I believe at the time when anti NANB testing was not possible and heat treatment of plasma had started, the advice from both BPL and Dr Gunson was that plasma from donations involved in a NANB post-transfusion case could be used was not unreasonable at the time. However, once Anti-HCV testing commenced, my view was that all donors should be tested and that any donors who had positive tests should be removed from the panel permanently. No blood or components from such donors should be used and none of their plasma should be sent to BPL.

***Quality control***

**149. In 1990, a Medicines Inspectorate inspection report of the NETRTC stated that "a formally organised and effective system of Quality Assurance - including a programme of Quality Control - is almost totally lacking in this Centre, giving rise to a number of procedural failings and ignorance of product quality" (NHBT0006247). Did you agree with this conclusion? If so, why? If not, why not? What steps, if any, were taken following this report?**

532. I note that in document [NHBT0006247] the inspector acknowledged that by the time of the report "*a full-time Quality Assurance Manager has been appointed, having been in-post for six weeks at the time of the present inspection. Interviews for the*

*position of Deputy QA Manager are imminent. (Job descriptions for both posts are held on file). The appointment of further staff is planned. A QA laboratory has been identified but has not yet been brought into use*".

533. I also note that in the post-inspection summary in document [NHBT0006247] it states: "*The Inspector acknowledged that several issues - notably the question of alarms on product fridges and freezers - were in the process of being addressed and he accepted that the completion of the building and computerisation programmes would result in much-needed improvements*".

534. I thoroughly agree with the conclusions of the inspector and we were in the process of expanding our Quality Assurance department having already appointed a new Quality Assurance manager. Subsequently the Quality Assurance manager implemented the changes requested by the inspector and a thorough system for quality assurance of blood components at the RTC was put in place.

535. We were required to write to the inspector immediately addressing the issues raised and steps we were going to take to resolve them, along with a timescale. We were also required to report back to the inspector to advise him of the improvements that had been made, to ensure he was satisfied with the actions we had taken.

***Fresh warm blood***

**150. In an email from Dr Marcela Contreras to NBTS staff dated 18 March 1999, she stated that you had accompanied Dr Contreras at a meeting at Harefield Hospital with Sir Yacoub and other senior medics to once again discuss the use of fresh warm blood ("FWB")**

**(NHBT0101360). Please answer the following questions, as far as you are able:**

536. Unfortunately, I do not recall this meeting. I assume I was there as it is recorded that I attended the meeting. I was the Transfusion Service Consultant on the Hospital Transfusion Committee at the Royal Brompton Hospital, but I do not recall attending this meeting at Harefield hospital.

537. I felt strongly against the use of fresh whole blood, especially if it had not been tested at the RTC.

538. I note that in document [NHBT0101360] it states, "*The Royal Brompton Hospital has declined to bleed donors for Professor Yacoub and they do not seem to have more complications than Harefield Hospital*". I think I may have been invited to this meeting as I was on the transfusion committee at the Royal Brompton which carried out similar operations to Harefield Hospital but did not use fresh warm blood. Similar operations are performed at Harefield and the Royal Brompton Hospitals.

539. In fact, Royal Brompton Hospital staff were at the forefront of new procedures for salvaging red cells shed during surgery and returning them to the patient. I recall that at one point around 50% of all open-heart surgery patients at the Royal Brompton did not require transfusion of red cells other than their own salvaged red cells.

**c. Was Sir Yacoub still using untested FWB at this time? If yes, what measures, if any, had been put in place to reduce the risks posed by the use of FWB since 1988?**

540. I do not recall this meeting, but I remember that it was an issue for Marcela Contreras that Professor Yacoub and possibly other

clinicians in the NW Thames Region wanted to use fresh whole blood. But there were no clinicians in NE Thames hospitals to my knowledge, who used fresh whole blood.

**d. Where did Sir Yacoub source the FWB?**

541. I do not feel able to comment. Professor Yacoub worked in the NW Thames region at Harefield hospital.

**e. It was stated this would be reviewed in 6 months time. As far as you are aware, what was the result of the 6 month review of the situation?**

542. I do not feel able to comment. Professor Yacoub worked in the NW Thames region at Harefield Hospital. Dr Contreras dealt with the problem of his requests for fresh, whole blood.

***Autologous transfusion***

**151. The Inquiry is aware that you were a member of a Working Group on Autologous Blood Transfusion (BPLL0007223). In particular:**

**a. What was your view on when and for whom autologous transfusion was appropriate? Did your views change over time? You may find JPAC0000152_070 of assistance.**

*Pre-deposit Autologous Transfusion*

543. Initially I was enthusiastic about pre-deposit autologous transfusion.

544. Pre deposit autologous transfusion was a process whereby someone who had planned surgery would donate blood every week from 4 weeks prior to surgery and would receive

supplementary iron tablets between donations. The idea was that the patient's haemoglobin would rise between donations. Subsequently, during the surgery, if a transfusion was required, the patient could receive his/her own blood and avoid exposure to donor blood. We later showed that this form of autologous transfusion was not effective. This was because the donations of blood made before the person had surgery made the patient anaemic and there was no time for the haemoglobin to rise between donations to make up the loss with red cells. All that would happen in these situations is that the patient would become anaemic and therefore require a transfusion during surgery. If that patient had not pre-deposited the blood, they would have been less likely to need a transfusion.

*Cell Salvage*

545. Another form of autologous transfusion is cell salvage. This is a procedure whereby blood shed at operation is collected from the operative field and the red cells are centrifuged and washed in saline in a cell salvage machine, then transfused to the patient. Not all surgery is suitable for this cell salvage procedure. It is not used for example in bowel operations, since the operative field and blood shed might be contaminated, nor for most cancer operations, in case there are cancer cells in the blood, but it is very suitable for cardiac surgery and for orthopaedic surgery such as spinal surgery and complicated hip replacements. It can successfully be used in major abdominal/thoracic trauma and liver, heart and lung transplants.

546. In expert hands, 70% of the red cells shed at surgery can be salvaged and reused for the patient. This type of autologous transfusion has found widespread acceptance, particularly in cardiac surgery which is performed in such hospitals as the Royal Brompton. It does require the purchase of cell salvage machines,

harnesses in which to centrifuge the blood and someone to operate the machine in the operating theatre. It is also acceptable for surgery in many Jehovah's Witness patients who otherwise may have refused a transfusion. Some Jehovah's Witness committees have purchased cell salvage machines for hospitals.

*Acute Normovolaemic Haemodilution*

547. A third type of autologous transfusion is called Acute Normovolaemic Haemodilution. Two or three units of blood are collected from the patient during surgery. The blood volume lost is replaced by saline, so that any bleeding is of diluted blood, thus reducing the number of red cells lost. At the end of the operation the 2-3 units (1-1.5 litres) of non-diluted blood, containing not only red cells but also platelets and clotting factors, can be transfused to the patient. This procedure does not provide much autologous blood to compensate for blood shed during surgery, but it has been used effectively together with intraoperative cell salvage.

*Post-operative Salvage*

548. Another method is post-operative salvage, where blood is collected from a wound drain and re-infused into the patient. Only limited quantities of blood can be collected in this way and the fact that this blood is not washed with saline to remove any activated clotting factors is a concern. I think that this method has limited value.

**b. In your opinion, why was autologous transfusion never introduced on a wide scale?**

549. In my opinion only intraoperative cell salvage is a useful procedure and this has been introduced in several hospitals. I

think the scale of introduction has been limited in light of the fact that trained operatives are required in order to operate the machines and it is only suitable for certain operations when large amounts of blood are shed.

550. I understand that since I have left the service cell salvage has been introduced for use in post-partum haemorrhage.

**c. What were the advantages and disadvantages of autologous transfusion?**

551. See my response to Q151a and b

**d. What would have been required to allow autologous transfusion to become a widespread practice?**

552. See my response to Q151a and b.

**e. What role did NETRTC have in autologous blood transfusion practice during your tenure?**

553. I was enthusiastic about intra-operative cell salvage (ICS) as performed at the Royal Brompton Hospital. I learned about it when I was a member of the hospital transfusion committee, so I organised a training day at the RTC so that staff from other hospitals could attend. I invited the machine manufacturers to come and demonstrate the cell salvage machines. Hospital staff were invited to talk to the cell salvage machine manufacturers and to talk about the procedure. The staff from the Royal Brompton Hospital also came to talk to other hospital staff.

**152. In your 2004 article 'Getting Your Own Back - An Update on Autologous Transfusion' in 'Blood Matters' (SCGV0000203_048) you discuss the three main types of autologous transfusion available:**

**pre-operative autologous donation (PAD); acute normovolaemic haemodilution (ANH) and intraoperative cell salvage (ICS).**

**a. To the best of your knowledge when were these three methods introduced in the UK?**

554. I have no recollection of the dates other than those dates that can be gleaned from the documents provided to me.

**b. In your opinion, why was pre-operative autologous transfusion (PAD) used extensively in the USA and Continental Europe from the mid-1980s but not within the UK?**

555. This procedure began to be implemented in the UK, but our observations and experience showed that this was not an effective method. See my response to Q151a and b.

556. I note in [SCGV0000203_048] I state: "*Pre-operative autologous donation (PAD) prior to planned surgery was used extensively in the USA and Continental Europe from the mid 80's when there was increasing concern about the safety of donated blood. In practice, the haemoglobin rises little, if at all between weekly autologous blood donations and the patient who embarks on a PAD programme with a haemoglobin (Hb) of 13g/dl will end up undergoing surgery with an Hb of approximately 10g/dl and 3 units of autologous blood in the blood bank. So, the use of PAD with iron supplementation has suffered a decline in the USA and elsewhere and is no longer recommended by the NBS unless there are exceptional circumstances, e.g. a patient has a rare blood type or combination of antibodies which would make provision of donor blood very difficult. In these cases, autologous blood may be frozen in preparation for planned surgery*".

557. From memory this method was used more in the USA and Continental Europe because patients could request it and clinicians could choose to do it as it was a 'paid for' service.

**c. You estimated "if all hospitals in England established the use of ICS...for all procedures where a blood loss of more than one litre was anticipated, then more than 160,000 units of red cells per annum would be saved. This would not only be a significant improvement in patient safety, but would make an enormous contribution to the conservation of blood stocks..."**

558. The conclusion actually refers to the use of the ICS with *current indications* which is significant as it means that it would only be used when appropriate. At the time this was mainly for cardiac or orthopaedic procedures. The full quotation is as follows: - "*If all hospitals in England established the use of ICS with the current indications, for all procedures where a blood loss of more than one litre was anticipated, then more than 160,000 units of red cells per annum would be saved. This would not only represent a significant improvement in patient safety, but would make an enormous contribution to the conservation of blood stocks at a time of potential decline in donor numbers because of more stringent selection criteria*".

**i. In your opinion could wide scale use of ICS have been introduced earlier in the UK and if so what year could this have been possible?**

559. Wide scale use of ICS could have been introduced earlier. I am not sure of the date when ICS procedures first became available. However, it could certainly have been introduced sooner than the date of my article in 2004, but the problem was that both surgeons and anaesthetists needed to be enthusiastic about the procedure, cell salvage machines needed to be purchased and

an Operative needs to be employed to operate the machine. I think these factors may have prevented some hospitals from introducing it as well as the obvious resource implications. Introducing and managing ICS procedures, are responsibilities of hospital staff, Surgeons, Anaesthetists and Theatre managers, not the blood services.

**ii. What factors delayed the use of ICS as a risk reduction method?**

560. See my response to ii above.

**iii. What were the developments in usage of autologous methods in the UK following the publication of this article?**

561. I do not know what effect, if any, my article had on the usage of autologous methods in the UK following the publication.

562. Throughout the years there was certainly a decline in pre-operative autologous transfusions (even in the private sector) so this procedure is hardly ever used today. I do not think post-operative salvage is used much today either, possibly for the reasons discussed in the article and above.

**153. An article by Professor C. Politis (NHBT0100905) was sent to you in 1998.**

**a. This states that "The European Community in its Resolution 95/C 164/01 for self-sufficiency and safety of blood within the community, calls on the member states to promote autotransfusion programmes wherever possible" (page 3). What was the impact of this Resolution upon the subsequent use of autologous transfusion within the UK?**

563. I do not recall what the impact of this Resolution had upon the subsequent use of autologous transfusion within the UK. All methods of autologous transfusion were investigated in the UK. Only Intraoperative Cell Salvage (ICS) was found to be an efficient and valuable method.

564. I believe this report in 1998 pre-dates cell salvage which proved to be a very useful process as discussed above.

565. I note in [NHBT0100905] it states: "*The commonest technique, autologous pre deposit transfusion, is included in Council of Europe Recommendation No R (95) 15 on the preparation, use and quality assurance of blood components, In this recommendation, the selection of patients, the role of the physician in charge of the patient, informed consent, medications, contra-indications, predeposit blood components preparation, storage and distribution and record keeping are all thoroughly covered*".

566. "*Accumulated experience in the field concludes that the commonest practice, the pre deposit of autologous blood, may be encouraged for about 10% of patients programmed to undergo elective surgery such as hip and knee replacement, orthopaedic spine operations, major vasosurgical operations, bypass cardiac surgery, selected neurosurgery, certain gynaecological operations, and in cases of patients with rare blood groups or alloantibodies against red cell antigens*".

**b. The article also states that in the USA "about 8% of transfused blood is donated by autologous blood donors" (page 3). In your opinion, would this level of uptake ever have been possible in the UK during the same time period?**

567. USA had a different blood supply, mostly from paid donors. Patients may have had a lower confidence in blood safety in the USA than in the UK.

568. It would have been possible to introduce pre-deposit autologous transfusion more widely in the UK, but we tried it and did not find it to be helpful as it caused patients to become anaemic and then receive their blood back, which conferred no benefit. We also discovered that otherwise healthy patients do not require blood transfusions unless they are severely anaemic or suffer substantial blood loss. We came to realise that the method of 'topping people up' who had not lost a substantial amount of blood, was not necessary. We tried to educate staff and patients so fewer transfusions were given.

***General***

**154. Please describe all other steps or actions taken at NETRTC 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.**

569. At NETRTC we improved training for nurses and all session staff in the care and selection of donors. Appropriate training was also given to donor recruitment staff so that they could explain to potential recruits about 'risk groups' and thus deter those unsuitable to give blood. I recall that we tried to educate hospital staff on the judicious use of blood and blood components. We tried to get people not to overuse blood and blood components, for example red cells.

570. We also encouraged regular and enthusiastic donors to attend as regular donors are the safest as we have tested them many times before. As part of this effort, my deputy and I undertook

research to show that fit, regular donors could safely continue to donate between the ages of 65 and 70. After we published our work, the upper age for donating blood was extended to 70 for regular donors throughout England and Wales.

571. I and members of my staff gave lectures on Quality Assurance and Haemovigilance (a system of reporting errors and poor practice and learning from these to improve performance and quality), to staff at all levels.

572. I participated in research with the NETRTC bacteriology department to improve the quality of donor arm cleansing prior to venepuncture. This was to try and prevent bacteria from the skin contaminating the blood donation.

573. At NETRTC we persuaded our user hospitals to accept red cells in additive solution instead of whole blood so that we could harvest plasma from each donation to send to BPL for processing, thus contributing to the aim of UK self-sufficiency. I participated in research to investigate the possibility of using gamma irradiation to destroy viruses in frozen plasma.

574. I worked on the development of a portable battery-operated apheresis machine so that plasma could be collected at mobile donor sessions and further contribute to efforts to achieve UK self-sufficiency in blood products. At all times, NETRTC staff were encouraged to promote the use of BPL products rather than imports.

575. I undertook a research project with colleagues at the Whittington Hospital, to collect 2 units of red cells from individual blood donors by apheresis. These double units were transfused to young patients with B-thalassemia. The idea was to give these patients donations of red cells of standard size and to reduce the

number of donors to whom each patient was exposed, thus increasing safety.

**155. 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?**

576. We were not prevented from taking a course of action if it was considered important for blood safety.

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

577. The fact that we were working together with other RTCs meant we made more of an effort to achieve blood safety. In particular, we worked with other London RTCs and we learned a lot from them.

**157. 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?**

578. RTDs did rely on the decisions of other bodies because we were subject to them. When we had RTD meetings we could voice our dissent or ask questions. I, myself did feel that our views were taken into account.

579. In terms of safe blood relating to infection of blood we took advice from virologists and bacteriologists.

580. I usually agreed with the advice that was given by experts about blood safety. If ever I disagreed on any matter, I felt free to voice my opinion to the group, committee or individual who advised me.

**158. 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.**

581. I do think that there was a shift in attitude from the early 1980s onwards. This shift was not by the BTS but in the Government's attitude towards blood transfusion. Before the advent of AIDS, the transfusion service was regarded as a sort of voluntary organisation, which collected blood from donors. It was regarded as a safe British institution. In fact, some members of the Government and Civil service did not realise that the Transfusion Service is part of the NHS and publicly funded: one Civil Servant said to me when he visited NETRTC, that he thought we were part of The Red Cross. With the realisation that HIV/AIDS could be spread by transfusion, the Government realised the importance of preventing spread of HIV and began to consider the funding of RTCs via Regional Health Authorities. So, more money was made available for training staff, testing when a suitable test was available and publicity to deter people 'at risk' from donating blood. At the same time, more funds were made available to BPL for processing of plasma and the drive to produce enough plasma for self-sufficiency began.

582. The transfusion service was rather underfunded and neglected before the risk of HIV became apparent. When the risk of HIV transmission was appreciated, the Government wanted the transfusion service to start testing for HIV as soon as possible because of pressure from the public. I do not think that cost was a consideration. Of course, the transfusion service could not start testing until there were suitably specific and sensitive screening and confirmatory tests available. In my opinion, costs should not be the main factor in deciding what action should be taken.

583. If there is a test that is suitable for mass screening and a confirmatory test which is accurate, it should be done regardless of the cost, but not at the price of using an unsuitable test.

584. When the risks of Hepatitis C were realised, there was a similar scenario. The necessary funds were available and there was pressure from the Government and the public for the transfusion service to start testing as soon as possible. Again, funding was not the main problem and the delay in commencing the testing programme was because suitable tests had to be identified.

**159. If you do agree:**

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

585. The DOH realised that blood transfusion was important and risky when HIV came on the scene in the early 1980s. They were then willing to spend money on testing.

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

586. It is my understanding that there was no specific policy. Public and medical opinion changed the view.

**c. What caused the change to occur?**

587. I believe it was the emergence of HIV and the risk of transmission by transfusion.

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

588. There is merit in understanding the cost of blood transfusion. Prior to the emergence of HIV as a transfusion risk, the general public, the Government and even hospital staff probably thought that blood transfusion cost very little, if anything, because the blood is donated freely. When people began to appreciate the cost of recruiting, selecting and testing donors as well as production costs for components, then blood and components began to be regarded like other hospital treatments. I do not believe that safety should be compromised to reduce costs. When hospitals were charged for blood and components at cost price, this resulted in the more judicious use of these products and the reduction of waste. This resulted in increased patient safety.

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

589. No, it was not. I believe that the earlier approach to the transfusion service was due to ignorance of its importance and not to a wish to save money. The Government was willing to provide funds for testing for transfusion-transmitted infections as they arose. Later, this was achieved by charging hospitals for the cost of producing components including the testing.

**160. In 1990, Dr Hewitt wrote a note to Dr Contreras, in which she stated that you suggested "testing 'at the beginning of treatment of any illness likely to need multiple transfusions'" (NHBT0085684_001). As far as you can recall, why did you suggest this? Was this suggestion ever implemented?**

590. On occasions, we were asked to investigate transfusion-transmitted infection, but we did not know if the infection had been caused by transfusion as we did not know if a donor was positive before they were transfused. I suggested testing for Hepatitis B, Hepatitis C and HIV for patients who were likely to receive multiple transfusions. If the patient tested positive before receiving any transfusions, we would then know that they were not infected by the transfused blood. This would avoid a lot of work in trying to get to the source of the infection. Unfortunately, this was not implemented as colleagues felt it was too expensive and time consuming for the hospitals.

## Section 13: Look back programmes at NETRTC

### *HIV*

**161. Were you involved in setting up any national or local HIV look back programmes during your time at NETRTC? If so, please describe this process and your role in it and how it was funded.**

591. I was not involved in setting up any national or local HIV look back programmes. Any look back work at NETRTC was delegated to Dr Angela Gorman.

592. In my experience, there were very few HIV positive donors who had donated previously. They were almost exclusively first-time donors so there was no need for look back. There were very few HIV positive donors as our donor selection procedures proved to

be very effective. I remember that there were about 3 people who were identified as HIV positive when screening was first introduced, but I handed over responsibility for organising counselling and any look back work, to Dr Gorman.

**162. Were you involved in implementing any HIV look back programmes during your time at NETRTC? Please give details.**

593. I was not personally involved. Dr Robinson and Dr Hewitt worked out the system and we followed the national rules set by them but the need for HIV look back was minimal. Riva Miller (from the Royal Free Hospital) and Dr Gorman were involved in counselling and managing donors who were HIV positive. She also maintained liaison with colleagues at the other London RTCs as people sometimes donated blood at different London sessions on different occasions.

594. All RTC Consultants were trained to counsel donors who tested positive for HIV. This training was relevant to 'look back' as counselling might reveal the occasion when a donor acquired the HIV infection and therefore how far back the 'look back' might need to go.

***HCV***

**163. The Inquiry understands that NETRTC was involved in HCV lookback in August 1995. Dr Angela Gorman wrote to Dr Keith Patterson and noted that you were "au fait" with the arrangements (NHBT0025823_003). To what extent were you involved in setting up any HCV look back programmes during your time at NETRTC? Please describe this process and your role in it and how it was funded.**

595. I was not involved in setting up the HCV Look back and I am not aware how it was funded. Dr Robinson was responsible for setting up the HCV look back programme. By 1995, I believe that any testing programme would have been funded by cross-charging hospitals for the cost of RTC blood, components and services. The paper referenced in the question describes part of the process which I believe is well documented.

596. Dr Gorman was following national guidelines and instructions. The reference to being 'au fait' with the arrangements was said in the context of Dr Gorman going on holiday. She had informed me about a particular case she was dealing with and I was there to deal with any issues relating to that case.

**164. In a letter from Dr A. Gorman to Dr H. Gunson in March 1991, it is stated that "in the past many centres did not investigate non-A non-B Hepatitis where very many donors were involved" (NHBT0009201).**

**a. What approach did the NETRTC take in such cases? Did the NETRTC not investigate these cases? If so, why not? Has your opinion changed over time?**

597. NETRTC took the view that it was not productive to investigate NANB Hepatitis in particular cases where there were many donors involved. Historically, sometimes there could be hundreds of donors when a person had been treated for a long time with platelets, red cells and all sorts of blood components and then developed symptoms of NANB Hepatitis.

598. On occasions there could be up to 200 donors involved. At the time we could not test for NANB Hepatitis except by looking at liver function or other parameters in the donor's blood. It was very difficult to identify the donor(s) who may have been responsible for transmitting NANB Hepatitis without a specific test. We did not

quite appreciate the chronic nature of NANB Hepatitis and the seriousness of it at that time.

599. My opinion has changed since that time. When HCV testing became available, we would investigate every case, but it took quite some time when there were very large numbers of donors involved. We had stored frozen samples of serum, which were collected at each donation and which could be re-tested for HCV before there was any need to recall donors.

**b. Do you know which centres did not investigate non-A non-B Hepatitis? Were very many donors involved?**

600. I do not know which RTCs did not investigate NANB Hepatitis when there were large numbers of donors involved and no test for HCV was yet available.

**165. Please confirm whether you were involved in a look back process relating to any other infection during your time at NETRTC. If so, please provide an overview of the relevant programmes and detail your involvement.**

601. I was not personally involved in the Look back process once Dr Gorman was in post. Prior to that, I was involved in some look back processes which involved Hepatitis B. Stored samples from relevant donors were re-tested in more detail than the original screening test. If a positive result was obtained the donor would be re-called for repeat testing and counselling. We tested for Hepatitis B core antibody and Hepatitis B surface antibody in addition to the routine Hepatitis B surface antigen. Occasional donors who have a positive HB core antibody test but where the other tests are negative can transmit the Hepatitis B infection.

**166. Did you consider there was an ethical obligation to inform patients who may have received transfusions from infected donations? If not, why not?**

602. I believe there is an ethical obligation to inform those who have received transfusions from infected donations so they can act accordingly and receive appropriate counselling and treatment.

**167. To what extent could an RTC implement its own local look back programme? Did NETRTC do this? If so please give details. If not, why not?**

603. We did implement our own look back programme for Hepatitis C and HIV before the national one was put in place by Dr Robinson. We also had our own Look back programme for Hepatitis B. We collaborated with other RTCs and we had regular meetings so that we did similar things. When we were notified of a recipient who had tested positive for a transfusion transmissible infection, we always followed it up.

**Section 14: Your relationship with commercial organisations**

**168. Have you ever:**

**a. Provided advice or consultancy services to any pharmaceutical company involved in the manufacture and/or importation and/or sale of blood products?**
**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?**
**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?**

**d. Received any financial incentives from pharmaceutical companies to use certain blood products?**

**e. Received any non-financial incentives from pharmaceutical companies to use certain blood products?**

**f. Received any funding to prescribe, supply, administer, recommend, buy or sell any blood product from a pharmaceutical company?**

**If so, please provide details.**

604. The answers to all of the above questions is 'no'. I have not provided advice or consultancy services to any pharmaceutical company involved in the manufacture and/or importation and/or sale of blood products.

**169. 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?**

605. I am not aware of any regulations concerning declaratory procedures for involvement with a pharmaceutical company. I was a member of a national committee whose function was to assess new machinery and equipment related to apheresis on behalf of the National Directorate or later the National Blood Authority (NBA). If a new machine came on to the market, the committee was asked to assess its suitability for collection of components from donors and to consider the pros and cons. We looked at the guidelines, how easy the machines were to use, the processing time, the quality of products or machinery and we made recommendations to the national authority. This was all in the interests of safety and security of supply of blood components. It mainly involved plateletpheresis rather than plasmapheresis.

606. NETRTC worked with Baxter Healthcare to develop plastic pouches to hold recovered plasma to send to BPL for processing. The project was commissioned by the blood service nationally since NETRTC sent large quantities of recovered plasma to BPL. I believe Baxter Healthcare funded the costs of the plastic bags to test and they may have given some financial support for the purchase of blast freezers in order to freeze the plasma quickly. BPL were also involved in this project as it was a national one. I cannot remember the date when this work was performed. The use of the plastic pouches was adopted nationally for all recovered plasma sent to Elstree.

**170. 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.**

607. I was never involved in research for a company involved in manufacture, importation or sale of blood products.

**171. Have you ever provided a pharmaceutical company with results from research studies that you have undertaken? If so, please provide details.**

608. Only when providing Baxter Healthcare with the results following the plastic pouch studies and feedback on the quality of machines from our national committee. These results and recommendations would have been provided to the companies via the National Blood Service Managers to whom we reported.

**172. 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?**

609. We did not receive any funding. Baxter Healthcare probably paid for the plastic pouches and may have given money to Brentwood for special blast freezers as discussed above, but no funding was received by individuals.

**173. In February 1982, you received a letter from C. W. Hawkins of HD Supplies which stated "it would not be improper for Blood Transfusion Centres to consider the sale of excess blood products" (DHSC0006896_066). Did the NETRTC ever sell their excess blood products? If so, to whom and what was the money gained used for?**

610. NETRTC did not sell excess blood products and we would not have done so. In any case we did not have 'excess blood products.' If any waste material was ever 'sold', this would have been organised nationally. I believe that the letter from HD supplies referred to waste material from blood samples, which could be used for reagent production.

**Section 15: Organisation of the blood services**

**174. At an Eastern Division meeting in December 1984, you stated that you were "against national direction or amalgamation but saw a possible role for a national co-ordinator" (NHBT0092839, page 2). Why were you against national direction or amalgamation? What do you think the benefits of national direction or amalgamation would have been? What do you think the drawbacks would have been? Has your view changed over time?**

611. I was against national direction or amalgamation at the time due to problems with funding. I was fearful that the RHA would immediately withdraw funding whilst the amalgamation was being implemented or even after implementation.

612. I did think there was a benefit to having a National Director to oversee the work of all the RTCs. However, the drawbacks proved to be that the National Director did not have executive power to promote implementation of policies and developments as funding was still derived from the Regional Health Authorities.

613. My view changed later as the National Directorate was useful but proved to have the disadvantage of not having enough executive power to implement policies whilst the Regional Health Authorities were responsible for funding each RTC.

**175. In his witness statement for the *A v Others* litigation, Dr Gunson discussed the creation of the National Directorate to oversee the work of RTCs, although he noted that the Directorate "did not have executive authority and its successes came about by persuasion" (NHBT0000025_001; NHBT0000026_009). What are your views on the success or otherwise of the National Directorate?**

614. I was supportive of Dr Gunson and the creation of the National Directorate. It did have some limited successes. One benefit was better management of stocks of blood and the ability to move blood products from places in surplus to places of deficit. It also helped when stock control was introduced. Minimum stock levels were implemented and monitored on a daily basis. I also think that the National Committee for recruitment of donors was successful and commissioned some extremely good publicity campaigns. I do not believe we had such good publicity campaigns after this committee was disbanded.

**176. In the same statement, Dr Gunson commented that the work of the National Directorate became marginalised as a result of the devolution of health budgets to District level and eventually replaced by the creation of the National Blood Authority (NBA), which had**

**responsibility for "both the central laboratories and the RTCs." What are your views on the need for centralised responsibility for RTCs?**

615. The development of the National Blood Authority was necessary. This would work very well provided that funding was also national and replaced by cross-charging so that Hospitals paid for products they received.

**177. The Inquiry understands that you were interviewed by Ernst & Young in April 1991 about the future management arrangements for the NBTS (NHBT0001777). Were you in favour of national direction at this time? If so, please provide details of what you recommended at your interview. If not, why not?**

616. I was in favour of national management of NBTS provided that the financial arrangements were national and not devolved to individual RHAs. Also, I was in favour of RTCs specialising in certain functions rather than having 15 RTCs who all provided the same services.

**178. What in your view were the strengths and weaknesses of the NBA?**

617. Some of the advantages were that RTCs were able to specialise in what they were best at. For example, there were some RTCs, who could process large numbers of donations or others that could specialise in research, testing or investigating transfusion reactions.

618. One weakness I found, was that a national organisation may not appreciate local problems in RTCs as they might not understand weather conditions, poor roads, staff recruitment problems or non-availability of sufficient donors in certain areas.

**179. In 1995, NETRTC was one of five RTCs to be amalgamated into other centres to rationalise the NBAs function and eliminate inconsistency (NHBT0005855, page 16; NHBT0009877_009). It appears that you were unhappy about this (DHSC0004010_165; DHSC0004010_163). Please explain, as far as you are able, the view you held at the time and why you did not think the NETRTC should shut. Has this view changed over time?**

619. Naturally I was unhappy with the decision for the NETRTC to be amalgamated. As outlined in my letter referred to in the question (DHSC0004010_165), there were many reasons why I felt NETRTC should not be amalgamated. NETRTC was responsible for collection, processing, testing and the issue of blood and components to Hospitals in Essex, parts of Hertfordshire, the East End and the City of London. The Centre was located on the M25 so there was easy access. There was good transport access and delivery time was around one hour or less. I was concerned that delivery times would increase, it would also incur additional transport costs, and that we would see blood shortages since donors are loyal to their local RTCs.

620. We also had a modern unit with spare capacity to process large volumes of donations whereas other RTCs did not have this spare capacity and we could provide services on a 24-hour, 7 days a week basis.

621. Brentwood excelled in certain functions. We had a flourishing unit for platelet collection, a good lecture theatre where we held courses attended by trainee Haematologists from all areas of the country, and we held training for transfusion service nurses and scientists from NET and other Regions.

622. At the time, I did not think NWTRTC, at Colindale, could take over all these functions so I made representation to Government

officials and our local MP at Brentwood who supported the idea that Brentwood should remain open. We lobbied Parliament and we made representation to both local and national authorities. The decision to close Brentwood was then reversed. My view has not changed over time and it was the right decision to keep the RTC open.

## Section 16: Variant Creutzfeldt-Jakob disease (vCJD)

**180. When and in what circumstances did you first become aware of the risks of transmission of vCJD associated with the use of blood and blood products. How did your knowledge develop over time? What if any involvement did you have in addressing or responding to these risks?**

623. At the time CJD was recognised as a potential transfusion transmitted disorder, I was no longer the Director of NETRTC and I was working as a Consultant at the Colindale Centre. I became aware of the risks by reading and keeping up to date with Public Health bulletins, which gave details of patients with variant CJD and provided articles looking at possible causes of the disease. Knowledge developed over time.

624. I spoke regularly to specialists such as Dr Hewitt and I was aware of steps taken in the blood transfusion services to reduce transmission of variant CJD, such as leucodepletion of blood and components, cessation of the use of UK clinical fresh frozen plasma and exclusion of donors who had received a blood transfusion. I knew there were also investigations of filtration systems to remove any vCJD protein from blood components.

625. I did not have any personal involvement in implementing these produces. However, I was involved in dealing with blood donors and I made sure medical and nursing staff for whom I was

responsible, were knowledgeable and were able to talk about vCJD with donors. Staff were made aware of the need to stop accepting donors who had had blood transfusions.

## Section 17: Other matters

**181. Please provide a list of any articles you have had published relevant to the terms of reference.**

626. Some relevant ones include:

i) Nurses in the Transfusion Service. Jean F Harrison. The Lancet. November 14. 1987

ii) WITN7046002 - Incidence and Significance of Hepatitis B core Antibody in a Healthy Blood Donor Population. Kitchen et al. Journal of Medical Virology 25: 69-75 1988

iii) WITN7046003 - Effect of Gamma Irradiation on the Human immunodeficiency Virus and Human Coagulation Proteins. A D Kitchen, G F Mann, J F Harrison, A J Zuckerman. Vox Sang. 1989:56:223-229

iv) WITN7046004 - Use of a battery operated Haemonetics Ultralite machine for plasma collection. J F Harrison, T K McCarthy. ISBT/AABB Conference Los Angeles. 1990

v) WITN7046005 - Senior Citizen Donors: A Valuable Group. H Boralessa, J F Harrison: Transfusion Today. 10: June 1991

vi) WITN7046006 - Evaluation of Donor Arm Disinfection Techniques. McDonald et al. Vox Sanguinis (2001) 80, 135-141

vii) WITN7046007 - Standardised Double Dose Apheresis Red Cells Reduce Blood Consumption and donor exposure in B-Thalassemia. Prescott et.al. Abstract Submission to 9th International Conference on Thalassemia & the Haemoglobinopathies. Palermo. 15-19 October 2003.

viii)SCGV0000203_048 - Getting your Own Back – An Update on Autologous Transfusion. J F Harrison. Blood Matters. Issue 16, Autumn 2004.

**182. 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).**

627. I wish to state how sorry I am that recipients of blood components and products died as the result of transfusion transmitted infections. I would also like to express my sympathy for those who have suffered ill health as the result of infections transmitted by blood components and products and acknowledge the anxiety and distress caused to their family and friends.

628. There is no doubt that mistakes were made. When new infections were first recognized, there was ignorance of the mode of spread and sometimes about the severity and chronicity of the infection. The transfusion service in England was not well coordinated in the 1980s and probably moved too slowly in the effort to collect enough plasma to achieve self-sufficiency in blood product manufacture.

629. Hospital clinicians could have moved more quickly to restrict the use of blood components and products to situations where transfusion was absolutely necessary to maintain health. When it became available, the use of intraoperative cell salvage should have been adopted more widely.

630. Positive developments included the rapid response of the transfusion service to identify groups who were 'at risk' of developing and transmitting HIV and later Hepatitis C to deter such people from donating blood. This was extremely successful, even before testing or heat treatment was available. After testing

and heat treatment were implemented, the UK transfusion services introduced improved systems of quality assurance and haemovigilance. These measures ensured a remarkably low incidence of transfusion transmitted infection, a standard which is envied by many other countries.

631. Hospitals have reduced their use of blood components and products to essential use only. Successful treatments for HIV infection and Hepatitis C have been introduced and Hepatitis B vaccination is available. Perhaps most remarkable is the development of genetically engineered Factor VIII, so that people with haemophilia no longer have to worry about contracting a transfusion transmitted illness.

632. I wish the various improvements in care could have been made sooner so that more people could have been saved, long term illness prevented and the anxiety and stress suffered by relatives and friends avoided.

633. I hope that the Inquiry will enable explanations to be given to those who have been affected and their family and friends and that this will provide answers to their questions so that they might at last find some resolution.

**183. During Parliamentary questions on 10th December 1985, Mr Hayhoe, Minister of State for Health from 1985-86, 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?**

634. Yes, I believe the UK was self-sufficient in its need for blood for transfusions.

**184. During your tenure at NETRTC, 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?**

635. I was aware of exceptional cases where this happened. On very limited occasions, in exceptional circumstances, we imported one or two units of frozen blood. This occurred when there was a particularly complex or complicated red cell antibody or group of antibodies within a patient's blood and a transfusion of red cells was needed. Blood of 'rare' types which might be needed in such situations, are frozen at low temperature. Currently, I believe that the UK frozen blood bank is in Glasgow. But if insufficient blood of the rare type required is not available in the UK, such blood might be available in the European Bank in Amsterdam, or in the USA and would then be imported. Samples from the donor are always available to test the blood before it is used. I am not aware of any other instances where red cells for transfusion were imported. Red cells and other components for transfusion have been exported for UK military staff serving abroad.

**Statement of Truth**

I believe that the facts stated in this witness statement are true.

**Signed** GRO-C

**Dated** **...23 March 2022.....**

**Table of Exhibits**

| Date | Description | Document ID |
|---|---|---|
| 14/11/1987 | "Nurses in the Transfusion Service" Jean F Harrison. The Lancet. November 14. 1987 | SBTS0004256_114 |
| 26/10/1987 | Incidence and Significance of Hepatitis B core Antibody in a Healthy Blood Donor Population. Kitchen et al. Journal of Medical Virology 25 69-75 (1988) | WITN7046002 |
| Undated | Effect of Gamma Irradiation on the Human immunodeficiency Virus and Human Coagulation Proteins. A D Kitchen, G F Mann, J F Harrison, A J Zuckerman. Vox Sang. 1989.56.223-229 | WITN7046003 |
| 1990 | Use of a battery operated Haemonetics Ultralite machine for plasma collection. J F Harrison, T K McCarthy. ISBTAABB Conference Los Angeles. 1990 | WITN7046004 |
| 10/06/1991 | Senior Citizen Donors A Valuable Group. H Boralessa, J F Harrison Transfusion Today. 10 June 1991 | WITN7046005 |
| 21/12/2000 | Evaluation of Donor Arm Disinfection Techniques. McDonald et al. Vox Sanguinis (2001) 80, 135-141 | WITN7046006 |
| 15-19/10/2003 | Standardised Double Dose Apheresis Red Cells Reduce Blood Consumption and donor exposure | WITN7046007 |
| 2004 | Getting your Own Back – An Update on Autologous Transfusion. J F Harrison. Blood Matters. Issue 16, Autumn 2004 | SCGV0000203_048 |